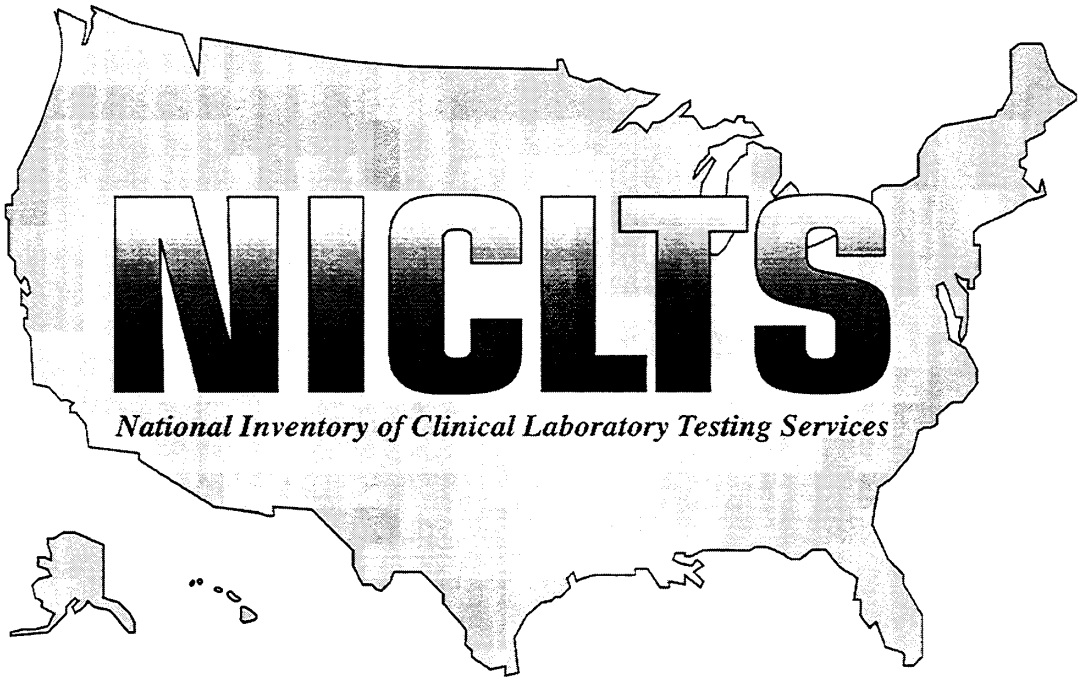
Final Report



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1. INTRODUCTION

The National Inventory of Clinical Laboratory Testing Services (NICLTS) is a statistically rigorous inventory of laboratory testing services conducted for patient care in the United States in calendar year 1996. The inventory was produced by drawing a national probability sample of CLIA-certified clinical laboratories in the Health Care Financing Administration's (HCFA) July 1996 Online Survey, Certification, and Reporting (OSCAR) database. In each sampled laboratory, all tests performed for patient care in calendar year 1996 were enumerated and counted.

This Chapter of the NICLTS final report describes the background for NICLTS and provides an overview of the project. Chapter 2 provides a detailed description of the sample design. Chapter 3 describes the major computer systems developed for the project. Chapter 4 describes project operations. Chapter 5 describes the statistical issues encountered in each phase of the study and provides an overall summary of project results. Chapter 6 describes quality assurance measures utilized during the study.

1.1 Background

In 1967, Congress passed the Clinical Laboratory Improvement Act of 1967 (42 USC§263A). The law (CLIA 67) was passed on the theory that laboratories accepting specimens across state lines were engaged in "interstate commerce" and therefore subject to Federal regulation. The law stipulated that all such laboratories be licensed by the Federal government. The responsibility for writing, implementing, and enforcing the regulations was initially delegated to the Centers for Disease Control and Prevention (CDC). The law brought approximately 13,000 laboratories, mostly hospital and independent laboratories, under Federal regulation.

Later, as a result of public and congressional concerns about the quality of laboratory testing in the United States, Congress passed the Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578). CLIA 88 set standards to improve the quality of laboratory testing in all laboratories that conduct testing on human specimens for health assessment or for the prevention, diagnosis, or treatment of disease. The regulations that resulted from CLIA 88 were implemented in 1992 and set minimum standards for the practice and quality of clinical laboratory testing.

With the publication of the final rule implementing CLIA 88, the delivery of laboratory medicine in the United States changed. CLIA 88 extended Federal regulation to approximately 144,000 additional laboratory sites, mostly physician office laboratories (POLs) and other testing sites, including community clinics, home health agencies, blood banks, health maintenance organizations, student health services, hospices, ancillary testing sites, mobile units, and rural and walk-in screening sites.

CLIA 88 and its subsequent regulations provided for specific regulatory language relative to proficiency testing, quality control, patient test management, personnel, quality assurance, certification, and inspections. CLIA 88 was designed to be site neutral. That is, the designers of the law felt that any person having a clinical laboratory test performed had to be assured that the test would be of the same quality regardless of the testing location. The law allowed for changes in technology and recognized that test quality could be controlled, in part, by technology and therefore allowed differing standards based on the complexity of testing methodology.

Complexity is determined by a set of criteria that reflect how difficult it is to test. In determining complexity, criteria include:

- Knowledge needed to perform the test;
- Training and experience required;
- Reagents and preparations used;
- Characteristics of operational steps;
- Calibration, quality control, and proficiency materials characteristics and availability;
- Troubleshooting and maintenance required; and
- Interpretation and judgment required in the testing process.

The default complexity of a laboratory test is referred to as "High Complexity." These tests require proficiency testing (verification of test performance using outside, graded samples sent periodically to the laboratory), strict quality control and quality assurance programs, personnel trained in laboratory medicine at the director and supervisory level, periodic on-site inspections, and other lesser requirements. Most laboratories thought of as traditional testing sites, such as hospitals and commercial independent laboratories, perform high complexity testing and must adhere to these requirements. Many laboratories located in physicians' offices also

qualify for high complexity testing, with the more traditional ones being those that serve multiple practitioners.

At the other extreme of the complexity scale are waived tests. These are tests designated by the Secretary, Department of Health and Human Services (DHHS), as those examinations or procedures that a) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; b) pose no reasonable harm to the patient if the test is performed incorrectly; and c) have been cleared by the Food and Drug Administration for home use. At the time of introduction of the initial regulations implementing CLIA 88, in 1992, eight generic tests were designated as waived. These included dipstick urinalysis, glucose determinations by a glucometer, and spun hematocrit. As of December 1996, 10 additional generic tests were designated as waived tests.

Laboratories performing only waived tests are issued a Certificate of Waiver and are exempt from all CLIA standards. The Health Care Financing Administration may inspect laboratories holding a Certificate of Waiver if a complaint is received about the laboratory or for random compliance checking. Many laboratories performing only waived tests are POLs.

Two categories of tests are subject to CLIA standards: moderate complexity and high complexity. Laboratories performing moderate complexity tests are required to perform proficiency testing and have periodic on-site inspections. Moderate complexity laboratories have less restrictive personnel requirements at the director and supervisory level but maintain most of the other attributes of laboratories performing high complexity tests. Many smaller, modern automated clinical laboratory tests fall into this classification. Most POLs can qualify as a laboratory performing moderate complexity testing with little or no change in personnel. Many are thought not to perform moderate complexity testing because of perceived cost issues, regulatory oversight implied by an on-site inspection, and especially managed care restrictions on laboratory testing reimbursement.

Soon after the 1992 regulations were implemented, DHHS introduced a subset of moderate complexity testing called Provider Performed Microscopy (PPM). These are tests that must be performed by a physician, a midlevel practitioner under the supervision of a physician, or a dentist. Laboratories may perform PPM testing if they meet certain requirements under the law and if they restrict PPM examinations to a predetermined list of tests. Examples of PPM tests include direct wet mounts, potassium hydroxide preparations, pinworm examinations, fern tests, direct post-coital qualitative examinations of vaginal or cervical mucus, urine sediment examinations, nasal smears for granulocytes, fecal leukocyte examinations and qualitative semen analysis

(Federal Register, Volume 60, Number 78, Monday, April 24, 1995, Rules and Regulations, p.20044).

Under CLIA, the DHHS has the responsibility for developing standards, implementation through the issuance of certificates based on complexity testing, and for both on-site inspection and enforcement. The Public Health Practice Program Office (PHPPO) of the Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems (DLS) has the responsibility for CLIA program and policy evaluation, and oversight to review clinical laboratory testing systems in order to categorize testing into one of the complexity testing categories. The default for an unreviewed or laboratory modified test system is high complexity. A laboratory certified to perform high complexity testing may perform any test within its certified specialty or specialties (chemistry, microbiology, cytology, etc.), including both moderate and waived complexity tests. Laboratories certified to perform only moderate complexity tests may not perform high complexity tests but may perform waived tests. Laboratories certified to perform PPM tests may also perform waived tests. Laboratories having only a Certificate of Waiver may perform only waived tests.

1.2 Justification

With the passage of CLIA 88, the delivery of laboratory medicine in the United States changed. The intent of Congress in passing CLIA was to ensure the safety and accuracy of all clinical laboratory testing regardless of where the testing was performed. Although there is general agreement about the need and importance of the Clinical Laboratory Improvements Amendments, the regulations resulting from CLIA 88 have caused many changes in the way laboratories function, especially among those that are under Federal regulation for the first time. Extending Federal regulation to all laboratories has created a concern that access to needed clinical laboratory testing services, particularly in smaller laboratories and in rural areas, may be jeopardized.

In 1990, the CDC was assigned responsibility for the development of CLIA regulations, for monitoring the impact of the regulations on the nation's laboratories, and for assessing the potential impact of any proposed changes in these regulations on the practice of laboratory medicine in the United States. In this capacity, CDC is required to respond to Congress, the DHHS, and the public in reference to questions concerning the impact of both regulatory and nonregulatory changes in the delivery of laboratory medicine. However, CLIA 88 was passed without a clear understanding of the extent of laboratory testing being performed, especially at locations other

than hospitals and independent laboratories engaged in interstate commerce (Federal Register, Volume 57, Number 40, Friday, February 28, 1992, Rules and Regulations pp. 7106 and 7139-7144). The CDC lacked validated, site-specific information on analytes, test systems, specimen types, and volumes of laboratory testing being performed at laboratories of all sizes and types.

The DLS requires information on analytes, test systems, specimen types, and standardized test volumes to respond to questions concerning the impact of both regulatory and nonregulatory changes in the delivery of laboratory medicine. Assessing the impact of regulatory changes on the delivery of laboratory testing is especially important as the health care delivery system moves toward managed care.

The need for a statistically valid inventory of laboratory services, and the need to produce a model to test proposed regulatory changes from that data, formed the basis for the National Inventory of Clinical Laboratory Testing Services Survey (NICLTS). Conducting this and future periodic inventories of laboratory testing services will allow the government to track changes in access to laboratory tests, to determine what and where tests are available, and to better understand and predict the impact of policy decisions and proposed regulatory changes on laboratory services. Both the development and implementation of national policies will be guided by the results of NICLTS.

Prior to NICLTS, no scientifically valid inventory of laboratory testing existed believed that at least 4 billion laboratory tests are performed annually in the United States.

1.3 Authority and Confidentiality of Data Collection

Data for the NICLTS were collected under the authority of Section 306 of the Public Health Service (PHS) Act (42 USC 242k). Participants were assured that the information they provided would be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m). While many participants were initially hesitant to participate, the strict confidentiality afforded by Section 308(d) clearly contributed to the high response rates obtained for this study.

1.4 Study Overview

The remainder of this chapter presents a summary of the design and conduct of NICLTS. Chapters 2 through 6 provide further details on these topics.

The objective of this research effort was to carry out a statistically valid national inventory of clinical laboratory testing services by analyte, test system, specimen type, and test volume in a stratified random sample of laboratories in the United States. The population consisted of facilities that performed clinical laboratory testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and who were listed on the Health Care Financing Administration's July 1996 Online Survey, Certification and Reporting (OSCAR) database as certified for performing high, moderate, waived, or PPM testing.

The sampling frame consisted of 157,779 laboratories. Prior to sampling, the frame was stratified by the 10 DHHS designated geographical regions and 6 laboratory groups based on the 23 HCFA clinical laboratory types. Territories and Commonwealths of the United States were excluded. Within each stratum, the frame was further sorted by physician office laboratory category (POL vs. non-POL), certification category (moderate/high complexity vs. waived/PPM), laboratory group (other than POL), and laboratory type. This procedure helped to ensure the selection of laboratories with a variety of characteristics.

The sample was designed to allow determination of the proportion of laboratories performing specific clusters of analytes, test systems, and biological specimens and at what complexity. Given this objective and cost constraints, no attempt was made to ensure that every rare analyte would be included in the sample design. Although test volume was obtained for each cluster, the sample was not optimally designed to provide national estimates of test volume.

The POLs, which comprised about 57 percent of the laboratories holding CLIA certificates, were sampled at one-half the rate of other laboratories. Laboratories holding moderate and high complexity certificates were tabulated on site using a computerized data entry system written in PARADOX for Windows that was developed specifically for the inventory (Phase I). This computerized data entry system, termed the "Tabulation Device," allowed for standardized and structured data collection, utilized the CDC Complexity Model database, and contained a thesaurus of analyte and test system names mapped to their Complexity Model equivalents. Laboratories holding waived/PPM certificates were tabulated using a combined mail-telephone methodology

(Phase II). During Phase I, subsampling was used to reduce costs in three circumstances: (1) when hospitals or health maintenance organization laboratories had nursing stations that performed identical test menus; (2) when daily logbooks were the only source of volume data; and (3) when laboratories with multiple locations with a wide geographic dispersion performed the same tests at all locations.

To meet the desired precision requirements, the study design called for 1,834 participating laboratories. The sample for NICLTS was selected in several stages. After stratification, an initial sample of 6,000 laboratories was systematically selected. A subsample of 2,503 laboratories was then selected for the primary sample. The primary sample was further divided into two parts corresponding to Phase I and Phase II samples. The 3,497 laboratories not in the primary sample were held as a reserve sample, allowing a substantial margin to offset possible losses in the primary sample because of nonresponse or out of business facilities. The reserve sample was sorted by region (10 levels), and laboratory type (23 levels). Within these groups, facilities were randomly divided into four release groups. Each release group constituted a representative subsample so that the addition of a release group did not invalidate the representative nature of the overall sample.

Operationally, the data collection effort consisted of two stages:

- A laboratory enrollment stage in which the sampled laboratories were contacted by telephone to recruit them into the study and
- A tabulation stage in which test data were tabulated through followup contact with the enrolled laboratories on site (Phase I) or by telephone (Phase II).

For Phase I, a primary sample of 820 laboratories and 110 laboratories added from the reserve sample were contacted for enrollment for a total released sample of 930 laboratories. For the Phase I telephone enrollment, the response rate was 85 percent. For field tabulation of Phase I, the response rate was 95 percent.

For Phase II, a primary sample of 1,683 laboratories and 176 laboratories added from the reserve sample was contacted for enrollment for a total released sample of 1,859 laboratories. For the Phase 11 telephone enrollment, the response rate was 86 percent. For telephone tabulation of Phase II, the response rate was 90 percent.

1.5 Design Issues

Three unique design issues had major impacts on the study: laboratory sensitivity regarding reporting of CLIA ID number and the volume of their testing, use of CDC's Complexity Model database, and standardizing the definitions of the concepts "test" and "test volume." Each of these topics is addressed separately below.

1.5.1 Laboratory Sensitivity Regarding CLIA ID Number and Volume of Testing

Each laboratory that registers with HCFA is issued an alphanumeric identifier commonly referred to as a CLIA ID number. The CLIA ID number is used in official communications between laboratories and HCFA and is also linked to the OSCAR database containing laboratory attribute information. The survey instrument included a question which asked for CLIA ID number. CLIA ID numbers were sampled from the OSCAR database and the number was used to ensure the statistical integrity of the sample by confirming that the laboratory being inventoried conformed to the corresponding sampled CLIA ID number, that the tabulated tests included only those tested under the sampled CLIA ID number, and that the tabulated tests included all tests conducted under the CLIA ID number. This protocol was a crucial component in compiling a valid national database on the scope and volume of testing in CLIA certified laboratories. Creating such a database is part of the CDC's mandate in implementing the Clinical Laboratory Improvement Amendments of 1988.

Although the CLIA ID number was requested only for record linkage, tracking, and endpoint ascertainment purposes, asking for the number during the inventory was nonetheless a sensitive issue, with some laboratories fearing regulatory implications as a result of their participation. Volume of testing performed under a given CLIA ID number was considered by respondents to be confidential business information. In response to these concerns, study participants were assured that the data for the NICLTS were collected under authority of Section 306 of the Public Health Service (PHS) Act (42 USC 242k), that the information they provided would be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m), that no regulatory actions could or would result from their participation, and that inventory data would be aggregated and summarized during the analysis to prevent any link to a particular laboratory. As a result of these assurances, item nonresponse for CLIA ID number was practically nonexistent. All of these factors, including CDC sponsorship, contributed to the high laboratory response rates for this inventory.

1.5.2 Complexity Model Database

In order to collect data in an organized, standardized, and consistent manner, CDCs Complexity Model database of linked analytes and test systems was used to classify all testing. The database contains about 19,000 entries. It is dynamic, changing periodically as new analytes and test systems are approved by the Food and Drug Administration (FDA) and older ones are abandoned. Even though the database is stratified by laboratory specialty (12 levels), data collection proceeded without reference to specialty, since many laboratories test the same analyte in different departments. The inventory employed the Complexity Model database as it existed in February 1997.

Before data collection began, Westat supplemented the Complexity Model database by the addition of analytes and test systems not found in the Complexity Model. Many of these were in the specific specialty areas of anatomic pathology, histology, and microbiology. New entries were assigned temporary codes while awaiting official CDC coding. When additional analytes and test systems were identified in the field, they were forwarded to CDC for coding.

Since the database does not include a separate variable for specimen, and because CDC Complexity Model analyte and test system codes are sometimes confounded by specimen, specimen type was added to the database. A total of 42 biological specimen codes were added to the database. This expanded version of the database is referred to as the "expanded Complexity Model database." The data collected from all laboratories therefore consisted of analyte, test system, biological specimen, and 1996 calendar year volume. The first three elements are referred to as a "cluster."

1.5.3 Definition of Test and Test Volume

Only procedures measuring analytes were considered tests for purposes of NICLTS. Calculated values for patient testing were not tabulated. For example, a CBC consisting of hemoglobin, hematocrit, white blood cell count (WBC), red blood cell count (RBC), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), and mean corpuscular hemoglobin concentration (MCHC) was recorded as four separate tests since hemoglobin, hematocrit, WBC, and RBC are measured and MCH, MCV, and MCHC are calculated.

In order to ensure the comparability of volume data across tabulators and across laboratories, the process of counting volumes of testing was standardized. In general, counting was based on a method developed by HCFA and used by HCFA surveyors. Where counting guidelines did not exist, additional rules were established following the logic of the HCFA method. All measured values for patient testing were counted as tests. Quality control, proficiency testing, method comparison studies, or repeat patient testing were excluded from volume counts. While counting was straightforward for most testing, some specific rules were developed. For example, manual antibiotic susceptibility testing was counted as a single test regardless of the number of disks placed on the agar.

1.6 Phase I Enrollment and Field Procedures

1.6.1 Enrollment

Data were collected on site in moderate and high complexity facilities by trained medical technologists during Phase I of the study. The medical technologists used the Tabulation Device developed specifically for this inventory to record the data. Enrollment of laboratories began on January 6, 1997. Initial contact with the sampled laboratories was by an advance notification letter signed by Edward L. Baker, Jr., Assistant Surgeon General and Director, Public Health Practice Program Office, CDC. The advance letter informed participants about the study and its purpose, gave the authorization for the study, described the random nature of their selection, stressed the importance of their participation, reviewed confidentiality protections afforded participants, and alerted them to expect a telephone call from an enrollment specialist who would address the specifies of their participation.

Approximately 1 week after the letter was mailed, a trained telephone enrollment specialist initiated telephone contact with each sampled laboratory to request its voluntary participation in the study. Additional objectives of the telephone contact included confirmation of the participant's CLIA ID number with information provided in OSCAR, securing both an enrollment contact person and field contact person, identification of other locations performing testing under the sampled CLIA ID number, and clarification of any laboratory demographic inconsistencies.

An Eligibility Screener Questionnaire, which incorporated a series of structured probes, was implemented whenever a sampled facility claimed that it was not a laboratory or did not perform clinical testing during calendar

year 1996. The screener allowed the enrollment specialist to determine whether or not a facility performed testing during 1996 that was subject to CLIA. For example, if a facility performed occult blood testing on stool specimens, it was classified as a laboratory even though its staff had stated that they did not perform laboratory tests.

Each laboratory agreeing to participate in the study received a personalized confirmation letter from the NICLTS project director. The letter thanked the laboratory for agreeing to participate, referenced the enrollment telephone call, identified the laboratory by name and address, reinforced the information provided in the enrollment call, and specified that a medical technologist would call in the near future to set an appointment to visit the facility. It reaffirmed the confidentiality afforded participating facilities and provided the laboratory with a toll-free number to use if its staff had any questions about the study, the site visit, or specific technical matters.

1.6.2 Field Procedures

Field Tabulator Recruitment and Training

To collect the data, the study required certified medical technologists at the baccalaureate level with at least 2 years of generalist experience, good communications skills, the ability to travel overnight from their home locations, computer skills, and demonstrated interpersonal skills. Since the technologists were needed across the country, advertisements were placed nationwide in three major medical technology journals. Qualified candidates were invited to attend a paid training program in Rockville, Maryland.

The training curriculum was designed to ensure standardized data collection and strict adherence to field, administrative, and operational protocols. A significant proportion of the training time was devoted to learning to use the Tabulation Device and ensuring standardized counting of tests. Toward the end of training, tabulators were sent to laboratories that had been recruited to serve as practice sites. The tabulators carried out the full on-site protocol and data tabulation at their assigned facilities.

Data Tabulation

Phase I data tabulation began at the end of the training session in January and was completed in July 1997. Tabulators followed a standardized on-site protocol that ensured the comparability of data across tabulators and across laboratories. Tabulators called the contact person for participating laboratories and arranged a date and time to visit. Once on site, the tabulator confirmed the CLIA ID number and probed for other possible testing sites under that number. After touring the laboratory and documenting visible test systems, tabulators asked for existing records from which to tabulate. The information was typically provided in the form of computerized annual or fiscal year billing records, annual volume logs, and daily and/or monthly hand-written logs. When existing records were not available, a standardized protocol was used to obtain testers' estimates.

After obtaining the testing records, the tabulator used the Tabulation Device to record the data. The protocol included additional checks at this point to again verify that the site was indeed the one sampled and to ensure that data were being entered for the current location. Data were entered separately for each site at a geographic location. The Tabulation Device included menu-driven algorithms for randomly subsampling nursing stations and daily log books.

Data entry was standardized and consisted primarily of analyte, specimen, test system, and volume. When the analyte or test system names provided by the laboratory differed from those in the expanded Complexity Model, the tabulator used the built-in thesaurus to locate and link the analytes and test systems to the expanded Complexity Model. Analytes and test systems not in the expanded Complexity Model were, after the tabulator obtained confirmation and permission from the technical support line, entered in a standardized format and subsequently forwarded to CDC for coding.

1.7 Phase II

Phase II laboratory enrollment and data collection occurred in the Fall and Winter of 1997-1998. Data were collected in waived and PPM facilities by trained medical technologists. The principal collection method was a telephone interview using standardized telephone survey research telephone protocols.

1.7.1 Advance Letter, Telephone Enrollment, and Data Collection Packet

Initial contact with the sampled laboratories was by an advance notification letter similar to the one used in Phase I. Approximately 1 week after the letter was mailed, a trained telephone enrollment specialist initiated telephone contact with the laboratory to request its participation in the study. The objectives and protocol of the telephone contact were similar to Phase I, the only difference being that laboratories were requested to respond to a mail-telephone data collection rather than to allow a tabulator to visit the laboratory.

The eligibility screener developed for Phase I was also used in Phase II. The screener allowed the determination at the telephone enrollment stage of whether or not a facility performed testing during 1996 subject to CLIA. As in Phase I, many waived and PPM facilities holding CLIA certificates did not consider themselves a "laboratory" or claimed not to have performed testing in calendar year 1996. Upon screening, however, many were determined to have performed testing subject to CLIA.

Each laboratory agreeing to participate in the study received an individualized data collection packet. The packet included a personalized confirmation letter from the NICLTS project director, which thanked the laboratory for agreeing to participate, referenced the enrollment telephone call, identified the laboratory by name and address, reinforced the information provided in the enrollment call, reaffirmed the confidentiality afforded participating facilities, and provided the laboratory with a toll-free number to use if there were any questions about the study, the forms, or specific technical matters. The packet also included a set of data inventory forms and instructions for the laboratory to use in assembling and standardizing its recording of the data. These mailed forms were, however, not the ultimate data collection instruments. They served only as an intermediate form used by the sampled facility prior to the actual collection of data by telephone. Sampled laboratories were requested not to mail back completed forms.

1.7.2 Telephone Tabulator Recruitment and Training

Medical technologists with qualifications similar to those in Phase I were recruited to work in the Washington, DC metropolitan area as telephone tabulators. The medical technologists attended a training session in Rockville, Maryland. All candidates successfully completed the training program. The training curriculum was designed to ensure standardized data collection and strict adherence to telephone, administrative, and operational

protocols. A significant amount of the training time was devoted to learning standard telephone data collection techniques and ensuring adherence to the standardized telephone data collection protocol.

1.7.3 Telephone Tabulation

The telephone tabulation protocol standardized all activities associated with the telephone data collection effort. This protocol ensured the comparability of data across tabulators and across laboratories.

In general, telephone tabulators called the laboratory contact person approximately 1 week after the mailing of the confirmation letter and data inventory forms. The primary purposes of this initial phone contact were to confirm that the laboratory had received the packet, to address any technical questions or concerns expressed by respondents, and to prompt laboratories to complete the inventory form in a reasonably short time frame. Many laboratories provided the data during this initial contact. For laboratories that had not yet received the mailing or had misplaced it, the tabulator arranged for a new packet to be mailed. For facilities that had received the packet but had not yet completed the inventory, the tabulator requested a date and time that would be most convenient to the laboratory for collecting the information. This early initial phone contact made operations more efficient and reduced the total time for completing the inventory.

The precoded data collection instrument used by telephone tabulators for collecting waived/PPM data mimicked the mailed inventory form. The tabulators used a scripted protocol that directly referenced the inventory form in the study participant's hands. Because the test menu for waived/PPM facilities was limited, the tabulator explicitly read each of the tests approved for waived/PPM facilities and asked whether the laboratory had performed that test during calendar year 1996. Additional probes were used to elicit any moderate or high complexity testing that might have been performed.

1.7.4 Key Entry

All data were double key entered. Systems staff subsequently reviewed a random subset of entered data by cross-checking the electronic data file with the original data collection instrument. No errors in key entry were found during this check.

1.8 Statistical Issues

The issues discussed in this section apply to the entire sample, both Phase I and Phase II.

1.8.1 CLIA ID Number Verification and Problem Resolution

For purposes of NICLTS, a laboratory was defined as the unit corresponding to a CLIA ID number. It was CLIA ID numbers that were sampled from the OSCAR database and the CLIA ID number was the unit of analysis. Therefore, verification of these numbers was important to the validity of the data collection effort.

During NICLTS, three general types of CLIA ID number verification problems were encountered. These included (1) the CLIA ID number on the laboratory's certificate did not match the sampled number or could not be located; (2) more than one CLIA ID number was found at the sampled location; and (3) more than one location was included under the sampled CLIA ID number. When the CLIA ID number at the laboratory did not match the sampled CLIA ID number, or when it could not be located, a standardized set of rules was used to determine whether or not data collection should proceed. When more than one CLIA ID number was provided at a sampled location, the participant was asked to provide data only for tests performed under the sampled number. If the respondent could not distinguish testing conducted under the sampled number, all data were collected and the information was forwarded to the survey statisticians for review. When more than one geographic location was included under the sampled CLIA ID number (other than multiple sites within a facility), and the number of multiple locations was three or less, and the various facilities were located in the same approximate area, all such facilities were tabulated. For laboratories with more than three widely dispersed locations, the survey statisticians reviewed the situation to determine whether to tabulate all locations or to subsample them.

1.8.2 Clusters within Each Location

In creating volume estimates for distinct sets of clusters of analytes, specimens, and test systems within each location, statistical adjustments were made for subsampling of daily logs and nursing stations, nonresponse among sampled logs and nursing stations, and subsampling of locations. These adjustment are discussed in Chapter 5.

1.8.3 Weighting and Nonresponse Adjustment

As noted already, for definitional and operational purposes, a sampled CLIA ID number (laboratory) could have multiple geographic locations--for example, when a public health laboratory had several clinics with different addresses scattered across the state. A location, in turn, could have multiple sites within it-for example, a hospital with several nursing stations.

For weighting, NICLTS survey statisticians first reviewed the Tabulation Problem Forms[1] to determine if any situations described affected weighting. Next, survey operational result codes for every laboratory location were assigned a response code. Operational result codes for locations were reduced to four response codes for weighting purposes (see Table 5-1). These included respondent, eligible nonrespondent, ineligible, and nonrespondent with unknown eligibility.[2] For laboratories with multiple locations, a single response code was assigned that characterized the final response outcome at the level of the sampled CLIA ID number.

The laboratory base weight was simply the inverse of the probability of selection. As discussed earlier, physician office laboratories were sampled at one-half the rate of other laboratory types. The base weights account for any such differing probabilities of selection. After calculating the base weights, three nonresponse adjustments were calculated. The first adjustment was to account for nonrespondents of unknown eligibility at the enrollment stage, the second was to account for eligible nonrespondents at the enrollment stage, and the third was to account for all nonresponse at the data collection stage.

1. Tabulation Problem Forms were completed by the field staff to describe unusual situations related to multiple locations, multiple CLIA ID numbers, use of billing data, availability of data for only part of 1996, and other unusual situations.

2. To be eligible for the study, a sampled laboratory needed to perform laboratory tests for patient care during calendar year 1996.

1.8.4 Raking and Calculation of Final Laboratory Weights

After completing the nonresponse adjustment, the adjusted weights were raked. Raking is a procedure wherein survey estimates are adjusted to match certain known values. For the NICLTS, the adjusted weights (after nonresponse adjustment) were raked to counts of laboratories by the six laboratory groups and 10 regions. All counts were obtained from the HCFA July 1996 OSCAR database used for the sampling frame. The final laboratory weight was the product of the base weight, nonresponse adjustments, and raking adjustments.

1.9 Phase I Verification and Validation of On-Site Data Collection

The NICLTS Phase I included two mechanisms for verifying that data collection actually occurred on site at the sampled laboratory and according to the standard protocol. These mechanisms included telephone verification with all of the tabulated laboratories and a second site visit to 30 selected facilities.

1.9.1 Phase I Telephone Verification

The telephone verification quality assurance program consisted of a brief followup interview by home office staff with all of the laboratories tabulated during Phase I. The purpose of the interview was to verify that the tabulator had visited the laboratory and performed the data tabulation in conformity with the on-site protocol. Results of the interview were graded and coded according to three criteria: (1) unconditionally verified, (2) verified after specific review, and (3) unable to reach respondent.

The verification process revealed a high degree of conformance with the data collection protocol. It showed that 98.3 percent of field tabulators unconditionally adhered to the protocol (i.e., every protocol-related question was answered with the desired response); 1.2 percent conditionally adhered to the protocol (i.e., one protocol-related question was answered with an unexpected response and, after further review by project staff, the tabulator was determined to have followed the protocol); and0.5 percent were incomplete verifications (project

staff could not reestablish contact with a laboratory contact knowledgeable about the site visit).

In light of these results (99.5% verified, 0.5% no contact), it was not necessary to pursue additional quality assurance checks for verifying site visits. The overall finding of tile verification process was that the tabulators visited every site in person and carried out the study according to the data collection protocol.

1.9.2 Phase I Site Validation Visits

Because this was the first scientifically valid probability sample of clinical laboratory testing conducted in the United States, a validation test of the NICLTS protocol was performed. This involved retabulation in a sample of 30 laboratories that had already been tabulated. A different tabulator was assigned to revisit the laboratory to carry out a duplicate but independent tabulation. The protocol and methodology for the validation retabulations were identical to those used for the original tabulations.

The purpose of the validation study was to evaluate the field protocol and reliability of data tabulated in the field during Phase I of the NICLTS. A comparison of the original field tabulation data (survey data) with data collected during the validation visit (validation data) was performed.

Regression analyses showed that differences between survey data and validation data were not significant enough to make adjustments to the survey data. The validation study did not reveal any constant or systematic errors in the tabulation of analytes, triples (clusters), or volume.

1.10 Phase II Verification and Validation

Since Phase II used a mail-telephone methodology, no telephone verification was performed with participating laboratories. However, the telephone tabulation supervisor silently monitored the telephone data collection performed by tabulators daily to ensure adherence to the standardized telephone data collection protocol, to check progress and problem reporting, and to ensure efficient and proper utilization of tabulator time. No problems were encountered of an individual or collective nature that had any implications for the validity of the NICLTS protocol or the resulting data.

The Phase II data collection was validated by collecting data on site from a sample of responding laboratories. A nationally distributed team of validation field tabulators was selected from among those who had worked on Phase I. The team members were individually assigned to visit the Phase II validation sample in their geographic areas to carry out a duplicate but independent on-site tabulation. The protocol for the validation site visits was similar to that used for the Phase I tabulations, with the exception of enrollment and the use of paper and pencil methodology rather than laptop computers.

Validation enrollment operations were similar to those used in the Phase II main study with the exception that laboratories which had already participated by telephone were now asked to allow a site visit by a different data tabulator to repeat the tabulation process in person. Laboratories were purposively chosen from a two-way grid of telephone data tabulator by laboratory type (waived, PPM). All telephone tabulators who participated in the mail-telephone data collection effort were represented in the sample. The data tabulators completed retabulations in a total of 110 locations.

The purpose of the Phase II validation study was to evaluate the reliability of mail-telephone data collection versus on-site data collection in waived/PPM laboratories. A comparison of the original mail-telephone data (survey data) with data collected during the validation site visit (validation data) was performed. The analysis was broken down by number of analytes recorded, number of clusters (analyte, test system, specimen) recorded, and estimated total volume for each location. The Phase II validation analysis showed consistent differences between survey data and validation data, though they were not significant enough to require adjustments. Specifically, the validation study indicated consistent underreporting in the mail-telephone modality by about 10 percent. This amount is, however, well within the sampling error of the overall estimates.

1.11 Overall Survey Estimates of Laboratory Volume

The NICLTS found that hospital laboratories collectively tested 8,164 distinct clusters (i.e., analyte, test system, specimen), while POLs collectively tested 1,604. The POLs in Region 1 (Northeast) tested 148 distinct clusters. The average number of distinct clusters per laboratory type varied by region. For example, POLs as a whole tested an average of nine distinct clusters, though this was somewhat higher for POLs in the Northwest (about 15 distinct clusters). Nationally, the estimated mean distinct clusters tested per laboratory was 15.2, and the

95 percent confidence interval around this point estimate was 13.9 to 16.4.

Based on NICLTS data, the estimated total national volume of testing performed in calendar year 1996 was 7,250,519,342 (7.25 billion) tests and the 95 percent confidence interval around this point estimate was 5.12 to 9.38 billion tests. Chapter 5 gives more detailed information of volume of testing by region and laboratory group and type.

1.12 Issues to be Considered when Interpreting NICLTS Data

Depending on the types of analysis being undertaken, there are several issues which should be kept in mind when analyzing NICLTS data. First, there is a small degree of underestimation in collection of waived/PPM data (see Chapter 6). Second, the regional estimates obtained in the NICLTS represent the region where tests were performed, not where they were ordered. Finally, the survey was designed as an exploratory study to estimate the prevalence of analyte, test system, and specimen combinations in laboratories, not to generate test volume estimates.

Chapter 6 discusses in detail the design, implementation, and results of the Phase I and II validation studies. While the Phase I results showed close correlations between the initial and retabulated data, the Phase II validation study indicated a consistent tendency for the field tabulators to undercount tests. This point should be considered when analyzing data from laboratories performing waived and PPM testing. The contribution of these laboratories to overall test volume and to the number of unique triples was relatively small (about 4%), however, so this issue is not important when considering overall estimates.

When evaluating regional estimates obtained in the NICLTS, it should be remembered that specimens may be shipped to a laboratory from anywhere in the United States. While it is likely that tests performed in a given region are associated with patients residing in that region, it is not known to what extent this assumption is true.

Finally, except for undersampling POLs, the survey was designed with proportional representation. While this design gives a broad representation of different types of laboratories, it is not the most efficient design for generating estimates of test volume. Volume could have been estimated more efficiently with a design that

oversampled large laboratories to a greater extent. Such a design would, however, have been less efficient as an exploratory survey.

2. SAMPLE DESIGN

This chapter documents the procedures used to select laboratories for the National Inventory of Clinical Laboratory Testing Services. The sample was designed to allow CDC to determine the proportions of laboratories measuring specific analytes, performing specific tests, and performing specific combinations of analytes, test systems, and biological specimens.

The sample for the NICLTS was selected in several steps. First, an initial sample of 6,000 laboratories was selected. Next, a subsample of 2,503 laboratories was selected for the primary survey sample. This sample was divided into two parts, corresponding to the Phase I and II samples. Laboratories holding moderate and high complexity CLIA certificates were fielded in Phase I and tabulated on site. Laboratories holding waived or Provider Performed Microscopy (PPM) CLIA certificates were surveyed in Phase II. This second part of the survey employed a mail-telephone methodology where laboratories were mailed a short data collection form and then contacted by telephone by a trained data tabulator to assist with the completion of the form and collect the data.

2.1 Sampling Frame

The sampling frame consisted of 157,779 records in the July 1996 OSCAR database maintained by the Department of Health and Human Services. Each record corresponded to a CLIA ID number in the PROVNUM field. The frame was stratified by the 10 DHHS designated geographic regions and six laboratory groups based on the 23 Health Care Financing Administration clinical laboratory types. To simplify the survey, territories and Commonwealths of the United States were excluded from the geographic regions. These laboratories were (1) located in the 50 states or the District of Columbia and (2) had completed a Form HCFA-116, Clinical Laboratory Application. Table 2-1 shows a distribution of these laboratories by geographic region and by the six major laboratory groupings.

Prior to sampling, the frame was stratified by physician office laboratory category (POL vs. non-POL), application category (moderate/high complexity testing vs. waived/PPM testing), then sorted by region (ten

Table2-1. Distribution of laboratories on the sampling frame by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	4,819	886	1,143	434	346	893	8,521
2. New York, New Jersey	10,037	724	708	557	620	1,412	14,058
3. Mid-Atlantic	9,666	1,244	1,306	829	572	2,262	15,879
4. Southeast	17,941	2,839	2,240	1,824	1,080	4,508	30,432
5. Midwest (North)	16,209	2,624	3,398	1,513	765	4,708	29,217
6. South (Central)	9,764	3,915	2,081	1,378	734	3,181	21,053
7. Midwest (Central)	4,033	957	1,531	602	207	1,654	8,984
8. Mountain	2,313	730	536	390	176	826	4,971
9. West	11,931	2,171	1,369	980	884	2,144	19,479
10. Northwest	2,830	496	465	295	212	887	5,185
Total	89,543	16,586	14,777	8,802	5,596	22,475	157,779

levels) and laboratory type within group (see Tables 2-2, 2-3, and 2-4). This procedure helped to ensure the selection of laboratories with a variety of characteristics. While the main focus of the study was on laboratory group (rather than type), sorting by laboratory type within group marginally improved the sample distribution by laboratory type without changing the expected sample sizes by laboratory group. Region and laboratory type were taken from the OSCAR database. Application category was constructed from the CLIA application type. POL category and laboratory group were constructed from laboratory type. Laboratory group had six levels, separating POLs from other ambulatory sites. This allowed the sample size of POLs to be monitored more closely.

2.2 Sample Design Parameters

The sample was designed to allow CDC to determine what proportion of laboratories in various categories measured specific analytes; what proportion perform specific tests; and what proportion perform specific combinations of analytes, test systems, and biological specimens. No attempt was made to ensure that every rare analyte would be 'included in the sampled data. Although the study design included the collection of volume data, the sample was not optimally designed to provide national estimates of test volume.

Because of the large proportion of POLs in the sampling frame, POLs were sampled at one-half the rate of other laboratory groups. This subsampling led to substantial cost savings with only a small loss in the precision of estimates for the POL laboratory group.

2.3 Sample Selection

To meet the desired precision requirements, the study design called for 1,834 participating laboratories. Westat first selected a sample of 6,000 laboratories. This large initial sample was then subsampled to a primary sample of 2,503 as described below. The increase from 1,834 to 2,503 allowed for nonresponse. The balance of the initial sample of 6,000 that was not in the primary sample constituted the reserve sample. The reserve sample allowed a substantial margin to offset the possible losses in the primary sample from larger than expected nonresponse, laboratories no longer in business, and possible duplicate records on the frame. The initial sample of 6,000 laboratories was selected with equal probability using systematic random sampling. Table 2-5 shows the

Table 2-2. Definition of regions

	Region	State
1.	Northwest	CT, ME, MA, NH, RI, VT
2.	New York, New Jersey	NJ, NY
3.	Mid-Atlantic	DE, DC, MD, PA, VA, WV
4.	Southeast	AL, FL, GA, KY, MS, NC, SC, TN
5.	Midwest (North)	IL, IN, MI, MN, OH, WI
6.	South (Central)	AR, LA, NM, TX, OK
7.	Midwest (Central)	IA, KS, MO, NE
8.	Mountain	CO, MT, ND, SD, UT, WY
9.	West	CA, HI, NV, AZ
10.	Northwest	AK, ID, OR, WA

Table 2-3. Definition of laboratory groups

Laboratory Group	Laboratory Type
1. Physicians Office Laboratory (POL)	Physician office
2. Other Ambulatory	Community clinic Home health agency Student health service Health Maintenance Organization (HMO)
3. Hospice/Nursing Home	Hospice Skilled nursing/nursing facility
4. Hospital	Hospital
5. Independent/Blood Bank	Independent Tissue bank/repository Blood bank
6. Specialty	Ambulatory surgery center Comprehensive outpatient rehabilitation Ancillary test site End stage renal disease dialysis Health fair Industrial Insurance Intermediate care facility mental retarded Mobile unit Pharmacy Other practitioner Other

Table 2-4. Definition of application categories

Application category	Application type (type of CLIA certificate)
1. Waived/PPM	Waived Microscopy
2. Moderate/High complexity	Certificate Accreditation Partial accreditation

distribution of these 6,000 laboratories by region and laboratory group.

The primary sample of 2,503 laboratories was selected from the initial sample of 6,000 using stratified systematic sampling. In stratified systematic sampling, every n_s-*th* laboratory is sampled from a sorted file, where n_s is set for each stratum *s* so that the target sample size is achieved for each stratum. Four sampling strata were formed by cross-classifying POL category (POL versus not POL) and application category. Table 2-6 shows the distribution of the final sample by region and laboratory group. Table 2-7 shows the distribution of the 2,503 laboratories by the POL and application strata.

Release of Reserve Samples

In both Phase I and Phase II, additional laboratories were released in controlled groups from the respective reserve samples. The release took place after enrollment had been attempted with a sufficient number of the primary sample laboratories to make projections of final enrollment rates.

To form the release groups, the reserve sample for each phase was sorted by region, group, and laboratory type. Within these categories, facilities were sorted at random and then the entire file was systematically divided into four release groups of approximately equal size. Each resulting release group constituted a representative subsample, so that adding the release groups to the primary sample did not invalidate the representative nature of the overall sample.

Table 2-5. Distribution of laboratories in the initial sample by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	184	34	43	17	12	35	325
2. New York, New Jersey	382	27	27	21	23	55	535
3. Mid-Atlantic	367	46	51	31	21	87	603
4. Southeast	682	108	85	69	42	171	1,157
5. Midwest (North)	617	100	129	57	30	178	1,111
6. South (Central)	371	149	79	53	28	121	801
7. Midwest (Central)	154	37	57	23	8	63	342
8. Mountain	88	28	20	15	7	31	189
9. West	453	82	52	38	34	82	741
10. Northwest	108	18	18	11	8	33	196
Total	3,406	629	561	335	213	856	6,000

Table 2-6. Distribution of laboratories in the primary sample by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	54	20	26	9	6	21	136
2. New York, New Jersey	109	16	17	11	13	32	198
3. Mid-Atlantic	107	28	30	17	12	50	244
4. Southeast	196	65	51	38	23	100	473
5. Midwest (North)	181	59	78	31	17	105	471
6. South (Central)	107	90	47	30	14	72	360
7. Midwest (Central)	44	21	35	13	4	37	154
8. Mountain	25	16	13	8	4	18	84
9. West	133	48	32	21	19	47	300
10. Northwest	32	11	11	6	4	19	83
Total	988	374	340	184	116	501	2,503

Table 2-7. Distribution of laboratories in the initial, primary, and reserve samples by stratum

7a. Initial sample:

Stratum	POL category	Application category	Number of laboratories
1	POL	Waived/PPM	2,089
2	POL	Moderate/high complexity	1,317
3	non POL	Waived/PPM	1,715
4	non POL	Moderate/high complexity	879
Total			6,000

7b. Primary sample:

Stratum	POL category	Application category	Number of laboratories
1	POL	Waived/PPM	637
2	POL	Moderate/high complexity	351
3	non POL	Waived/PPM	1,046
4	non POL	Moderate/high complexity	469
Total			2,503

7c. Reserve sample:

Stratum	POL category	Application category	Number of laboratories
1	POL	Waived/PPM	1,452
2	POL	Moderate/high complexity	966
3	non POL	Waived/PPM	669
4	non POL	Moderate/high complexity	410
Total			3,497

Phase I Sample

For Phase 1, a primary sample of 820 laboratories and a reserve sample of 110 laboratories were contacted for enrollment, for a total released sample of 930 laboratories. Table 2-8 shows the distribution of the Phase I primary sample by region and laboratory group. Table 2-9 shows the Phase I reserve sample.

Phase II Sample

For Phase II a primary sample of 1,683 laboratories and a reserve sample of 176 laboratories were contacted for enrollment, for a total released sample of 1,859 laboratories. The distribution of the waived/PPM laboratories on the OSCAR database is shown in Table 2-10. Table 2-11 shows the distribution of the Phase II primary sample by region and laboratory group. Table 2-12 shows the Phase II reserve sample.

2.4 Other Sampling Issues

Several other sampling issues affected the study. These are subsampling laboratories with multiple locations, and matching laboratories with CLIA ID numbers. Each of these is discussed in detail in the sections that follow.

Subsampling

During Phase I, subsampling was used in two situations. The first of these was that nursing stations were subsampled in hospitals, HMOs and nursing homes; the second was that daily logbooks were subsampled wherever encountered.

At hospitals, HMOs, and nursing homes, tabulators were instructed to enter a list of all nursing stations, and the Tabulation Device randomly selected the stations to tabulate. First, the tabulator identified "homogeneous" nursing stations, meaning that the same tests were performed at all stations. For example, nursing

Table 2-8. Distribution of Phase I primary sample by region and laboratory group

Region	Laboratory Group						
	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	20	7	0	7	5	7	46
2. New York, New Jersey	39	4	1	10	7	10	71
3. Mid-Atlantic	39	6	0	15	9	17	86
4. Southeast	79	11	0	32	17	32	171
5. Midwest (North)	59	11	0	26	12	30	138
6. South (Central)	38	9	0	24	11	20	102
7. Midwest (Central)	17	4	0	12	3	10	46
8. Mountain	10	5	0	7	3	6	31
9. West	38	10	0	18	16	16	98
10. Northwest	12	4	0	5	3	7	31
Total	351	71	1	156	86	155	820

Table 2-9. Distribution of Phase I reserve sample by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	53	5	0	7	5	5	75
2. New York, New Jersey	111	4	0	9	7	9	140
3. Mid-Atlantic	106	4	1	13	7	15	146
4. Southeast	218	9	1	28	15	27	298
5. Midwest (North)	160	10	1	23	10	25	229
6. South (Central)	107	8	1	20	11	17	164
7. Midwest (Central)	47	4	0	9	4	9	73
8. Mountain	28	4	0	6	2	6	46
9. West	103	9	0	15	13	15	155
10. Northwest	33	3	0	4	4	6	50
Total	966	60	4	134	78	134	1,376

Table 2- 10. Distribution of waived and PPM laboratories on the OSCAR database by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	2,917	587	1,137	74	61	597	5,373
2. New York, New Jersey	6,083	496	694	42	255	933	8,503
3. Mid-Atlantic	5,847	959	1,295	88	143	1,439	9,771
4. Southeast	10,128	2,312	2,210	232	252	2,950	18,084
5. Midwest (North)	10,471	2,085	3,365	216	200	3,240	19,577
6. South (Central)	5,946	3,469	2,062	220	167	2,200	14,064
7. Midwest (Central)	2,345	757	1,522	54	22	1,142	5,842
8. Mountain	1,320	512	533	51	30	515	2,961
9. West	8,221	1,665	1,362	123	129	1,335	12,835
10. Northwest	1,656	312	463	47		542	3,042
Total	54,934	13,154	14,643	1,147	1,281	14,893	100,052

Table 2-11. Distribution of Phase II primary sample by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	34	13	26	2	1	14	90
2. New York, New Jersey	70	12	16	1	6	22	127
3. Mid-Atlantic	68	22	30	2	3	33	158
4. Southeast	117	54	51	6	6	68	302
5. Midwest (North)	122	48	78	5	5	75	333
6. South (Central)	69	81	47	6	3	52	258
7. Midwest (Central)	27	17	35	1	1	27	108
8. Mountain	15	11	13	1	1	12	53
9. West	95	38	32	3	3	31	202
10. Northwest	20	7	11	1	1	12	52
Total	637	303	339	28	30	346	1,683

Table 2-12. Distribution of Phase II reserve sample by region and laboratory group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	77	9	17	1	1	9	114
2. New York, New Jersey	162	7	10	1	3	14	197
3. Mid-Atlantic	154	14	20	1	2	22	213
4. Southeast	268	34	33	3	4	44	386
5. Midwest (North)	276	31	50	3	3	48	411
6. South (Central)	157	51	31	3	3	32	277
7. Midwest (Central)	63	12	22	1	0	17	115
8. Mountain	35	8	7	1	1	7	59
9. West	217	25	20	2	2	20	286
10. Northwest	43	4	7	1	0	8	63
Total	1,452	195	217	17	19	221	2,121

stations at one nursing home might all perform the same simple test menu such as measuring glucose levels with a single analyte instrument and performing fecal occult blood tests using a single manufacturer's test system. Then, two homogeneous nursing stations were subsampled per location. The random sampling procedure was self contained in the Tabulation Device. All nursing stations that were not homogeneous were fully tabulated.[3]

In sampling daily logbooks, 20 days per log were selected. As with nursing stations, a subsampling module was created in the Tabulation Device to select days from logbooks. The selection algorithm used systematic sampling with a random start date. The tabulator activated this module as necessary. The tabulator entered the days of the week that the laboratory was open for business and the number of holidays observed in 1996, and the Tabulation Device selected a sample of 20 dates for the tabulator to look up in the logbook. The Tabulation Device used the number of days that a laboratory was open in calendar year 1996 to calculate the number of business days to use as the interval between selected days.

Subsampling was not used at all during Phase II of the survey.

Laboratories with Multiple Locations

Many laboratories operated in several locations under the same CLIA ID number. Such laboratories were encountered both in Phase I and PhaseII. In most cases, the individual locations were treated as separate laboratories for purposes of data collection. For example, in Phase I, tabulators were sent to each location and a separate data collection site visit was conducted for each.

Laboratories that operated in four or more locations were evaluated for possible subsampling. In most of these cases, Westat selected a sample of the locations for tabulation. During the data processing, an adjustment was made to the estimates to reflect this procedure. Subsampling of locations occurred only in Phase I, where there was a large cost associated with visiting each location. In Phase II, the tabulators were able to obtain data from all locations of cooperating sampled laboratories.

3 In theory, a hospital, HMO, or nursing home could have two or more sets of nursing stations with each set performing a well-defined but distinct list of tests. In practice, however, this situation occurred only once. The largest set of nursing stations was subsampled and the remaining nursing stations were fully tabulated.

The largest number of locations under one CLIA ID number encountered during Phase I was 80, 20 of which were subsampled for tabulation. The largest number encountered in Phase II was 228, but one contact was able to provide the needed information for all locations.

Identification of CLIA ID Numbers

Part of the data collection protocol was to confirm the CLIA ID number. While the laboratory's reported CLIA ID number and the sampled CLIA ID number usually matched, the laboratory was occasionally unable to find the number or, more rarely, its reported CLIA ID number did not match the sampled CLIA ID number, or it had several CLIA ID numbers. Sections 5.1.1 and 5.2.1 discuss how Westat resolved these cases in Phases I and II, respectively.

The underlying principle was that the laboratory was sampled by selecting the CLIA ID number on the OSCAR database. In the case of unconfirmed or nonmatching numbers, if the address and name of the laboratory matched, or a chain of evidence existed that linked a new laboratory name or address to the one associated with the sampled CLIA ID number in OSCAR, it was assumed that the laboratory located should be included in the sample.

The case of multiple CLIA ID numbers presented a more complex problem. Westat attempted to identify the testing performed for the sampled CLIA ID number and to tabulate only that testing. Where this was not possible, data were tabulated for all CLIA ID numbers and a record of the numbers was kept.

Multiple CLIA ID Numbers on the OSCAR Database

Where the CLIA ID number at the laboratory did not match the sampled number, all numbers were recorded and referred back to the home office. Some of these numbers matched other CLIA ID numbers in the OSCAR database and turned out to be affiliated with the same laboratory. It is not clear if these numbers resulted from multiple certification applications. In any case, the presence of multiple CLIA ID numbers for the same laboratory presents a sampling problem often encountered in establishment surveys. Some

establishments-typically larger ones- may have multiple listings and thus multiple chances of selection. In extreme cases, this problem can result in biased estimates.

One correction for the problem is to identify all multiple certificate holders on the sampling frame and assign a single identifying number to all certificates belonging to the same holder. Another correction is to identify all such laboratories only among sampled establishments. The latter solution is usually simpler but must be built into the survey protocol at the start of the study; CDC and Westat made a joint decision early in the NICLTS not to allow for such multiple listings in the on-site protocol. Because the number of cases was small, it is unlikely that this problem has affected the survey estimates from the NICLTS. However, this problem should be considered carefully in any future survey work using the OSCAR database as a sampling frame.

3. SYSTEMS

This chapter describes the NICLTS computer systems and related activities needed for data collection, data transmission, key entry, data cleaning, and data summarization. Since these activities differed between the two major phases of the study, the discussion is presented in two parts:

- Phase I--Collection and processing of data from laboratories with moderate and high complexity CLIA certificates and

- Phase II--Collection and processing of data from laboratories with waived and PPM CLIA certificates.

3.1 Phase I-Collection and Processing of Data from Laboratories with Moderate and High Complexity CLIA Certificates

Data collection in laboratories with moderate and high complexity CLIA certificates was performed by medical technologists reviewing hard-copy laboratory records in clinical laboratories. These technologists, who were referred to as "tabulators," recorded the data using a laptop computer running a PARADOX for Windows program called "the Tabulation Device." The data were then transmitted to Westat's home office where they were converted to SAS files, cleaned, and summarized.

The following discussion is divided into two sections:

- Tabulation Device and

- Data Processing.

These sections correspond to activities taking place in the field and those taking place at Westat's Rockville offices.

3.1.1 Tabulation Device

The Tabulation Device allowed the tabulators to record identified clusters of triples consisting of an analyte, a test system, and a biological specimen that represented tests performed in a clinical laboratory and to

record the number of each cluster performed during calendar year 1996 at the laboratory. The Tabulation Device contained numerous features designed to protect the confidentiality of the data, while ensuring that it was collected as completely and consistently as possible.

3.1.1.1 User Identification

Each user of the Tabulation Device was assigned a computer-generated password consisting of a randomly selected collection of eight numbers and letters. This provided 1.7656×10^9 different possible passwords. Fewer than 50 of these passwords were assigned. Whenever a tabulator started the Tabulation Device software, he or she was required to enter this password. Only NICLTS IDs[4] of laboratory locations assigned to the tabulator possessing that password and currently in a "fielded" status were then active on the computer. Thus, a tabulator could enter data only for laboratories assigned to him or her. Each cluster (analyte, test system, biological specimen) that a tabulator recorded contained a unique identifier indicating who collected the data.

Each computer was also given a unique computer hardware identification number and was then assigned to a specific tabulator. Computer assignments were carefully tracked whenever a tabulator received a computer or returned one for diagnosis, repair, or closeout.

3.1.1.2 Laboratory Identification

In order to confirm that a laboratory was in fact the sampled laboratory, the Tabulation Device displayed the CLIA ID number of a laboratory after the tabulator logged on and selected it for data entry. This allowed the tabulator to compare the sampled CLIA ID number with the number on the CLIA certificate at the laboratory.

To ensure the confidentiality of the data, all assignments and data records used the NICLTS ID rather than the CLIA ID number. In order to preserve this confidentiality while making the CLIA ID number available to the tabulator when needed, the Tabulation Device contained an encrypted file that matched the NICLTS ID to the CLIA ID number. This file could be read only by someone using a valid password. The Tabulation Device was

[4] Each laboratory was given an arbitrary five-digit NICLTS identifier for use during the study.

designed to display the CLIA ID number only for the laboratory currently being worked.

3.1.1.3 Computer-Assisted Data Entry

The tabulators used the Tabulation Device to assign each identified laboratory test to an explicit cluster (analyte, test system, biological specimen); to record the calendar year 1996 volume of each cluster; and to record comments about the tests. Each full data record for a laboratory test consisted of the following:

- NICLTS location ID (five-digit NICLTS ID + two-digit location number) automatically inserted by the system;
- Site number (two digits) - automatically added by the system;
- Tabulator ID - automatically added by the system;
- Tabulation date - automatically added by the system;
- Analyte name - entered by tabulator (computer assisted);
- Analyte code 5 - automatically added by the system based on the tabulator's choice of analyte name from a lookup table (or left blank if no entry existed);
- Test system name - entered by tabulator (computer assisted);
- Test system code[5] - automatically added by the system based on the tabulator's choice of test system name from a lookup table (or left blank if no entry existed);
- Biological specimen name - entered by tabulator (computer assisted);
- Biological specimen[5] - automatically added by system based on the tabulator's choice of biological specimen name from a lookup table (or left blank if no entry existed);
- Volume[5] - entered by tabulator;
- Nonpatient Care Volume - entered by the tabulator, included any quality control, proficiency testing, method comparison testing, repeat patient testing and calculated values that were included in the Volume entry;[6]

[5] The analyte code, test system code, biological specimen code, and volume are the core information collected by the tabulator.

[6] The Nonpatient care volume entry was subtracted from the volume entry during data processing so that only patient care volumes are reported in this study.

- Comments - entered by tabulator (optional);
- Beginning and ending dates for the period represented by the entered volume automatically set to the beginning and end of the period being tabulated, usually 1/1/96 and 12/31/96, but could be edited by the tabulator if necessary; and
- New pair flag - automatically set to "I" if the analyte code and test system code pair did not exist in the expanded Complexity Model.

The Tabulation Device contained a number of features to assist the tabulators:

- Complexity Model;
- Data validation checks;
- Daily log sampling; and
- Nursing station sampling.

Each of these features is described separately below.

CDC Complexity Model

A database of analytes and test systems became the basis for data collection and was an integral component of the Tabulation Device. The database consisted of the CDC Complexity Model and additional analytes and test systems identified by Westat. The Complexity Model is a database of analytes and test systems linked to each other. Analyte is defined in the CLIA 88 regulations published in the Federal Register of February 28, 1992 (p.7139) as "a substance or constituent for which the laboratory conducts testing." An example is glucose. A test system measures the analyte present in a biological specimen derived from a human being, according to the regulations, for the purpose of "providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings."

Since specimen type helps to determine complexity and since specimen is sometimes confounded with analyte and test system in the Complexity Model, Westat and CDC agreed to include specimen type as part of the data collected. A total of 42 unique specimen types were identified and given two-digit codes. The data tabulator's primary task was to identify each cluster comprising an analyte, a test system, and a specimen in a laboratory and to record each cluster's calendar year 1996 test volume.

The CDC Complexity Model contains thousands of combinations of analytes and test systems, yet a study of the database revealed that many items were missing, particularly in the microbiology specialties. For example, although "Growth or No Growth of Bacteria on Solid Culture Media" was included, parallel entries did not exist for fungi or mycobacteria. or for organisms ruled out on certain selective and differential media. Westat needed a means for tabulating all growth or no growth tests. Other examples of entries missing from the database included various methods for performing antibiotic susceptibility tests such as manual minimal inhibitory concentrations, antifungal susceptibilities, serum killing levels, and synergy studies.

There were also no entries in the CDC database for tabulating tests in the Anatomic Pathology specialty. Westat developed a general approach to classifying information in the areas of Cytology, Histopathology, and Chromosome Analysis using reference laboratory service manuals from laboratories all over the country; textbooks in many of the specialties; expertise from the medical technologists assigned to the project; and nonproprietary databases.

Westat added 571 analytes and 763 test systems to the list used while collecting the inventory. These entries were assigned temporary Westat placeholder codes until CDC could study them and assign permanent codes. The CDC database and the additional entries identified by Westat became known as the expanded Complexity Model. This expanded database became an integral part of the Tabulation Device.

The expanded Complexity Model was used as a means of editing the data entered by the tabulators. Whenever a tabulator entered a cluster that did not exist in the expanded Complexity Model, the system warned of a potential data entry error. Since tabulators sometimes needed to enter clusters not in the expanded Complexity Model, the system allowed them to continue but set a "new pair" flag in the database so that the record could be examined and, if necessary, edited at Westat's home office. Tabulators were asked to complete a comment field, providing any relevant information, whenever they encountered such a cluster.

In some cases, as discussed later, home office editors found that the tabulator selected the wrong analyte or test system and corrected it. The most frequent instance of this was when a tabulator selected the analyte "hemoglobin" instead of "Hgb, single analyte inst. w/self-cont." In most cases, however, the tabulator's entry was correct. In these instances, Westat created a file of records containing analyte and test system pairs not in the expanded Complexity Model and sent it to CDC for resolution. All new pairs involving existing analyte and test

system codes were subsequently added to the Complexity Model by CDC and so did not require further editing.

Data Validation Checks

Several validation checks were built into the Tabulation Device to ensure that data were collected. These included the following:

- No records could be entered with blank analyte names;
- No records could be entered with blank biological specimen names;
- No records could be entered with blank test system names;
- The number of quality control tests performed had to be less than the total number of tests performed; and
- The tabulation for a location could not be set to "Complete" unless a volume was specified for all listed clusters.

If a tabulator violated one of these constraints, the system displayed a diagnostic message and provided a prompt to correct the error.

Daily Log Sampling

Some sites provided test volume information in the form of daily logs. To avoid having tabulators enter over 300 sets of volumes for each cluster in such sites, the Tabulation Device had an automated sampling feature. To use it, the tabulator first indicated the periods during which a laboratory was open for business (e.g., January I to May 31 and September 1 to December 31), then entered which days of the week a laboratory was open for business and the number of annual holidays on which it was closed. The system then calculated the number of days during which the laboratory was open for business in 1996 and divided this number by 20 to obtain the sampling interval, *S*.

A day was randomly selected from among the first *S* days that the laboratory was open, and the first time period was set to start and end on that day. Every *S*th day thereafter that fell on a day of the week on which the laboratory was routinely open was defined as an additional time period until 20 evenly spaced days were selected.

These 20 one-day-long periods were the days for which the tabulator recorded data. If one of these days fell on a holiday when the laboratory was closed or for some reason had missing data, the tabulator could set a flag indicating that fact. The total number of days that the laboratory was open and the number of days for which data were collected were used at the home office when estimating the annual volume for each cluster.

Nursing Station Sampling

When listing the test record sites within a geographic location, the tabulator provided a unique name to identify each site; its address or other locating information, as appropriate; the name and phone number of a contact at the site; and the type of the site. Site types could be one of the following:

- Blood donor center;
- Bone marrow unit;
- Cancer center laboratory;
- Cardiology/open heart/cardiac cath;
- Clinic (e.g., urology, pediatrics, coagulation);
- Dermatology;
- Emergency room;
- Endoscopy service;
- Health screen/health fair;
- Helicopter;
- Hematology;
- Hemodialysis;
- Intermediate or short-term care;
- Interventional radiology;
- Labor and delivery;
- Main laboratory;

- Mobile unit;
- Neonatology;
- Nursing unit;
- OR laboratory;
- Other, specify;
- Outpatient delivery (e.g., home birth suites);
- Outpatient surgery;
- Paramedic; ambulance;
- Pharmacy;
- Physicians Office Laboratory (POL);
- Point of care;
- Recovery room (post-anesthesia care);
- Respiratory therapy;
- Rheumatology;
- Shock trauma;
- Sites where microscopes were used;
- Skilled nursing facility associated with hospital;
- Syndrome-specific (diabetes);
- Urgent care (nonemergency clinic);
- Urology;
- Visiting nurse;
- Women's clinic/OB clinic; and
- X-ray, nuclear medicine.

If "Nursing Station" was selected, a supplementary window appeared that let the tabulator indicate whether the nursing station was "Standard (Homogeneous)" or "Specialized." "Homogeneous" in this context

meant that the nursing station performed the same set of tests as one or more other nursing stations. Any other nursing station was, by definition, "Specialized." In hospitals with more than two homogeneous nursing stations, the system randomly selected two for data collection. The tabulator could enter data for the selected sites but not for the remaining homogeneous nursing stations. The total number of nursing stations and the number from which data were collected were used at the home office when calculating an estimate for the annual volume in nursing stations for each cluster. All "Specialized" nursing stations were tabulated.

3.1.1.4 Data Communications

Each laptop was equipped with a 33,600 baud Hayes modem for use in communicating with Westat's home office. The modem was used for sending and receiving e-mail text messages, for automatically sending data files to Westat, for updating the software, for sending new assignments to the field, and for sending assignment status data to Westat.

3.1.2 Data Processing and Data Quality Assurance

Data processing encompassed the tasks performed at the home office to convert the data received from the tabulators into a delivery file containing the list of analyte test system biological specimen clusters conducted under each CLIA ID number in calendar year 1996 and the number of each cluster that was performed for patient care. The following batch processing steps were used to process the data:

- Editing and cleaning;
- Annualizing daily logs;
- Summarizing site data to location level data;
- Summarizing location data to laboratory level data (CLIA ID number level); and
- Making special adjustments.

Each of these steps is discussed in a separate section.

3.1.2.1 Editing and Cleaning

The editing and cleaning process had several stages, including quality assurance checks; using machine edit programs to check for defined error conditions; printing and reviewing all records for each laboratory; and making any needed corrections.

Quality Assurance Checks

Sometimes analytes and test systems were discovered in the field that were not included in the expanded Complexity Model. When this occurred, the data tabulators were asked to use the comment field on the Tabulation Device to describe the new analyte or test system or, less frequently, the new specimen type. They also completed a paper form, the Tabulation Problem Sheet, which was included in the hard-copy case folder.[7]

The systems staff maintained a log of computer-related problems and reviewed the log to ensure that any needed data corrections were made. Westat systems staff also searched for two conditions that would indicate a computer problem:

- There should be no clusters with zero volumes for sites with a single time period and
- There should never be null volumes.

After these cleaning operations were complete, Westat converted the files to SAS datasets.

[7] A hard-copy case folder was provided to the tabulator for each location when it was assigned. It included laboratory contact information and administrative forms. See Chapter 4 for more details.

Using Machine Edit Programs to Check for Defined Error Conditions

- To ensure clean data, Westat created SAS programs to check that each dataset following conditions:
- There were no blanks in key fields;
- The Volume should be a positive number and greater than the QC Volume;
- The New Pair Flag should be " 1 " (true) if and only if the analyte code and test system code pair did not exist in the expanded Complexity Model; and
- Within a site, all time periods should have data with nonzero volumes.

While many of these checks duplicated those built into the Tabulation Device, examining them outside of the Tabulation Device using independently written code provided an extra quality check. Except for errors that were generated when blank records were included in the files, no record failed any of these tests.[8] The blank records were deleted from the Paradox files, which were then reimported and rechecked.

Printing and Reviewing all Records and Selected Sets of Records for Each Laboratory

- Westat printed the following set of reports for each location:
- All analyte and test system records;
- Records with Westat codes for test systems;
- Records with Westat codes for analytes;
- Records with blank analyte or test system codes; and
- Records with new pairs (other than those included in the above reports).

[8] Blank records were created by an error in a labor saving routine that automatically made analyte, test system, and biological specimen clusters available to a tabulator who had entered them for one time period when he or she was entering data for subsequent time periods. The routine always created records for 20 time periods (the maximum allowed) even if the tabulator specified a smaller number. The extra records contained blank analyte, test system, and specimen names, as well as blank volumes. This error was noticed and corrected early in the field period.

These reports were reviewed by medical technologists at Westat, leading to two types of changes. One change was to replace a specific Westat code (W-code) with the appropriate code from the Complexity Model wherever it occurred.

The other change was more local. When the medical technologists reviewing the data found that it was possible to replace a blank code with either a W-code or a Complexity Model code, the update needed to be made to a specific record, not globally. Similarly, in the few cases in which the reviewer found that the tabulator simply made a spelling error, it was necessary to correct a specific record.

3.1.2.2 Annualizing Daily Logs

Annualizing daily logs involved estimating the total annual volume for each record collected by subsampling daily logs. The resulting volume was called adjusted volume 1 (ADJVOL1) and was calculated by multiplying each volume entered by the inverse of the effective sampling fraction. For example, if a laboratory was open 315 days, and data were collected for 19 days, then the volume would be multiplied by 315/19 to obtain ADJVOL1. The adjustment factor for all sites that did not undergo daily log sampling was 1, so that the ADJVOL1 was the same as the volume for each cluster recorded at these sites. (See Section 5.1.2 for further discussion.)

3.1.2.3 Summarizing Site Data to Location Level Data

Sites were places within a laboratory location where a tabulator accessed records used during the survey. For example, in a hospital, records might be dispersed among the emergency room, pathology lab, a dialysis unit, and multiple nursing stations.

After daily log data were annualized, any identical clusters recorded within a site were combined by adding together their volumes so that each cluster was represented only once for the site. If nursing stations were subsampled at a given location, an adjustment was made for the sampling by multiplying each recorded volume in a homogeneous nursing station by the ratio of the total number of homogeneous nursing stations listed in the Tabulation Device to the number sampled. Thus, if a hospital had seven homogeneous nursing stations and three specialized nursing stations, data were collected from two of the homogeneous nursing stations and all three of the specialized ones. Adjusted volume 2 (ADJVOL2) was calculated by multiplying the ADJVOL1 in each of the

two tabulated homogeneous nursing stations by 7/2. In all other cases, ADJVOL2 equaled ADJVOL1 I.

To determine the total volume for each cluster at a location, the values of ADJVOL2 each distinct cluster were added together across all the sites within the location.

3.1.2.4 Summarizing Location Data to Laboratory Level Data (CLIA ID Number Level)

To determine the total volume for each cluster at a laboratory, the total volumes for each distinct cluster were added together, across all locations within the laboratory (i.e., locations within a CLIA ID number).

3.1.2.5 Making Special Adjustments

Because of special conditions associated with a few laboratories, some special adjustments were required (also see Section 5.1.2). In one large organization, 20 of 80 locations were randomly chosen and visited on site. The central organization reported the total number of analytes tested, but test systems varied from location to location. Because the sum of the volumes (by analyte) from the 20 laboratories was not equal to one-fourth of the total reported by the central laboratory, the volumes were adjusted in each of the 20 sampled sites by creating an adjustment factor equal to

$$\frac{\text{total volume reported by central laboratory for the analyte}}{\text{sum of the volumes from the 20 sampled sites for the analyte}}$$

The volume recorded for each cluster associated with the analyte was multiplied by the adjustment factor for that analyte. Processing then continued as normal for the data from each site.

In 10 other locations, from which Westat was able to obtain data for only a portion of the time that they operated during 1996, volumes were adjusted by multiplying the recorded volumes by the number of days that the location was open, then dividing by the number for which the tabulator collected data.

In three laboratories with many locations, a subset of the locations was sampled prior to assignment to the tabulators for data collection. The recorded volumes for these laboratories were multiplied by an adjustment factor equal to the total number of locations divided by the number of locations sampled.

3.2 Phase II-Collection and Processing of Data from Laboratories with Waived and PPM CLIA Certificates

Data collection in laboratories with waived and PPM CLIA certificates was performed by mailing a Test Inventory Form to the laboratories and then calling to collect the data recorded on the form. Medical technologists at the home office called the participating laboratories and collected the data by recording it on a NICLTS Telephone Data Tabulation Form. The forms were then keyed into ASCII files and independently key verified by entering the data a second time. The ASCII files were converted to SAS files, cleaned, and summarized.

This telephone data collection and subsequent key entry was analogous to the field data collection using the Tabulation Device in Phase I. Data processing of the keyed data was analogous to the processing of Phase I data after it was transmitted to the home office.

3.2.1 Data Collection and Entry

The NICLTS Telephone Data Tabulation Form contained one line for each waived and PPM analyte-test system pair in the Complexity Model. Complexity Model codes for the analytes and test systems were preprinted on the form. The form also had spaces for recording the biological specimen, biological specimen code, and calendar year 1996 volume. When the biological specimen was known in advance, the biological specimen name and code were also preprinted on the form. For example, the biological specimen for the Bionike A/Q Pregnancy Test for Urine was preprinted on the form as "Urine" with specimen code "30." For the remaining clusters, the tabulators entered the specimen name and code on the form. For all clusters reported by the laboratory, the tabulators entered the reported calendar year 1996 volume.

After the tabulator completed the data collection form, a supervisory medical technologist reviewed it for completeness, legibility, and accuracy of coding and counted the number of clusters on the form with volume data recorded. The supervisor recorded this count on the front cover of the data collection form next to the NICLTS ID for the laboratory.

Only numeric fields from the data collection forms were keyed. These fields were as follows:

- NICLTS ID - The 7-digit location ID (from the front cover);
- Count (from the front cover);
- Analyte code;
- Test system code;
- Biological specimen code; and
- Volume.

Each batch was independently key verified and copied to Westat's network.

3.2.2 Data Processing

Data processing of the Phase II data consisted of two major steps: editing and cleaning and summarization of multilocation data to laboratory level.

No special adjustments were needed for Phase IL

3.2.2.1 Editing and Cleaning

The data editing and cleaning process was similar to that performed for the Phase I data, but simpler. Because there were no reports of problems from the field that needed to be resolved, there was no need to locate

the files or records with known problems and correct them. Westat did, however, need to perform the remaining data editing and cleaning steps:

- Using machine edit programs to check for defined error conditions;
- Printing and reviewing all records and selected sets of records for each laboratory; and
- Making needed corrections.

Using Machine Edit Programs to Check for Defined Error Conditions

Westat wrote and applied a number of routine edits including the following:

- The value for the volume in each record in the mail/telephone data was greater than zero;
- The number of records entered for an ID matched the manual count recorded by the data collection supervisor on the cover of the data collection form;
- The set of NICLTS IDs included in a data file matched one-to-one with the set of IDs recorded in the Survey Management System as having completed tabulations; and
- All and only the NICLTS IDs sent to key entry were included in the data files.

Westat created a file of all clusters containing W-codes and another file of all clusters containing blank codes. A report was produced for Westat and CDC staff to use in assigning Complexity Model codes to these analytes and test systems. The report showed that over 25 percent of the blank codes were caused by the absence of one specific test system from the expanded Complexity Model. Senior medical technologists edited each of the W-codes and blank codes by checking all documentation in the relevant laboratory's permanent hard-copy file, reviewing the Complexity Model for more complete test system names, and double checking the hard-copy data tabulation form. When possible, the reviewing medical technologists used the more complete information obtained in this manner to correct the entries. The remaining records were sent to CDC for coding.

There were a number of reasons for the observed coding problems. Phase II information was gathered by telephone tabulators who could not directly observe test systems. Some respondents could not give complete information about test systems. Timing of the tabulation process may also have been a factor. Tabulation occurred approximately a year after the 1996 period for which test data were collected, and many of the test systems used

in 1996 were no longer in use. Respondents could recall use of a glucometer, for example, but not the name of the manufacturer. The small number of records with this type of partial information was also sent to CDC for coding.

3.2.2.2 Summarizing Multilocation Data to Laboratory Level

Summarizing of multilocation data to the laboratory level was considerably simpler for Phase II data than for Phase I data. Some laboratories had multiple locations from which Westat collected data using separate data collection forms. However, because staff at these locations compiled all the relevant data in one place, the locations did not need to be further subdivided into sites for data collection purposes. Furthermore, Westat did not perform either daily log subsampling or nursing station subsampling, and thus had no need to adjust the volumes to reflect such sampling.

Data summarizing to the laboratory level consisted of adding the volumes of like clusters from all the locations of a laboratory so that a single value was reported for each cluster found within a laboratory (i.e., within a CLIA ID number).

4. OPERATIONS

The operations for the field study in Phase I differed considerably from those for the mail-telephone study in Phase II. The operations for each phase are discussed in separate sections below.

4.1 Phase I

The operational components of Phase I consisted of a staged series of processes and procedural steps. The principal stages were:

- Advance mailing to the laboratories;
- Telephone enrollment of laboratories into the study;
- Mailing of a confirmation letter to enrolled laboratories;
- Assignment of each laboratory to a specific field tabulator;
- Transmittal of electronic and hard-copy laboratory contact 'information from the home office to the tabulator assigned in the field;
- Field tabulator's preliminary telephone contact with the assigned laboratory;
- Field tabulator's visit to the assigned laboratories;
- On-site tour of the laboratory;
- On-site tabulation of test volumes using the Tabulation Device;
- Electronic transmittal of tabulated data from Tabulation Device to the home office computer;
- Transmittal of related hard-copy materials from the tabulator to the home office; and
- Receipt and review of transmitted data and materials by home office management and technical staff.

In addition to this operational main line, there were several general components operations of Phase I These included:

- Assigning and training telephone enrollment staff;
- Recruiting and training the field tabulators;
- Managing and monitoring the telephone enrollment and field tabulation;
- Providing ongoing informational support to personnel at the laboratories through a dedicated toll-free NICLTS laboratory hot line; and
- Providing ongoing technical support to the field tabulators through a dedicated NICLTS tabulator technical support line.

Finally, two quality assurance processes were incorporated into the Phase I operations are described in Section 6. 1, which specifically addresses NICLTS quality control:

- Telephone verification - telephone followup with each tabulated laboratory by home office staff, to verify that the tabulator visited the laboratory and performed the data tabulation in conformity with the protocol and
- Field validation - independent retabulation of a small sample of laboratories by a field tabulator other than the one who performed the original tabulation.

For purposes of both efficiency and security, the NICLTS project carried out most of the home office administrative functions of the operations from a single secure field operations room. The operations room was the location of four ongoing functions:

- Printing and assembly of hard-copy materials needed for the various operational stages;
- Distribution of materials to the several operational functions taking place in the telephone center and in the field, tracking of distributed materials, and receipt of materials from telephone and field operations;
- Permanent filing of all paper records and reports created for the project; and
- Operation of a technical support line for field tabulators.

The following sections describe the important aspects of these components. Section 4.1.1 describes the advance mailing. Section 4.1.2 covers the telephone enrollment. The confirmation letter is described in Section 4.1.3. Details about various field operations components appear 'in Section 4.1.4. Section 4.1.5 deals with the

specific protocol and procedures employed by the tabulator when in the laboratory. The computerized Survey Management System is described in Section 4.1.6. A brief description of the technical support lines appears in Section 4.1.7.

4.1.1 Advance Mailing

The initial contact with each selected laboratory commenced with the mailing of an advance notification letter from Edward L. Baker, Jr., Assistant Surgeon General and Director, Public Health Practice Program Office, CDC. This letter covered the following points:

- Informed the laboratories about the study and its purpose;
- Notified them that they had been randomly selected for the study;
- Stressed the importance of their participation;
- Informed them that the study was authorized under Section 306 of the Public Health Service (PHS) Act (42 USC 242k);
- Assured them that the information they provided would be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m); and
- Alerted them to expect a telephone call from a Westat representative, who would speak to them specifically about their participation.

Thus, this letter was designed to inform, encourage, allay any concerns, and attest to the legitimacy of the study and of Westat's involvement. It was one of the measures implemented for both quality assurance and operational efficiency of the study, especially in terms of the effect it would have on encouraging laboratories to participate and be candid and conscientious in providing data.

4.1.2 Telephone Enrollment

Approximately 1 week after the advance notification letter was mailed, telephone enrollment specialists initiated telephone contact with each sampled laboratory. The principal objective of the contact was to elicit the

laboratory's voluntary participation in the study. The other objectives were to do the following:

- Confirm that the facility with which contact was made was clearly the facility associated in the OSCAR database with the sampled CLIA ID number, or secure the information needed to locate that facility, if not;
- Explicitly confirm the CLIA ID number;
- Find a telephone Enrollment Contact, i.e., a telephone respondent who was knowledgeable about the laboratory and could speak for it authoritatively during the telephone enrollment process;
- Secure the name of the Field Contact, i.e., the laboratory staff person who could serve as the on-site, in-person contact for the field tabulator (if different from the telephone Enrollment Contact);
- Resolve any uncertainty about the exact laboratory name (e.g., changes since CLIA application, more explicit or clearer information than provided on application); and
- Identify any locations (other than the point of initial contact) where the laboratory might do testing under the sampled CLIA ID number.

To achieve these objectives, NICLTS employed a telephone enrollment protocol that consisted of a specifically designed set of forms and materials, procedures, and an enrollment specialist training program.

4.1.2.1 Telephone Enrollment Forms and Materials

The telephone enrollment protocol was built upon the use of four principal forms used to guide and structure the enrollment process. A set of these forms was used for each sampled laboratory.

These were:

Respondent Information Sheet (RIS) - The RIS was a printed form that provided the enrollment specialist with all the relevant data from the OSCAR file: laboratory name, address, phone number, CLIA ID number, and the unique anonymous NICLTS ID number assigned to the sampled laboratory. To further assist the enrollment process, the RIS also contained information about the type of laboratory (e.g., hospital, POL) and the date on which the advance letter was mailed to the laboratory.

Contact Questionnaire - The contact questionnaire was a paper form that consisted of a series of questions and statements that guided the enrollment specialist through the practical steps of confirming

contact with the laboratory named on the RIS and finding the appropriate person to speak to about enrolling the laboratory into the NICLTS study.

Enrollment Questionnaire -The Enrollment Questionnaire was a short paper questionnaire administered to the telephone Enrollment Contact. This questionnaire was the center point of the enrollment protocol, covering enrollment of the laboratory, CLIA ID number verification, identification of additional testing locations, and clarification of explicit laboratory name.

Laboratory Enrollment Form (LEF) - The Laboratory Enrollment Form was a paper form used to record the critical information obtained while administering the Enrollment Questionnaire. The blank recording blocks on the form corresponded to items on the Enrollment Questionnaire. When completed, the LEF contained all the information necessary to assign the case to a field tabulator preparatory to carrying out the site visit. A separate LEF was filled out for each location where a laboratory did testing under the sampled CLIA ID number.

Eligibility Screener - The eligibility screener was a supplementary questionnaire administered by the enrollment specialist when a sampled facility claimed that it was not a laboratory and did no clinical tests. Since many facilities that require a CLIA certificate are not laboratories per se or do not think of themselves as performing traditional clinical tests covered by CLIA, it was necessary to ask qualifying questions and structured probes to determine if the facility did indeed have a CLIA certificate and did do some form of testing during calendar year 1996 that would be subject to CLIA regulations. The original protocol called for the enrollment process to ignore this issue and err on the side of caution, by trying to enroll every facility that was confirmed as one of those sampled via the CLIA ID numbers on the OSCAR database. Early experience showed, however, that more facilities than anticipated were Justifiably claiming that they did no clinical testing in 1996. Following the original protocol would have resulted in considerable wasted effort in the field, as well as unnecessary burden for these nonlaboratory facilities. Thus, in consultation with CDC, the NICLTS project managers modified the protocol to screen out truly ineligible facilities at the point of telephone enrollment.

In addition to these principal forms, a variety of other routine, administrative forms were used, such as a Call Record to keep track of information about what occurred on each telephone call attempt and to schedule and record information for callbacks.

4.1.2.2 Telephone Enrollment Training

To ensure that the enrollment specialists and operations supervisors implemented theenrollment protocol correctly, uniformly, and consistently, the NICLTS project staff prepared and carried out a training program

covering protocol procedures and use of the associated forms. This training consisted of two formats:

- Written documentation and training materials and

- An 8-hour training session.

Written Documentation and Materials

There were several types of written documentation and training materials. Collectively, they served a dual purpose. First, they formally documented the activities and procedures performed by the enrollment specialist as part of the overall telephone enrollment protocol. Second, they served as text book and reference guide for the specialists in learning and carrying out their mission. The chief written materials were:

Enrollment Specialist Interviewer Manual - This manual described the various components and procedures for the laboratory enrollment process and provided a general overview about NICLTS and the role of the enrollment specialist. It gave general descriptions and full itemized details about the purpose, contents, and use of each form in carrying out the laboratory enrollment. A significant portion of the manual was devoted, first, to describing the various situations, problems, and roadblocks the specialists were likely to encounter and, second, to outlining the specific procedures to be followed when each situation was encountered. The combination of the various paper forms, the contact procedures, and the methods for handling respondents' questions and objections were the operational embodiments of the enrollment protocol design. Understanding and correctly implementing these components represented the core activities for fulfilling the enrollment protocol.

Question-by-Question Specifications ("Q-by-Qs") - These specifications, which appeared in appropriate chapters of the Interviewer Manual, presented detailed information about each question or data item in the four main enrollment forms. The specialists consulted the Q-by-Qs whenever they were unsure about how a particular situation or response related to the intent of the question or data item.

Training Session

The enrollment specialists were all experienced in general telephone interviewing techniques and in collecting data from business establishments. The NICLTS telephone enrollment training sessions were designed to familiarize them with the specific protocol for the enrollment of laboratories, give them hands-on practice with

the its operational components, and prepare them for the specific circumstances they might encounter when dealing with clinical laboratories. To this end, the NICLTS staff prepared an 8-hour training session.

The main pedagogical approaches were lectures, short exercises addressing specific forms and techniques, group practice sessions, and paired role plays. The group practice sessions and paired role plays consisted of mock interviews designed to give the trainees hands-on exposure to the specific items and processes involved in using the various forms and procedures of the protocol. These exercises were built around specific scenarios that were designed to gradually expose the trainees to different parts of the protocol, to the specific forms and items, and to specific anticipated situations and problems. The scenarios purposively raised important topics and issues that required the group to look up the solutions in the manual, Q-by-Q's, etc., and to work towards a solution by discussing various options. This approach permitted a common, universal exposure to the same training protocol and allowed the trainer to engage in explanations and group discussions about the issues being covered in the exercise.

4.1.2.3 Telephone Enrollment Operations

The preponderance of the enrollment operations consisted of executing the formal enrollment protocol, as embodied in the questionnaires, forms, material and procedures documented in the enrollment specialist manual. In addition, there were some significant administrative or operational components. These included controlling the sample to ensure statistical validity of the tabulated results, processing the information about the enrolled laboratories, managing and supervising the process, and management reporting.

Project managers used a Survey Management System to control the flow of each sampled laboratory from the point where it was sampled from the OSCAR database, through all the operational stages that led to its final disposition as a sample case that was or was not included in the final survey database. The SMS was also the system that captured the information and produced the output needed to support the operations. In terms of the Telephone Enrollment process, the SMS was used to control the assignment of sampled cases to the enrollment process, produce the RIS's, record the result of the enrollment effort for each sampled case, and capture electronically the operational information collected on the LEF as the final product of the enrollment process.

The NICLTS SMS was designed to support the progressive release of the sampled cases over time, with control available at the level of an individual case, if needed. When the enrollment process ended for each laboratory, the next step was to transmit the completed telephone enrollment materials to the field operations room, record the resulting information in the NICLTS SMS, and file the hard-copy materials. For the enrolled cases, all of the information collected on the paper LEF was entered into an SMS electronic record that mirrored the paper LEF's contents. This information was then used by the SMS in carrying forward future operational processes. For nonenrolled cases, a result code indicating the reason for nonenrollment was recorded in the SMS.

Enrollment Operations Management and Supervision. Under the direction of the NICLTS project managers, a team of telephone interviewing managers and supervisors oversaw the day-to-day telephone enrollment operations. In addition to participating in the design of the enrollment protocol and the enrollment training, their responsibility was to ensure that the enrollment specialists understood and adhered to the enrollment protocol, to observe the implementation of the protocol and make recommendations as needed for modifications, and to identify specific problems and work with project management to address them.

The final role played by the telephone enrollment supervisory staff was an important quality assurance measure. Throughout the telephone enrollment process, and especially at the beginning of the process, the supervisory staff monitored a selection of each specialist's telephone contacts. This silent monitoring was carried out from dedicated monitoring stations that allowed the supervisors to hear the enrollment protocol being administered without the specialists being aware of when they were being observed and without intruding on the conversation between the laboratory representatives and the specialists. This monitoring was designed both to ensure that the specialist followed the protocol and to identify any individual or generic difficulties that might exist in administering the forms or otherwise following the protocol. There were no problems of an individual or generic nature that had implications for the validity of the NICLTS protocol and resulting data. The most important finding of the monitoring activity was to detect the desirability of adding the eligibility screener to the protocol (see Section 4.1.2.1).

4.1.3 Confirmation Letter

Each enrolled laboratory received a personalized confirmation letter from the NICLTS data collection contractor's project director. This letter thanked the laboratory for agreeing to participate; referenced the telephone enrollment call; identified the laboratory location by name and address; and reinforced the information provided during the enrollment call, that a laboratory technician would call in the near future to set an appointment to visit the facility. It also reaffirmed the guarantee of confidentiality and provided a toll-free number to call if the laboratory had any questions about the study in general, the tabulation process, or specific technical matters. The purpose of this letter was to reinforce the enrollment call and to serve as a reminder of the impending visit by the field tabulator.

4.1.4 Field Operations

The NICLTS field operations encompassed all of the activities and processes that occurred during the on-site tabulation at the laboratories. These operations also supported them prior to or during the field period. The primary activities were:

- Preparing administrative and data collection materials for the field tabulation;
- Recruiting the field tabulators;
- Training the field tabulators in the tabulation protocol and operational procedures;
- Managing the field operations;
- Carrying out the tabulation protocol and specific field procedures, including the operation of the Tabulation Device;
- Controlling and tracking laboratory assignments; using the Survey Management System and
- Operating the technical support lines for the field tabulators.

The following sections discuss these topics in detail, except for the Tabulation which was described in Section 3. 1. 1.

4.1.4.1 Materials for Field Operations

The field protocol was based on the use of carefully designed forms to guide and standardize the process of contacting laboratories and preparing for the automated data tabulation during the in-person site visit. For each assigned laboratory, the tabulators received a separate case folder containing a set of paper forms that guided and supported their efforts to tabulate a complete inventory of the laboratory testing during calendar year 1996. The most important paper forms were the following:

Combined Laboratory Information/Call Record Form. The Call Record provided the laboratory information, such as identification numbers (CLIA ID and NICLTS ID numbers), laboratory name and address, contact name and telephone number. The remainder of the form served as a log to record each call and contact with the laboratory.

NICLTS Protocol Appointment Form. The tabulator used the Appointment Form to structure the process of contacting the laboratory by telephone. This contact script stated the purpose of the study and provided a sequence of questions and statements to contact the most appropriate respondent. Using this script, the tabulator would learn what kinds of records were available for the later on-site data tabulation and the extent of the test menu.

NICLTS On-Site Protocol. The On-Site Protocol guided the tabulator through each step of the on-site field procedures beginning with the verification of the CLIA ID number, address information and identification of other locations that were associated with the same CLIA ID number. The next step was to introduce the tour of the laboratory to establish the kinds of tests that were performed during calendar year 1996. As the last step before electronically tabulating the data, the On-Site Protocol provided guidance on how to obtain complete test volume information.

Laboratory Tour Form. The Laboratory Tour Form was used in conjunction with the On-Site Protocol to list on a paper spreadsheet detailed information about tests that were performed in calendar year 1996, such as test systems (including manufacturer model number), analytes and specimens. The form also served as a record to identify and distinguish backup systems and quality controls.

List of Waived and PPM Tests. The purpose of showing the list of waived and PPM Tests to each respondent during the laboratory tour was to ensure that all laboratory testing for calendar year 1996 was included in the tabulator's inventory. Pilot test experience had revealed a consistent pattern of laboratories overlooking simpler tests in enumerating the tests that they performed.

Volume Estimation Script. The Volume Estimation Script standardized the steps a respondent needed to take to provide test volume estimates when written or electronic records were unavailable or inaccessible.

Volume Estimation Form. The tabulator used the Volume Estimation Form to record the volume estimates a respondent derived by following the Volume Estimation Script for each analyte-test system-specimen triple.

Tabulation Problem Sheet. The Tabulation Problem Sheet provided space to describe any problem encountered either during the preparation for or during the actual data tabulation using the data Tabulation Device.

4.1.4.2 Field Tabulator Recruitment

A pilot study confirmed the existing belief that the best people for completing the inventory are those who speak the language of the laboratory and who have generalist laboratory technology experience. In addition, the project needed to hire people who could travel overnight from their home locations, who were comfortable around computers, and who had demonstrated interpersonal skills. Based on these needs, Westat advertised nationwide for medical technologists with the following major qualifications:

- Bachelor's degree;
- Current certification or registration;
- 2+ years of clinical laboratory experience;
- Laboratory generalist experience preferred;
- Good interpersonal skills; and
- Interviewing skills or field research a plus.

Nearly 300 candidates responded nationwide. Resumes were reviewed and ranked according to geographic need and then according to the desired characteristics and candidates' availability to attend a training session in January 1997.

Westat considered interviewing candidates in person either by flying them into the Washington, DC area or by having candidates fly to central locations, but these options were ruled out because of the expense involved. A telephone recruitment form was designed to screen candidates over the phone.

As a result of this screening procedure, some candidates were eliminated and the remaining were again ranked according to both technical and interpersonal skills. Those marked highest within targeted geographic regions passed to a reference check. Candidates passing the screening procedure and the reference checks were invited to the field tabulator training course in Bethesda, Maryland.

4.1.4.3 Field Tabulator Training

- During the training program, which took place in January 1997, the tabulators learned the following:
- The background of and necessity for the inventory;
- How to operate the laptop computer with its sophisticated Tabulation Device for recording data;
- How to operate the modem for data transmission;
- The expanded Complexity Model database;
- The tabulation protocol; and
- Administrative details such as how to complete a time and expense form.

Westat prepared a training program and materials for use both during the training sessions and later as a reference guide for the tabulators. The agenda was designed to hold the trainees' interest by introducing a variety of topics each day. The sessions began with a general overview of CLIA 88 and of the NICLTS project. Next, the trainees were introduced to the laptop computer and the Tabulation Device. By the third day, they were ready for specific information on the process of tabulating. They learned how to count tests and how to follow and complete protocol forms. A simple laboratory practice case was introduced. Instructors played the roles of tabulator and laboratory respondent and trainees began to enter data.

Discussions about the first practice case study followed the next day. Guidelines for reporting from the field were given and trainees received instruction on the e-mail system. More instruction followed on various aspects of the Tabulation Device, including use of time-saving features. Three additional practice cases were presented, providing an opportunity to review the protocol and enter mock data.

Training culminated with a practicum session, during which pairs of tabulators each visited one of several local laboratories that had agreed to serve as practice sites, where they carried out the full on-site protocol and tabulation.

4.1.4.4 Field Operations Management

There were five broad tasks associated with the operational and administrative of the field tabulation:

- Assignment of laboratories to field tabulators;
- Supervision and monitoring of the activities and performance of the field tabulators, including periodic and ad hoc reporting by the field tabulators to the field management;
- Communications between the home office management and the field tabulators;
- Ad hoc technical problem reporting, resolution, and documentation; and
- Administrative control, accounting for assigned cases, and management reports about individual case statuses and summary progress statistics.

Field Tabulator Laboratory Assignments

Once a laboratory was enrolled, the NICLTS field manager assigned it to a specific tabulator. This assignment was done primarily on a geographic basis: laboratories were assigned to the tabulator whose home base was the closest to the laboratory or who was on extended travel to handle all the laboratories in a state or region where there was no resident tabulator. Occasional departures from this practice occurred because of overriding considerations such as workload, restricted laboratory availability, or other issues.

The NICLTS SMS contained a module that allowed the field manager to review all enrolled laboratories that were not yet assigned and to assign one or more laboratories to a tabulator. Once a laboratory was assigned to a tabulator in the SMS system, the system flagged the case as being assigned to the specific tabulator for tracking

and reporting purposes. The case was then electronically dispatched to the tabulator's laptop computer over the NICLTS data communication channel.

Supervision and Monitoring of the Field Tabulators' Activities and Performance

A team of three NICLTS home office managers was assigned to oversee and support the day-to-day work of the field tabulators. These managers, designated as "field monitors," were assigned this responsibility because they were highly experienced in survey field operations and could support a field staff that was highly qualified from a technical standpoint but was not necessarily experienced in the field operations of travelling around the country and collecting information on business premises. However, the strong natural abilities of the recruited medical technologist staff in regard to this latter challenge, combined with the extensive NICLTS training program and the ongoing guidance of the field monitors, resulted in a field operation that ran as smoothly and efficiently as those employing veteran field survey data collectors.

In general, the monitors were responsible for overseeing and supporting the field tabulators' activities. Each monitor was assigned one-third of the tabulators, divided roughly into three geographic regions, East, Central/South, and West. Monitors were responsible for assessing the progress, productivity, and quality of each tabulator's overall effort. To accomplish this, they made use of such tools as:

- Regular half-hour weekly phone conference with each tabulator;
- Review of individual timesheets and expense reports;
- Review of summary time and expense statistics generated for each tabulator and for all tabulators;
- Review of various detailed and summary production reports generated from the NICLTS SMS;
- Regular weekly meeting of all home office field operations staff to discuss overall field progress, problems, and plans and to discuss each tabulator's assignments, production, and problems; and
- Individual discussions with other monitors or technical managers.

The monitoring focused on such issues as whether the tabulator was carrying out the field procedures according to plan; was making adequate progress in tabulating the laboratories given the tabulator's caseload and project schedule; and was operating efficiently in use of time, scheduling of appointments, and setting of travel itineraries.

The tabulator review and assessment function of the monitoring process was in itself only a tool to identify individual tabulation or operational processes that were working well or needed improvement, and to identify larger trends that might affect the overall project plan or schedule. The findings resulting from this process then had to be communicated and implemented. The monitors used these findings to provide helpful guidance, useful feedback, and constructive and corrective critiques to individual tabulators. They also used them as the basis for discussion and planning in a weekly field managers meeting and for informing the project director of emerging issues or problems that needed resolution or might dictate a change in procedures, plans, or schedule. For the most part, the individual tabulators and the overall field operations readily met the project plan and the project goals for operational productivity, efficiency, schedule, and product quality. In rare instances the monitors worked with selected individuals to improve their productivity or efficiency or to reinforce the operational procedures after training.

Ad Hoc Technical Problem Reporting, Resolution, and Documentation

The field monitors served as the first point of contact whenever the field tabulators needed to contact the home office with a problem or question. The monitors handled any operational or administrative issues themselves, but documented any other issue on a Problem Resolution Form and referred it to the appropriate technical manager. Complexity Model or clinical issues were referred to the NICLTS clinical managers. Questions about the operation of the Tabulation Device were referred either to the NICLTS field support staff or to the NICLTS systems managers, depending on the nature of the issue. Questions about data communications were referred to the NICLTS systems managers. Questions about laboratory eligibility, CLIA ID numbers, subsampling of daily logs or nursing stations were referred to the NICLTS statisticians. After questions and problems were resolved, the field monitor reported the result back to the tabulator; when appropriate, the resolution was also documented in a formal Field Memo and distributed to all field and home office staff.

A description of the handling of technical problems appears in Section 4. 1.

Field Communications

Because of the operational scope and the technical and operational complexity of the Phase I tabulations, it was essential to maintain several modes and channels of communication for field management purposes.

Field Management Data Communications. NICLTS maintained a data communications link to download assigned cases to the field tabulators' computers and upload tabulated data and case status information from their computers to the home office computer. This communications link was described in Section 3.1.1.4. From a field management standpoint, the key aspect of this system was the regular information it made available to the field managers about the progress of each individual case, each tabulator's caseload, and overall project progress.

Electronic Mail. NICLTS operated an e-mail system for text messages between the field tabulators and the home office that was separate from the data communications channel. Data transmission and text message e-mail links were established though daily (or more frequent) dial-ups from the tabulators' computers to the NICLTS data processing system and the NICLTS e-mail server. The text message e-mail channel allowed two-way communication of electronic memos from home office management to individual tabulators and globally to all tabulators, and from individual tabulators to one or more NICLTS managers in the home office. The e-mails from the home office informed the field staff in writing about general issues or decisions, alerted them to general problems and solutions, and informed them of changes or additions to field operational policies and procedures. E-mails addressed to individual tabulators generally informed them of specific instructions that applied only to their work, answered if specific questions about procedures or individual cases that they had previously communicated to the home office, and alerted them to any specific problems in their own activity or at a laboratory assigned to them.

Voice Communications. As described earlier, each tabulator was assigned to report to a field monitor located in the home office. Each monitor had a dedicated 800-number for her tabulators to call whenever they needed to speak to her, whether for the regularly scheduled weekly call or any other occasion. If the monitor was not available to answer the call, it rolled over in sequence to several other backups, such as to the tabulator

technical support line operated by two individuals during Eastern Time business hours (see Section 4.1.7.2).

Hard-copy Communications. NICLTS used one direct mode of hard-copy communication, a series of nine detailed Field Memos composed by appropriate NICLTS clinical and operations managers. The memos were distributed to the field tabulators weekly for the first month and then as needed. They functioned as a consistent, universal documentation and promulgation of ongoing refinements, elaborations, explanations, and reinforcements of the field protocol and operational procedures.

The commonest and most important topics dealt with the mechanics of the Tabulation Device and explanations of how to handle specific types of tests and analytes within the parameters of the Complexity Model and the tabulation protocol. Other substantive topics were the addition of protocol supplements that put in place operational steps for dealing with CLIA ID number discrepancies and with facilities that claimed not to have done testing in calendar year 1996. The memos also alerted the field staff when new releases (improvements and fixes) of the Tabulation Device software were automatically downloaded to them during the field period and explained what the changes involved. Collectively, the memos constituted a formal supplement to the NICLTS Tabulators Manual.

4.1.5 Field Protocol and Procedures

The field protocol and procedures can be conveniently conceived of as having two logical parts: (1) the on-site protocol that led to the information needed for tabulation and (2) the actual tabulation of the test data.

4.1.5.1 On-Site Protocol

The on-site protocol incorporated all activities associated with the tabulation process. It started with preparation for the visit and ended when all data had been tabulated at a location. Activities on site included confirming the CLIA ID number and touring the laboratory with one of the employees. The tour allowed direct observation of test equipment in use by the laboratory, observation of the testing process, and observation of any equipment that was not associated with any of the recorded tests. It also provided an opportunity to talk with

laboratory personnel. The tabulator asked about current and past use of tests during 1996 and documented the names of the test equipment for later entry into the Tabulation Device.

After completing the tour, the tabulator requested pre-existing volume records. Sometimes these did not exist, particularly in POLs. A special protocol was developed to estimate the volume in these instances.

Finally, with the data sources and the laboratory tour information in hand the tabulator entered all the clusters of analytes, test systems, and biological specimens into the computer.

4.1.5.2 On-Site Tabulation

After touring the laboratory and obtaining testing records, the tabulator used the Tabulation Device to record the data. Upon reaching a site in the laboratory, a tabulator first entered a collection of site details. Data entry then consisted of specifying the following information for each unique cluster encountered:

- Analyte name;
- Biological specimen name;
- Test system name;
- Volume of tests performed in 1996 for the specific combination of analyte, biological specimen, and test system; and
- Number of tests not for patient care that were included in the volume figure.

The system automatically provided the Complexity Model codes for the analyte and the test system as well as the Westat-created code for the biological specimen. Tabulators could also record comments about each test when they considered the information useful for later analyses.

In practice, the analyte name and volume were the only information included in the laboratory's records. Tabulators used information collected during the tour to determine the biological specimen and the test system

associated with each analyte. If necessary, they also asked laboratory personnel to provide additional information.

To ensure that all tests were included when volume data were derived from billing records, they specifically probed to obtain test volume for any test for which there was no charge. When the only available source for the data was tester's estimates, they followed a structured question-and-answer script (see Section 4.1.4. 1) to collect the volume data as consistently as possible.

When the tabulator completed work at a site, he or she entered a status code of "Complete" in the Tabulation Device. It then performed a check to ensure that all clusters had associated volume data and reported any problems to the tabulator. If any data problems existed, the system reset the status code to "In Progress." The tabulator could then go back into the data table, correct the problems, and re-enter the "Complete" status code.

4.1.6 Survey Management System Case Management and Reporting

Several sections of this report refer to aspects of the NICLTS Survey Management System, a computerized information system used to manage survey operations. The SMS was at the center of four other data processing/information management systems needed for NICLTS. The systems it intersected with were:

- CDC OSCAR database/NICLTS sampling process, which occupied a front-end position in relation to the SMS;
- Distributed data collection system (field tabulator portable computers with Tabulation Device), which operated in parallel with the SMS;
- Field data communications system, which operated in parallel with the SMS and field data collection system and tied together the data collection, SMS, and data processing systems; and
- Data processing system, which incorporated subsystems for editing, processing, and weighting the tabulated data. The data collection and SMS systems both served as front-end processes to the data processing system, which produced the final weighted database of test volume data.

The SMS covered the functional stages from sample selection to the point where field data tabulation operations had ended and all verification and validation operations had been performed on the tabulated laboratories. The SMS had five primary functions

- **Case Management.** The SMS was first and foremost a process control system that controlled, handled, and accounted for each sampled case at each stage of the process from initial sampling to final disposition of the case at the end of data tabulation operations.[9]

- **Operational Data Processing.** The SMS contained several types of data records where information needed to carry out operations was entered, stored, and updated. These included items such as laboratory names, addressees, and phone numbers, names of people who served as the laboratory contacts for NICLTS, and names of field tabulators.

- **Transaction Processing.** The SMS was based on a structural model that envisioned the NICLTS operations as a series of stages through which each sampled case passed until it reached its end stage. Not every case ended at the same stage, and some cases may not have passed through certain stages. Each time a case moved to a certain stage, or when certain data processing took place on it within a given stage, the act of movement or processing was considered a transaction. Each transaction was recorded in a transaction file within the SMS. This transaction file and associated transaction processing routines that were available to the operations managers constituted the spine of the system that controlled and accounted for each case.

- **Production.** The SMS was a production system, with capabilities to allow data entry, data updates, and output of data onto hard-copy or electronic files needed for field operations or for input to other NICLTS systems.

- **Reporting.** The SMS contained a large number of reports that were available on demand by NICLTS managers. These provided a variety of information at the level of individual cases, individual tabulators, and cumulative summary statistics that enabled the managers to monitor, track, and control the progress of the operations and the movement of specific cases through the transaction process.

[9] For NICLTS, "case" was defined as the sampled CLIA ID number. Operationally, however, a CLIA ID number could apply to more than one facility. Therefore, within the context of the SMS and field operations, a "case" was defined as the original location associated on the OSCAR database with the CLIA ID number up to the point of enrollment. After enrollment, it was defined as a discrete geographic location where tests were performed under the CLIA ID number. This was the result of the need to account for each such location when tabulating the test data covered by the CLIA ID number, and to send a tabulator to each such location when two or more locations were covered by the same CLIA ID number. (The sampling unit for NICLTS was always the CLIA ID number, and one of the functions of the back-end data processing was to collapse test data collected at multiple operational locations back into a single sample unit CLIA ID number case record.)

4.1.7 Telephone Support Lines

During Phase I, NICLTS operated two toll-free telephone lines for field support purposes. One was the Laboratory Information Line and the other was the tabulator technical support line. Westat home office technical and management staff operated these lines by monitoring and responding to the calls received on them.

4.1.7.1 Laboratory Information Line

The Laboratory Information Line was set up to answer questions from respondents regarding NICLTS. The telephone number was provided to the laboratories at various points in the NICLTS operations. Westat staff monitored the line, responded to queries within one business day, and carried out any needed followup calls until the reason for the call was resolved.

The calls on this line fell into six general categories:

- Requests for additional assurances of the authority for the study and confidentiality of the information collected.
- Requests for clarification of the kinds of records that the tabulator would need for tabulation purposes.
- Information about the process of data collection during the on-site visit, and how long this process would take.
- Updated information about laboratory names, CLIA ID numbers, and locations covered by CLIA ID numbers.
- Leaving messages for field tabulators after they had established contact with the laboratory.
- Occasionally, refusal of a site visit after initial enrollment, owing to a change of heart or subsequent overruling of the original agreement by a higher authority. In most cases, the laboratory representative ultimately agreed to a site visit after speaking to a Westat staff member.

The quality assurance purposes of this line included courtesy to the laboratories, improvement of response rate, improvement of data validity, and logistical support for the laboratories and the field tabulators.

4.1.7.2 Tabulator Technical Support Line

The tabulator technical support line was set up to answer technical questions and solve problems from data tabulators in the field. It was designed to provide real-time support for the tabulators if they had a question or problem during the course of performing the on-site visits and tabulating the data. It was answered by a NICLTS medical technologist who was assigned to this task on a dedicated basis. This person was also expert in the functionality and use of the Tabulation Device. When the line was busy or the call occurred outside business hours, a voice mail system was available as backup.

The calls on this line addressed questions and problems in four general categories:

- Computer-related (both hardware and software),
- Complexity Model,
- Statistical, and
- Administrative.

Most questions and problems were solved on the initial phone contact between the tabulator and the home office medical technologist. Occasionally, some needed to be referred to a NICLTS staff member with suitable knowledge or authority to address the issue (such as the project director, senior statistician, or senior systems manager).

Every issue raised on a call, whether resolved on the call or requiring further review and followup, was documented on a Problem Resolution Sheet, which was then routed to senior staff members for review. In addition to resolving specific questions or problems, this process identified common problems and their resolutions, often resulting in protocol refinements or computer program changes that were relayed to the field through the various communications channels. The quality assurance purposes of this line included technical and operational support for the field tabulators and improvement of data validity.

4.2 Phase II

The operational components of Phase II consisted of a staged series of processes and procedural steps. The principal stages were:

- Advance mailing to the laboratories;
- Telephone enrollment of laboratories into the study;
- Mailing of a cover letter, Test Inventory Form, and Test System Reference List to enrolled laboratories;
- Assembly and transmittal of hard-copy laboratory case folders (contact information and Data Tabulation Form) to the telephone data collection facility;
- Telephone tabulator's collection of test volumes using the Data Tabulation Form;
- Key entry of tabulated data from Data Tabulation Form;
- Transmittal of hard-copy laboratory case folders to field operations room;
- Receipt of transmitted case folders in field operations room; and
- Receipt of hard-copy Data Tabulation Forms in field operations room after key entry.

In addition to this operational main line, there were several general components to the operations of Phase II. These included:

- Assigning and training telephone enrollment staff;
- Recruiting and training the telephone tabulators;
- Managing and monitoring the telephone enrollment and tabulation; and
- Providing ongoing informational support to personnel at the laboratories through a dedicated toll-free NICLTS laboratory hot line.

Finally, two quality assurance processes were incorporated into the Phase II operations and are described in Section 6.2 of this report:

- Monitoring of telephone tabulators: live monitoring of the data tabulation calls by NICLTS supervisory medical technologists and

- Field validation: independent on-site retabulation of a small sample of laboratories by a small group of field tabulators using the same paper Data Tabulation Form used by the telephone tabulators and a special On-site Protocol.

For efficiency and security, the NICLTS project carried out most of the administrative functions of the operations from the same secure field operations room used for Phase I. The operations room was the location where three ongoing functions took place:

- Printing and assembly of hard-copy materials needed for the various operational stages;
- Distribution of materials to the several operational functions in the telephone center, tracking of distributed materials, and receipt of materials back from telephone and key entry operations; and
- Permanent filing of all paper records and reports created for the project.

Except for the natural differences attributable to the use of a mail-telephone methodology to tabulate the test data, the Phase II operations were similar to those for Phase I. For the sake of clarity and brevity, the remainder of Section 4.2 describes only the aspects that are unique to Phase II or significantly different from the analogous Phase I element. Except where operational differences require a different organization, this section parallels that for Phase I and indicates where the description for Phase I applies to Phase II.

4.2.1 Advance Mailing

The advance mailing process for Phase II was identical to that for Phase I.

4.2.2 Telephone Enrollment

The telephone enrollment process for Phase II was nearly identical to that for Phase I. The only significant difference was that the laboratories were requested to respond to mail-telephone data collection rather than to allow a tabulator to visit.

4.2.2.1 Telephone Enrollment Forms and Materials

The telephone enrollment forms and materials were nearly identical to those used for Phase 1. The major differences were:

Contact Questionnaire/Eligibility Screener. The eligibility screening questions were formally incorporated into the normal flow of the contact questionnaire, rather than being a stand-alone supplement as in Phase I.

Enrollment Questionnaire. The wording of relevant items was changed to reflect the fact that the lab was being requested to participate by mail and telephone, rather than being asked to allow an on-site visit.

Laboratory Enrollment Form. The labeling of contact information was changed to reflect a mail-telephone contact rather than a field contact.

4.2.2.2 Telephone Enrollment Training

The telephone enrollment training for Phase II was nearly identical to that for Phase 1. Minor changes were made to the written documentation and to the specific content of several training exercises, to reflect the slight changes to the enrollment forms, the differing nature of the request for the laboratory to participate by mail and phone, and possible difficulties and solutions associated with enrolling the higher concentration of physician office laboratories.

4.2.2.3 Telephone Enrollment Operations

The Phase Il telephone enrollment operations were identical to those used in Phase I.

4.2.3 Mailing Operations

The Phase II data tabulation protocol was a combination of mail and telephone data collection modes. The mail mode was based on a packet of NICLTS test data forms and materials that was sent by name to the mail-telephone contact identified during telephone enrollment at each enrolled laboratory. The contact was instructed in a cover letter to use the enclosed forms as guidance in assembling and recording the test data. The

mailed forms were not the ultimate data collection instruments but intermediate forms that the contact used to report the data to the NICLTS telephone tabulator by telephone. The telephone data collection forms were the ultimate data collection instruments. The mailed forms were not to be mailed back or otherwise physically retrieved for the study.

4.2.3.1 Mailing Materials

The mail component of the data collection protocol was built on the use of one form and three standard documents. These materials were mailed to each sampled laboratory as a single packet and included the following:

Customized Cover Letter. Each enrolled laboratory received a personalized cover letter from the Westat project director thanking the laboratory for agreeing to participate and referencing the telephone enrollment call. It briefly explained the enclosures in the packet and informed the recipient that a laboratory technician would call in the near future to collect the data. It reaffirmed the guarantee of confidentiality and provided a toll-free number to call if the laboratory had any questions about the study in general, the tabulation process, or technical matters. The purpose of this letter was to associate the mail package with the telephone agreement to participate in the study (to minimize any possibility that it would be discarded as a mass mail solicitation or marketing research); alert the contact to expect the telephone tabulator's call to collect the data in a few weeks; and encourage him or her to fill out the test data form before the call.

1996 Test Inventory Form and Customized NICLTS ID Label. The mail inventory form sent to the laboratories was a generic form, printed as an eight-page, 8 ½" x 11", saddlestapled booklet. The outside front cover contained the name of the study; CDC's name; the OMB number and disclosure language; and a unique NICLTS identifier label containing the sampled CLIA ID number, full laboratory name and address information as confirmed during the enrollment call, and the NICLTS ID. The inside front cover contained detailed instructions on how to fill out the form, definitions, and a place to record the laboratory's CLIA ID number. The body of the form contained a checkoff list of waived/PPM analytes, with blank lines to record test systems, specimens, and volumes. Where specimen was defined by the analyte, it was preprinted in the specimen line. The form also contained several open-ended items designed to probe for any tests being performed that were not waived/PPM tests. The toll-free technical assistance number was printed at the bottom of each page.

Test System Reference List. The generic Test System Reference List was an eight-page, 8 ½" x 11", saddle-stapled booklet. It listed all known manufacturers' names and models of test systems used for waived tests in 1996. The systems were grouped under their respective analyte categories, which were numbered and listed in the same sequence as in the 1996 Test Inventory Form. The list was designed to

assist respondents who were unsure of the specific full name of any test system that might have been employed in 1996.

NICLTS Mailing Envelope. The mailing envelope for the mail packet was a 9 ½" x 12 ½" white envelope, printed with the NICLTS name and logo and the NICLTS contractor's return address in the upper left-hand comer. In the lower right-hand comer, a short message and discreet graphic were printed to catch the recipient's eye and clearly differentiate this as a legitimate study and not a mass-mailed solicitation or market research. The NICLTS logo was used to catch the eye of recipients and to tie together the NICLTS package, since it also appeared on the front covers of the 1996 Test Inventory Form and the Test System Reference List.

4.2.3.2 Mailing Operations

The mailing operation was performed daily to maintain a steady flow of cases for the telephone tabulators, and to get the inventory form to the laboratory contact while the memory of the telephone enrollment call was still fresh. Each morning, the field room supervisor entered into the SMS the laboratory information on the LEFs from the laboratories enrolled by telephone the previous day. The operations manager ran the SMS mailing modules and computer mail merges to produce the hard copies of the customized materials. The field room supervisor then assembled the inventory form mail packets and posted them by close of business the same day.

Mailout Handling and Quality Assurance

At the beginning of the mail phase, mail support staff stuffed 2,000 blank NICLTS mailing envelopes with a copy of the generic Test System Reference List. The field room supervisor used these prestuffed envelopes when preparing the mail packets for each laboratory.

For overall quality assurance, the matched sets of customized letters and labels were maintained in identical sequence through each stage of the production process: electronic file output, printing/copying, checking, handling, and rechecking. The field room supervisor removed the first inventory form NICLTS ID label from the printed set of ID labels and affixed it to a blank Test Inventory Form, then affixed the corresponding mailing label to the envelope, and finally inserted the personalized letter and labeled Test Inventory Form into the envelope. This process continued through the mailing materials for all the laboratories in the batch.

After all the mailing packets for the day's batch were prepared, the field room supervisor reexamined each prepared set to ensure that the same NICLTS ID appeared on the letter, the Test Inventory Form ID label, and the mailing label. The supervisor counted the packets and verified the count against the control total on the mailing batch report.

4.2.4 Telephone Data Collection

The NICLTS telephone data collection operations encompassed the following primary components:

- Administrative and data collection materials for the telephone tabulation;
- Recruitment of the telephone tabulators;
- Training the telephone tabulators in the tabulation protocol and operational procedures;
- Tabulation protocol and specific telephone procedures, including the use of the Data Tabulation Form;
- Management of the telephone operations;
- Problem resolution; and
- Control and tracking of laboratory assignments.

The following sections discuss these components in detail. Section 4.2.4.1 describes the telephone data collection materials. Sections 4.2.4.2 and 4.2.4.3 describe the recruitment and training of the telephone tabulators. Section 4.2.4.4 presents a detailed explanation of the telephone tabulations operations and management.

4.2.4.1 Telephone Data Collection Materials

The Phase II data collection protocol was based on carefully designed forms us and standardize the process of contacting laboratories and tabulating the data by telephone.

For each assigned laboratory, the telephone tabulators received a separate laboratory casefolder containing the following forms:

Call Record. The Call Record was a combined laboratory information and call record form that was identical to the Call Record for the Phase I field tabulation. It provided the laboratory information, such as identification numbers (CLIA ID number and NICLTS ID) laboratory name and address, and contact name and telephone number. The remainder of the form served as a log to record each call to the laboratory and the resulting information.

NICLTS Telephone Data Tabulation Guide. The Telephone Data Tabulation Guide provided comprehensive guidance to the tabulators for collecting the laboratory test inventory data over the telephone. It contained a scripted protocol that they read aloud to the respondents during the tabulation interview. By explicitly refer-ring to the specific items printed in the mailed 1996 Test Inventory Form, the text in the Telephone Data Tabulation Guide focused the respondent's attention on the completed Test Inventory Form (in the respondent's hand). Each step of the data collection paralleled the steps in the Phase I OnSite Protocol. The guide established the verification of the CLIA ID number confirmed address information, and confirmed enrollment information about other locations associated with the same CLIA ID number.

Once the tabulator began the tabulation of the test data, the parallelism between the Telephone Data Tabulation Guide and the mailed 1996 Test Inventory Form enhanced the data collection process. The second part of the guide contained a numbered list of the waived analytes that was identical to the presentation of these items on the mailed Test Inventory Form. The guide then proceeded to the list of open probes designed to elicit any moderate/high complexity tests the laboratory may have performed, and finally to the open probes about microscopy tests.

NICLTS Telephone Data Tabulation Form. The Telephone Data Tabulation Form was a paper instrument that contained a complete printed list of waived/PPM analytes and the names of the test systems associated with each analyte in the Complexity Model. This list paralleled the list of analytes appearing in the mailed Test Inventory Form and the Telephone Data Tabulation Guide, and also the list of official Complexity Model test system names printed in the mailed Test System Reference List. In the Telephone Data Tabulation Form, each possible test system for a given analyte was listed alphabetically, line by line, below the analyte. Each test system was followed on its line by blank spaces to record specimen, specimen code, and test volume. The Complexity Model code for the test system was preprinted on the line. For any analyte/test system combination that, by definition, could be used for only one specimen, the specimen and specimen code were pre-printed in the space designated for recording these two items.

The Telephone Data Tabulation Form was designed to serve three functions: to support the valid and easy collection of the data from the telephone respondent; to simplify the process of accurately recording the information during the telephone call; and to simplify the accurate entry of data from the Telephone Data Tabulation Form into the NICLTS data file. For ease of use and to ensure the cohesiveness of the data, it was produced as a booklet printed in single-sided, landscape format and comb-bound across the top of the booklet, to allow the tabulator to open it flat on the desk. The three forms-the mailed 1996 Test Inventory

Form, the Telephone Data Tabulation Guide, and the Telephone Data Tabulation Form-paralleled each other precisely and established the controlled linkage among the laboratory respondent, the data collecting tabulator, and the completed test inventory tabulation.

NICLTS Data Collection Problem Form. The NICLTS Data Collection Problem Form was incorporated at the end of the Telephone Data Collection Guide and provided space to describe and flag any technical problems encountered in administering the Telephone Data Tabulation Guide or completing the Telephone Data Tabulation Form.

The telephone tabulators also used the Phase I Volume Estimation Script, which standardized the steps a respondent needed to take to provide test volume estimates when written or electronic records were inaccessible.

4.2.4.2 Telephone Tabulator Recruitment

For Phase II, Westat hired new tabulators living in the Washington, DC area with similar backgrounds and experience to those hired for Phase 1. NICLTS supervisory staff interviewed all qualified medical technologists at Westat headquarters and made final selections for training.

4.2.4.3 Telephone Tabulator Training

Training took place at Westat in November 1997 and was similar to that for Phase I. Details relating to computer use were eliminated since the Phase II protocol collected data using paper and pencil. Because the tabulators were local, administrative details regarding expense reporting and travel were also unnecessary.

As in Phase 1, there was a formal Tabulator Manual that documented the protocol, forms, and procedures for the telephone tabulation and operations. It included instructions for contacting laboratories and for handling typical contact problems. Since the tabulators had no access to the computerized data Tabulation Device, a second manual contained a hard copy of the expanded Complexity Model database. It also had reference materials, such as the volume estimation protocol and answers to commonly asked questions.

Training sessions used the same training formats as Phase 1: lectures, discussions, hands-on practice, and role plays. Trainees practiced making calls and collecting data through scripted case studies and role plays.

4.2.4.4 Telephone Tabulation Operations and Management

The preponderance of the telephone tabulation operations consisted of executing the formal tabulation protocol as embodied in the forms, materials, and procedures documented in the telephone tabulator manual. There were some additional significant operational and administrative components. As in Phase I, these included controlling of the sample to ensure statistical validity of the tabulated results, processing of the information from the enrolled laboratories and preparing the case folders for data tabulation, management and supervision of the tabulation process, and management reporting.

There were five broad tasks associated with the operation and management of the telephone

- Production of case materials;
- Tabulation procedures;
- Supervision and monitoring of the activities and performance of the telephone tabulators;
- Ad hoc technical problem reporting, resolution, and documentation; and
- Administrative control and accounting for assigned cases and management reports about individual case statuses and summary progress statistics.

Project managers used a Survey Management System similar to that in Phase I to manage the sample and carry out the necessary operational data processing. In terms of the telephone tabulation process, the SMS was used to control the assignment of enrolled cases to the tabulation process, produce the Call Records, and record the result of the tabulation effort for each sampled case.

Production of Case Folders

In advance, the field room supervisor assembled bulk supplies of generic case folders containing blank copies of the materials described in Section 4.2.4.1, except for the Call Record. Each day, after the daily batch of inventory forms was mailed, the field room supervisor used the SMS to produce the laboratory-specific case materials for each laboratory. The supervisor prepared the case folders by affixing a laboratory name and ID label to the outside of a folder and inserting that laboratory's Call Record in the folder. The supervisor prepared all the folders corresponding to each day's mailing batch as a comparable batch ready to be transmitted to the telephone tabulation operations. For quality assurance, after preparing the daily batch, the supervisor checked each completed folder to make sure that all of the materials were present in the folder and that the laboratory-specific materials pertained to the laboratory whose NICLTS ID label and laboratory name label were affixed to the outside of the folder.

After all case folders for the day's batch were prepared, the field room supervisor counted the folders and verified the count against the control total on the mailing batch report. The day's batch of case folders was stored in the NICLTS field operations room and transmitted to the telephone data collection facility I week after the date of mailing.

Telephone Tabulation Operations Procedures

The telephone tabulators began calling the laboratories 8 days after the mailing. The primary purpose of the initial call was as a courtesy followup to confirm that the laboratory had received the Inventory Form packet, and to see if the contact had any questions. If the recipient reported that he or she had not received the packet, or if the tabulator spoke with a third party to whom responsibility had been delegated and that person did not have the packet, the tabulator completed a remail request form, which was sent to the operations manager to fulfill the remail request. This early identification of the need to remail a packet or to speak with a new respondent made operations more efficient and reduced the total time it would otherwise have taken to work through the case. Moreover, the laboratories were often ready to provide the data at the time of the courtesy call.

Requesting and Processing Remailing of Inventory Forms to Laboratories

Completed remail request forms were sent to the operations manager to fulfill the remail request. The form allowed for changing the name and address of the mail-telephone contact. Each request was processed the day after the tabulator filled out the request form. The remailing operations were nearly identical to the original mailings, although the two operations were logistically distinct. The only difference was that the standard text for the cover letter in remailings was different from the text for the initial mailing, reflecting that the current mailing was a remailing specifically requested by the current laboratory contact.

Supervision and Monitoring of the Telephone Tabulators' Activities and Performance

Working under the direction of the NICLTS project managers, a NICLTS project medical technologist functioned as the day-to-day telephone tabulation supervisor, with support as needed from other project medical technologist staff. Their responsibility was to ensure that the tabulators understood and adhered to the tabulation protocol, to observe the implementation of the protocol and make recommendations as needed for modifications, and to identify specific problems and work with project management to address them.

The telephone tabulation supervisory staff played an important quality assurance role by monitoring a selection of each tabulator's telephone contacts. This silent monitoring was designed both to ensure that the tabulator followed the protocol and to identify any individual or generic difficulties that might exist in administering the forms or otherwise following the protocol. The telephone supervisors used the findings of the call monitoring to provide feedback to specific tabulators on individual issues, and also to provide general advice to the tabulators as a group on ways to correct minor problems in the way they followed the protocol or recorded the data, or to make improvements in their telephone data collection techniques. There were no problems of an individual or generic nature that had implications for the validity of the NICLTS protocol and resulting data. The telephone protocol and Telephone Data Tabulation Form fulfilled the operational and data validity goals of the NICLTS Phase II that they were designed to accomplish.

Ad Hoc Technical Problem Reporting, Resolution, and Documentation

The telephone tabulation supervisor served as the real-time resource for resolving specific questions, including ones about clinical or Complexity Model issues, protocol issues, or telephone operations and calling procedures. Decisions or problem resolution that related to protocol, clinical, or Complexity Model issues affecting individual laboratories were documented on the Data Collection Problem Form in the back of the Telephone Data Tabulation Guide.

Quality Assurance of Completed Hard-copy Tabulation Form and Materials

Throughout the day, the telephone tabulation supervisor carried out a quality assurance check on the case folders of laboratories for which data collection activity had been finished. These checks included both cases that were successfully tabulated and those that were concluded without a tabulation taking place. He reviewed and edited the tabulated cases to ensure:

- Correct and complete administration of and recording on the Telephone Data Tabulation Guide;
- Completed items on the Telephone Data Tabulation Guide corresponding one-to-one to completed items on the Telephone Data Tabulation Form;
- Correct, complete, and legible recording in the Telephone Data Tabulation Form; and
- Correct coding in the Telephone Data Tabulation Form.

The edit included a thorough review of the Data Collection Problem Form. After editing, the telephone tabulation supervisor confirmed the final status code of all the cases. He then counted the number of actual data lines to be key-entered from the Telephone Data Tabulation Form (i.e., one for each recorded cluster with a non-zero volume) and recorded this count on the front of the form. This count was subsequently key entered along with the volume data and used as a quality control counter to ensure entry of all data.

4.2.5 Survey Management System Case Management and Reporting

The Phase II Survey Management System was a modification of the Phase I SMS and reflected the dropping, adding, or changing of components from Phase I. The principal deletions were modules for assigning cases to individual tabulators and receiving electronic case results from the field. The principal additions were several modules related to the mailing of the Test Inventory Forms to the laboratories and the tracking of hardcopy Telephone Data Tabulation Forms sent to and received from the key entry department. Additionally, a stand-alone SMS was operated for the Phase II field validation component. This SMS was nearly identical to the Phase I SMS.

4.2.6 Laboratory Information and Technical Support Line

During Phase II, NICLTS operated a toll-free telephone line for laboratory support purposes. In contrast to their Phase I counterparts, the Phase II laboratory contacts were personally responsible for the assembly and provision of the 1996 test data. The Test Inventory Form they received and filled out prior to the telephone tabulation call was designed to be clear, simple, and well documented. Nonetheless, it could not anticipate every laboratory situation, and the respondents had to deal with the same kinds of analyte, test system, specimen, and volume counting issues that the field tabulators handled in Phase I. Consequently, the laboratory support line for Phase II performed a combination of the functions performed by the Laboratory Information Line and Tabulator Technical Support Line in Phase I. That is, it provided in a single channel both informational and technical support to the Phase II laboratory respondents.

As in Phase I, Westat home office technical and management staff operated this line by responding to the calls received on it. The telephone number was provided to the laboratories at a variety of points in the NICLTS operations, including at the time of enrollment by telephone, on the cover letter accompanying the mailed Test Inventory Form, on every page of the Test Inventory Form, and by the telephone tabulators as part of the process of making contact and arranging for a convenient time to conduct the telephone data collection. The line was answered by the medical technologist who had functioned as the Phase I Tabulator Technical Support Line operator and the Phase II telephone operations super-visor. When a laboratory respondent could not immediately speak to the medical technologist because the line was busy, the technologist was temporarily busy with other duties, or the call occurred outside of business hours, a voice mail system was available. The medical technologist

responded to voice mail messages as soon as possible (and always in less than one business day); he made any needed followup calls until the reason for the call was resolved.

The calls on this line fell into seven general categories:

- Reports that the CLIA ID number on the mailed Test Inventory Form did not match the CLIA ID number on the certificate, in response to instructions on the Test Inventory Form to report such discrepancies.

- Requests for technical assistance in completing the Test Inventory Form.

- Claims not to be or not to have a laboratory. After (re-)administration of the eligibility screening protocol to such callers, the determination in most cases was that the facility was, in fact, eligible for tabulation.

- General questions regarding confidentiality and the purpose of the study.

- Calls to report the test data, either before or after the telephone contact process began. Even though the instructions on the Test Inventory Form explicitly requested the laboratories not to call to report test data, the telephone tabulation staff always tried to accommodate the caller by determining where in the NICLTS operations system that laboratory's case folder was located and then either conducting the tabulation interview or arranging to call back to collect the data.

- Requests to set a specific, convenient appointment for telephone staff to call to collect the laboratory data. Westat always set the appointment at the caller's request.

- Refusal to participate in the study, subsequent to the initial agreement to participate at the time of the enrollment call.

The quality assurance purposes of this telephone line included courtesy to the laboratories improvement of response rate, improvement of data validity, and technical and logistical support for the laboratories.

5. STATISTICAL ISSUES

This section discusses a number of topics related to statistical issues and data analysis. These topics include methods used to resolve problems that arose when confirming CLIA ID numbers; weighting and nonresponse adjustments; and survey results.

5.1 Phase I

5.1.1 CLIA ID Number Problem Resolution

Strictly speaking, the NICLTS sample frame consisted of CLIA ID numbers listed on HCFA's July 1996 OSCAR database as certified for performing moderate, high, waived, or Provider Performed Microscopy (PPM) testing. Every attempt was made to confirm each laboratory's CLIA ID number both at the point of enrollment and during the field tabulation. After cataloging the types of CLIA ID number problems discovered during the startup period, NICLTS clinical and statistical managers prepared a memo that explained how the field tabulators should handle them. Possibilities included the following:

1. **The CLIA ID number of the laboratory did not match the sampled CLIA ID number or could not be found.** In this case, the tabulator asked questions to establish a possible explanation for this situation. If the number did not match, the tabulator recorded the laboratory's CLIA ID number and collected data under some circumstances. The memo specified the circumstances when tabulation proceeded and when it did not.

2. **More than one CLIA ID number was found at the location.** The tabulator asked if separate data were available for testing performed under the sampled CLIA ID number, and, if so, tabulated them. Otherwise, all the data were tabulated and the statistician was alerted to this fact.

3. **More than one location was included under the same CLIA ID number** (other than multiple locations identified during enrollment). The tabulator asked for the names and addresses of all the locations. All locations were tabulated if the number of additional locations was three or less. If four or more locations were identified, the case was pulled for further consideration.

A number of cases fell into each of the three categories and most were dealt with easily by following the protocol in the memo. The last possibility proved to be the most complicated and the most interesting. One CLIA

ID number was associated with 80 separate locations at some distance from each other and would have required days of traveling and tabulating to complete. The laboratory's central office determined by phone which analytes were performed, the biological specimens used, and the annual volumes for the year of interest but could not determine the names of the test system manufacturers. Test systems differed from location to location. The problem was how to tabulate efficiently and accurately. The solution was to collect summary data on analytes on site at the central office and then to collect detailed data on analytes, test systems, and volumes by telephone from a representative sample of locations.

Several other CLIA ID numbers were also associated with multiple locations identified during enrollment or after the field tabulator established contact with the laboratory. The central office generally confirmed that test menus were homogeneous. This allowed Westat to select a sample of laboratories for visiting and tabulating and to visit all nonhomogeneous locations. If all locations under a CLIA ID number could be tabulated within 2 days, they were all tabulated on site.

5.1.2 Weighting and Nonresponse Adjustments

This section describes the steps taken for weighting and related postprocessing of the NICLTS data. The discussion covers each step of the calculation of the sampling weights, including construction of the base weights, nonresponse adjustments, raking, and adjustments for the various types of subsampling used within laboratories. These steps apply to both Phase I and Phase II of the study. Phase II adjustments were, however, somewhat simpler since there was no daily log or nursing station subsampling.

To clarify the discussion, some definitions are in order. For purposes of the NICLTS, a **laboratory** was defined as the unit corresponding to a specific CLIA ID number. Thus, laboratories (i.e., CLIA ID numbers) were the sampled units and the units of analysis. To facilitate data tabulation, further operational subdivisions were created. A laboratory could have multiple geographic **locations**--for example, when a health clinic had several clinics distributed across the state. Each location was sent to the field for a separate tabulation (although multiple locations of a single laboratory were handled operationally by the same tabulator). A location, in turn, could have multiple **sites** within it--for example, a nursing home with several nursing stations.

Review of Tabulation Problem Sheets

The Tabulation Problem Sheets from the field were reviewed to see if any of the situations described affected the weighting--in particular, cases involving multiple locations, multiple or mismatching CLIA ID numbers, and the use of billing or partial year data.

Assign Response Codes to Laboratories

Westat reviewed the specific operational result codes for every laboratory location to assign an overall response code for the laboratory. The result codes for locations were reduced to four response codes for weighting purposes: respondent, eligible nonrespondent, ineligible, and nonrespondent with unknown eligibility. For laboratories with multiple locations, it was necessary to assign a single response code to characterize the final response outcome at the level of the sampled CLIA ED number.

Table 5-1 shows how overall response codes were assigned to CLIA ID numbers whose laboratory locations had different combinations of operational result codes. The response codes were respondent (R), eligible nonrespondent (NR), nonrespondent with unknown eligibility (NU; this group included laboratories which could not be located) and ineligible (I; this group included laboratories that were out of business). No combinations other than those shown in the table occurred.

Table 5-1. Overall response codes and CLIA ID numbers

Laboratories with location operational result codes that were:	Had overall response codes of:
All R	R
All NR	NR
All NU	NU
All I	I
Any combination of R and NR	R
Any combination of R and NU	R
Any combination of R and I	R
Any combination of NR and I	NR
Any combination of NU and I	NU

Calculate Laboratory Base Weights

In general, the laboratory (i.e., CLIA ID number) base weight was simply the inverse of the probability of selection. The laboratory base weight formula accounts for any different probabilities of selection and was calculated as:

$$\text{Base weight} = \frac{1}{p_1 x p_2 + (1 - p_1 x p_2) x p_3}$$

where

p_1 = probability of selecting a laboratory for the initial sample;

p_2 = conditional probability of selecting a laboratory for the primary sample; and

p_3 = conditional probability of selecting a laboratory from the reserve sample.

Calculate Final Laboratory Weights

The final laboratory weight was the product of the base weight, nonresponse adjustments, and raking adjustments. Westat did three nonresponse adjustments: one to account for nonrespondents of unknown eligibility at the enrollment stage, one to account for eligible nonrespondents at the enrollment stage, and one to account for all nonresponse at the field data collection stage.

Nonresponse adjustments are made by computing an adjustment factor:

$$\text{Adjustment factor} = \frac{\sum_{\text{Full sample}} \text{Base weights}}{\sum_{\text{Responding laboratories}} \text{Base weights}}$$

This adjustment factor may be calculated over the entire sample or within various subgroups. For the NICLTS, nonresponse adjustment factors were computed separately for each phase, using region and laboratory type as subgroups. Some laboratory types were combined where the sample sizes were small.

Once the adjustment factors were computed, the nonresponse-adjusted weights were computed as

Adjusted weight = (Adjustment factor) x (Base weight).

Raking is a procedure where survey estimates are adjusted to match certain known values. In the NICLTS, after performing the nonresponse adjustments, Westat raked the resulting adjusted weights to counts of laboratories by the six levels of laboratory group (see Table 2-3) and ten levels of region (see Table 2.2). These counts were obtained from the original sampling frame (i.e., the July 1996 OSCAR database). The raking adjustments and final laboratory weights were calculated using Westat's WESWGT computer software.

Creating Total Volumes of Distinct Clusters within each Laboratory

In creating total volumes of distinct clusters within each laboratory, Westat adjusted for the following factors:[10]

- Subsampling of daily logs and nursing stations;
- Nonresponse among sampled logs and nursing stations; and
- Subsampling of locations.

Each of these adjustments is discussed separately.

Accounting for Daily Log Subsampling and Nonresponse

Dally logs were subsampled separately by site. For the sites that subsampled daily logs, Westat applied a factor to the volume amounts so that they represented the volume at the site as if subsampling and nonresponse had not occurred. Westat calculated the daily log adjustment factor as:

[10] Subsampling of daily logs, nursing stations, and locations occurred only during Phase I. Conceptually, the corresponding adjustment factors during Phase II are all "1."

$$\text{Adjustment factor} = \begin{cases} \dfrac{\text{days site was open}}{\text{days with data}} & \text{for sites that subsampled daily logs} \\ 1 & \text{for sites that did not subsample daily logs} \end{cases}$$

The adjusted volume amount was calculated by first subtracting the QC amount[11] multiplying by the daily log factor as follows:

$$\text{Volume adjustment} = (\text{Volume} - \text{QC}) \times (\text{Adjustment factor})$$

In a few cases, volumes were not collected for some of the subsampled days. This occurred in some laboratories because the selected days were holidays during which the laboratories were closed. These laboratories were treated as if the holidays were never selected. For instance, if a laboratory was open for 305 days during the year and one of the 20 subsampled days occurred on a holiday, then the adjustment factor was 305/19 instead of 305/20.

Data also could not be collected for some days in three laboratories. In one, data were not available for some analytes at various points during the year. This affected 40 of 300 potential data points. At the second laboratory, no daily log records were available from January 1, 1996 through May 24, 1996, and the contact person who might have provided estimates was out of the office during the tabulation visit. In the third laboratory, daily log records were available only from August 1, 1996 through December 31, 1996 for some analytes, and no one could provide estimates for the rest of the year.

For tests performed by nurses, daily log data were available for the full year. The total number of daily log data points not collected from all laboratories was 399, or 0.8 percent of the total of 47,699 data points selected for daily log tabulation. Table 5-2 summarizes the characteristics of the daily log nonresponses.

[11] QC is the nonpatient care volume included in the Volume value. See Section 3.1.1-3.

Table 5-2. Characteristics of daily log nonresponse

Location	Number of days with some data missing	Number of Distinct clusters	Number of clusters with some data unavailable	Expected number of data points (20 x number of distinct triples)	Number of data points unavailable	Percent of data points unavailable
23362-01	20	15	12	300	40	13.3
25599-01	12	35	28	700	335	47.9
34939-01	8	7	3	140	24	17.1

Accounting for Nursing Station Subsampling and Nonresponse

At some locations, homogeneous nursing stations were subsampled. To adjust the volumes collected to represent the volumes at all homogeneous nursing stations, Westat calculated the nursing station factor as:

$$\text{NURSEFC} = \begin{cases} \dfrac{\text{total nursing stations}}{\text{nursing stations subsampled}} & \text{for laboratories where nursing stations were subs} \\ 1 & \text{for laboratories where nursing stations were not sul} \end{cases}$$

The adjusted volume amounts were calculated by multiplying the amounts after adjusting for daily logs by the nursing station factor. Because all nursing stations at participating locations responded, no nonresponse adjustments were needed.

Accounting for the Subsampling of Locations

In some laboratories with many geographically dispersed locations, the locations were subsampled. Westat adjusted the volumes for these locations to represent the volumes as if locations had not been subsampled

by calculating a location subsampling factor; new volumes were calculated as:

$$\text{LOCFC} = \begin{cases} \dfrac{\text{locations at laboratory}}{\text{locations subsamples}} & \text{for laboratories where locations were subsampled} \\ 1 & \text{for laboratories where locations were not subsampled} \end{cases}$$

$$\text{Adjusted volume} = \text{LOCFC} \times \text{Volume}$$

5.1.3 Phase I Summary Case Result Reports

This section presents summary statistics and a discussion of the operational results for each laboratory sampled for Phase I. Summary results are presented separately for each Phase I operational stage: Telephone Enrollment, Field Tabulation, Telephone Verification, Validation Telephone Enrollment, and Validation Field Tabulation.

5.1.3.1 Phase I Telephone Enrollment Results[12]

The final outcomes of the Phase I Telephone Enrollment process for all 930 laboratories (i.e., CLIA ID numbers) released as active sample appear in Table 5-3. The categories appearing in this table are further defined as follows:

Enrolled - The laboratory agreed to participate in the study.

Ineligible - The facility was confirmed as not having performed any Complexity Model tests in calendar year 1996 under the sampled CLIA ID number.

Refusal - The laboratory refused to respond to the enrollment interview or, during the interview, explicitly refused to participate in the on-site tabulation.

Out of Business - Contact with someone associated with the laboratory or with a third-party source provided definitive information that the lab was no longer in business (ceased operations, physician

[12] The numbers of laboratories assigned to the various result categories in the tables appearing throughout this section may represent a slightly different distribution of result categories from that used for statistical weighting purposes. These tables present descriptive statistics of the outcomes of operational processes, specific to NICLTS. Weighting uses standard rules for assigning cases to weighting classes.

retired, bought out by/merged with facility having its own CLIA ID number)

Nonlocatable - Unable to locate the laboratory through any available telephone numbers or telephone tracing efforts (e.g., Directory Assistance calls, lookups in telephone databases, AHA yearbook; forwarding address information provided by the U.S. Postal Service on advance notification letters that were returned undelivered because the laboratory had relocated and the forwarding order had expired.).

Other - Enrollment process concluded for any other reason, such as inability to identify or achieve contact with a respondent after repeated attempts, respondent not available during telephone enrollment period, laboratory not available for visit during the time period for field operations, and miscellaneous individual situations not otherwise categorizable.

Table 5-3 presents the absolute number of cases falling into these categories, as well as the percentage of the total sample represented by each category. Overall, 773 (83.1%) of the sample was enrolled for the Field Tabulation and 91 (9.8%) refused to participate at the Telephone Enrollment stage.

Table 5-3. Phase I telephone enrollment results

Result	Number of laboratories	Percent
Enrolled	773	83.1
Ineligible	13	1.4
Refusal	91	9.8
Out of Business	12	1.3
Nonlocatable	16	1.7
Other	25	2.7
Total	930	100.0

Response Rate

The response rate excludes from the calculations cases that were confirmed as not belonging to the population the sample is meant to represent. Put another way, it excludes cases that were on the sampling frame but, if perfect information had been available, would not have appeared on the frame. For NICLTS, the population covered is those laboratories that performed at least one test during calendar year 1996. Thus, laboratories identified during the NICLTS operations as being ineligible (no 1996 testing) were excluded from the response rate calculation.

Less clear-cut is the situation of laboratories that were confirmed as out of business. This group can be divided into two logical groups: those out of business prior to calendar year 1996 and those that went out of business any time on or after January 1, 1996. It is easy to see that the first group is ineligible for the study, since they could not have performed any tests in 1996. In contrast, it is possible, and even likely, that members of the latter group were part of the population covered by NICLTS, i.e., did perform eligible tests at some time during calendar year 1996. Practically speaking, however, it was generally impossible to determine during the Phase I data collection period (1997) to which group an out-of-business laboratory belonged. Moreover, even if an out-of-business laboratory's 1996 eligibility could be established after the fact, it was almost certainly impossible to collect useful, detailed data after the laboratory ceased operations.

Given these considerations, the response rate calculated for the NICLTS Phase I Telephone Enrollment excluded both ineligible and out-of-business laboratories from the denominator of the response rate calculation. This produced a response rate of 85.4 percent:

(773 enrolled) / (930 sampled - (13 ineligible + 12 out of business))

The complement of the response rate was the nonresponse rate, i.e., the percentage of the eligible sample population that did not provide a useful response that could be incorporated into the final estimates. For the Phase I Telephone Enrollment, the nonresponse rate was 14.6 percent.

Because it excludes entities that did not properly belong to the population of interest (ineligibles), the response rate is generally considered an indicator of potential bias that could be associated with nonresponse. In simplified terms, the more the 14.6 percent who did not respond differed from the 85.4 percent who did respond, the greater the chance that the final estimates could be biased because the 14.6 percent are not represented in the final sample. It should be emphasized that the issue is how different the estimates would be if the nonresponders had been 'included. As the response rate increases, there is a concomitant reduction in the size of the effect that the decreasing number of nonresponders could have on the estimates derived from the responders. Hence, all other things being equal, higher response rates are associated with more accurate estimates.

5.1.3.2 Phase I Field Tabulation Results

The final outcomes of the Phase I Field Tabulation process for the 827 enrolled laboratory locations appear in Table 5-4. The categories are nearly identical to those described in Section 5.1.3.1 for Telephone Enrollment, with two differences. First, Tabulated replaces Enrolled as the desired successful outcome of this stage of the process. A laboratory location was classified as "Tabulated" if and only if data were successfully tabulated at the laboratory. Second, the category Nonlocatable does not appear, since all laboratories that passed to this stage were, by definition, located at the Telephone Enrollment stage.[13]

Table 5-4. Phase I Field Tabulation results

Result	Number of laboratories	Percent
Tabulated*	757	91.5
Ineligible	29	3.5
Refusal	36	4.4
Out of Business	2	0.2
Other	3	0.4
Total	827	100.0

* Includes three satellite locations visited but tabulated on the single record of the central office location.

To knowledgeably interpret the Phase I Field Tabulation results, it is essential to remember that the cases represented in Table 5-4 are laboratory locations, not CLIA ID numbers. In situations where a CLIA ID number covered more than one geographical laboratory location, separate cases were created for field operational purposes. After the Telephone Enrollment stage, tracking and accounting for cases was always done at the location level. Examination of Tables 5-3 and 5-4 shows that the 773 CLIA ID numbers enrolled at the Phase I Telephone Enrollment stage became the 827 total laboratory locations sent to the field in the Phase I Field Tabulation stage. All results presented in Table 5-4 apply to the individual locations.

[13] In that context, another point must be mentioned. While the same logic should apply in regard to the determination of ineligible and out-of-business laboratories during telephone enrollment, in reality the on-site tabulator could investigate these issues in greater depth. This could result in recategorizing of laboratories deemed eligible and in business in the Telephone Enrollment phase as actually ineligible or out of business after the Field Tabulation stage was implemented. Ineligibles and, more rarely, out-of-business laboratories were identified in the Tabulation stages of Phase I and Phase II.

Table 5-4 presents both the absolute number of Phase I Field Tabulation cases falling into the result categories and the percentage of the total sample represented by each of these categories. Overall, 757 (91.5%) of the fielded laboratory locations were tabulated in the Phase I Field Tabulation, and 36 (4.4%) refused to allow the on-site tabulation after initially agreeing to be enrolled in the study during the Telephone Enrollment stage. An additional 29 (3.5%) locations were recategorized as ineligible during the Phase I Field Tabulation and 2 (0.27%) were determined to be out of business.[14]

Response Rate

For the Field Tabulation stage, as for the Telephone Enrollment stage, laboratories identified during NICLTS operations as ineligible or out of business were excluded from the response rate calculation. This produced a response rate of 95.1 percent:

(757 tabulated) / (827 fielded - (29 ineligible + 2 out of business))

5.1.3.3 Phase I Telephone Verification Results

Table 5-5 presents the results of the Phase I Telephone Verification quality assurance process (described more fully in Section 6.1.1). It presents the verification outcomes for the 757 laboratory locations that were tabulated during the Field Tabulation stage, showing that the verification process was completed for all but four tabulated laboratories. These four incomplete verifications were the result of inability to re-establish telephone contact with the laboratory's field contact person or a suitable substitute.

[14] The 29 ineligible locations identified in the Field Tabulation stage were more than twice the number identified as ineligible at the Telephone Enrollment stage. This phenomenon was due less to the superior opportunity to confirm eligibility on site than to the fact that the Telephone Eligibility Screener was implemented several weeks into the Phase I Telephone Enrollment process. This occurred when it became apparent that there were more ineligible laboratories than anticipated and that it was undesirable to expend field resources unnecessarily on ineligible laboratories. Before the NICLTS protocol was revised to implement a Telephone Eligibility Screener several ineligibles had already passed to the Field Tabulation stage; consequently, these were categorized as ineligibles at that later stage. Many of the 29 ineligibles at the Field Tabulation stage are explained by this phenomenon. Fortunately, the NICLTS home office field support staff administered the screener to most of these cases before the field tabulator made an unnecessary trip to the laboratory. In such cases, the tabulator was instructed by telephone to record the final result of the case as Ineligible.

Table 5-5. Phase I Telephone Verification results

Result	Number of locations	Percent
Verified (unconditionally)	744	98.3
Verified (after specific review)	9	1.2
Unable to reach respondent	4	0.5
Total	930	100.0

The verification process confirmed that the tabulators adhered to the protocol in the tabulation of the other 753 laboratories. Of these 753, all but nine received perfect scores on the verification questionnaire (i.e., every protocol-related question was answered with the desired response). The findings of the verification process are further discussed in Section 6.1.1.3.

5.1.3.4 Phase I Validation Telephone Enrollment

Table 5-6 shows the final outcomes of the Phase I Validation Telephone Enrollment process for the 51 tabulated laboratory locations released as the validation sample. The categories appearing in this table are the same as those defined in Section 5.1.3.1. Phase I Validation is more fully described in Section 6.1.2.

Table 5-6. Phase I Validation Telephone Enrollment results

Result	Number of laboratories	Percent
Enrolled	31	60.8
Ineligible	0	0.0
Refusal	11	21.6
Out of Business	0	0.0
Nonlocatable	0	0.0
Other	9	17.6
Total	51	100.0

* Only one location was retabulated at each validation laboratory

Thirty-one (60.8%) of the validation laboratories sample were enrolled for the Phase I Validation study and 11 (21.6%) refused to participate. Since the laboratories had recently gone through a process they were now being asked to repeat, this rate of refusal was actually lower than expected; a refusal rate as high as 50 percent could have been expected.

Much of the credit for the enrollment success rate of 60 percent belongs to the laboratory staff for their willingness to accommodate the needs of the study, their understanding of its importance, and their appreciation of the purpose of quality assurance. As in the Telephone Enrollment for the Phase I main study, CDC's sponsorship was also a contributory factor, as were the technical and interpersonal skills of the enrollment specialists who handled this specialized enrollment. Additionally, in the case of the Phase I Validation study, testimonial evidence pointed clearly to the professionalism and courtesy of the field tabulators during the original site visits as the principal factor in the willingness of the laboratories to bear the burden of a second tabulation.

There is no quantitative indicator of the specific effect of any one of these factors, nor of their relative effect, for any of the enrollment activity that occurred at this stage, or at any of several other stages of both phases. However, for all such activity, anecdotal evidence provided by the telephone enrollment staff is that CDC's sponsorship opened doors that might otherwise have been closed to the tabulation. While no count is available, the enrollment staff frequently found that it made a difference to fax another copy of the original CDC advance letter whenever they encountered any resistance or uncertainty. Unfortunately, it is not possible to determine how much of this effect is attributable to CDC's name on the letterhead, as compared to that of any other reputable sponsor.

As expected, the enrollment staff also encountered some expressions of dissatisfaction with the CLIA regulatory process itself. However, they again found that emphasizing CDC's sponsorship of NICLTS usually mitigated such negative attitudes. Finally, as the enrollment staff developed their learning curve over the course of the project, they found that, when they encountered certain specific circumstances or specific barriers in the enrollment process, a well-timed reference to CDC's sponsorship often was instrumental in breaking through resistance.

The nine cases (17.6%) of the Phase I Validation Survey Enrollment sample with other results consisted mainly of laboratories whose staff were not available to respond to the enrollment request during the short period allotted for this process. Or, if they were available for the enrollment request, they informed the enrollment specialist that the appropriate laboratory staff to coordinate the site visit would not be available during the relatively brief period allotted for the Phase I Validation Field Tabulation activity. Since the Phase I Validation study took place during the July 4th holiday and the start of summer vacations, this outcome is not surprising.

Response Rate

The response rate for the NICLTS Phase I Validation Survey Enrollment was 60.8 percent, as shown by the following response rate calculation:

(31 enrolled) / (51 sampled - (0 ineligible + 0 out of business))

5.1.3.5 Phase I Validation Field Tabulation Results

The final outcomes of the Phase I Validation Field Tabulation process for the 31 enrolled laboratory locations appear in Table 5-7. For the sake of parallelism, this table presents the same categories as in the comparable table for the main Phase I Field Tabulation, Table 5-4. Thirty of the 31 fielded cases were tabulated; the other laboratory was visited but could not be successfully tabulated because of a Tabulation Device problem. Using the same formula as in the preceding sections, the Validation Field Tabulation response rate was 96.8 percent.

Table 5-7. Phase I Validation Field Tabulation results

Result	Number of locations	Percent
Tabulated	30	96.8
Ineligible	0	0.0
Refusal	0	0.0
Out of Business	0	0.0
Other	1	32
Total	31	100.0

5.1.3.6 Summary of Phase I Response Rates

Table 5-8 is a convenient overview of the response rates for each of the Phase I operational stages.

Table 5-8. Summary of Phase I response rates

Operational stage	Total sample (n)	Response rate (percent)
Telephone Enrollment	930	85.4
Field Tabulation	827	95.1
Validation Telephone Enrollment	51	60.8
Validation Field Tabulation	31	96.8

5.2 Phase II

5.2.1 CLIA ID Number Problem Resolution

To resolve CLIA ID number problems in Phase II, the telephone tabulators used decision rules similar to those in Phase 1. Because tabulation was a very short process in every facility during Phase II, the issue of whether the laboratory would require more or less than 2 days of tabulation time was eliminated. A supervisor was in the telephone center at all times and, if necessary, could help the tabulator with any decisions about how to proceed. Since tabulators were not physically touring a facility, the decision was made to collect information about all testing performed and to record all CLIA ID numbers found at the primary location.

5.2.2 Phase II Summary Case Result Reports[15]

This section presents summary statistics and discussions concerning the operational results (case outcomes) for each laboratory sampled for Phase II. The summary results are presented separately for each Phase II operational stage: Telephone Enrollment, Telephone Tabulation, Validation Telephone Enrollment, and Validation Field Tabulation. The organization and content of this section are similar to that of Section 5.1.3, Phase I Summary Case Result Reports. Issues and topics covered in the earlier section are covered here by reference to that section. Where relevant, the discussion addresses meaningful differences between the results of the two phases.

[15] The numbers of laboratories assigned to the various result categories in the tables appearing throughout this section may represent a slightly different distribution of result categories from that used for statistical weighting purposes. These tables present descriptive statistics of the outcomes of operational processes, specific to NICLTS. Weigh ting uses standard rules for assigning cases to weighting classes.

5.2.2.1 Phase II Telephone Enrollment Results

The final outcomes of the Phase II Telephone Enrollment process for all 1,859 laboratories (i.e., CLIA ID numbers) released as active sample appear in Table 5-9. The categories in this table were defined in Section 5.1.3.1.

Table 5-9. Phase II Telephone Enrollment results

Result	Number of laboratories	Percent
Enrolled	1,473	79.2
Ineligible	78	4.2
Refusal	77	4.1
Out of Business	73	3.9
Nonlocatable	108	5.8
Other	50	2.7
Total	1,859	100.0

Table 5-9 presents both the absolute number of cases falling into these categories and the percentage of the total sample represented by each category. Overall, 1,473 (79.2%) of the sampled laboratories were enrolled for the Telephone Tabulation, and 77 (4.1%) refused to participate at the Telephone Enrollment stage. This percentage of enrolled laboratories is very close to the Phase I percentage (83.1%). The Phase II enrollment refusal percentage of 4.1 percent is less than half of the Phase I percentage (9.8%). This difference in the rate of refusals is further discussed in Section 5.2.2.2.

While still fairly small, the percentages of laboratories that were ineligible and out of business in the Phase II Telephone Enrollment (4.2% and 3.9%, respectively) were both three times as high as in the Phase I Telephone Enrollment. This trend is attributable to three factors. First, the Phase II sample contained a higher concentration of physician offices and other small laboratories. In terms of ineligibility, they were more likely to have acquired a CLIA ID number when they did not need one because they misunderstood when CLIA certification was required. Alternatively, they may have needed one because they had been performing one or two tests requiring CLIA certification but subsequently stopped performing them. They were more likely to go out of business because of retirement, sale, consolidation, or absorption than the larger laboratories in the Phase I sample. These explanations of the higher prevalence of ineligible and out-of-business laboratories are all

functions of the sample population's own characteristics.

The second factor, which applies only to explaining the higher percentage of ineligibles, is a function of the NICLTS protocol. The Telephone Eligibility Questionnaire was added to the Phase I Telephone Enrollment protocol several weeks after enrollment was underway. As discussed in Section 5.1.3.2, this caused a number of ineligible cases to be enrolled that would otherwise have been detected by the screener and immediately categorized as ineligible at the Telephone Enrollment stage. Thus, the percentage of cases found to be ineligible during the Phase I Telephone Enrollment was artificially low and, as a corollary, the percentage of ineligibles found at the Phase I Field Tabulation stage was artificially high. This view is supported by Table 5-10, which shows the relative ineligibility percentages between the Telephone Enrollment and Field Tabulation results of Phase I and Phase II, respectively. Whereas the Phase I Field Tabulation had over twice the number and percentage of ineligibles as Phase I Telephone Enrollment, Phase II Field Tabulation had a smaller number and only slightly larger percentage of ineligibles than the Phase II Telephone Enrollment.

Table 5-10. Ineligibility, Telephone Enrollment and Field Tabulation stages, Phase I and Phase II

	Telephone Enrollment Ineligibles		Field Tabulation Ineligibles	
	Number	Percent	Number	Percent
Phase I	13	1.4	29	3.5
Phase II	78	4.2	71	4.6

The third factor, which applied only to the out-of-business prevalence, was a function of timing. Phase II operations began 10 months after Phase I began, and ended 8 months after Phase I ended. Since both the Phase I and Phase II samples were drawn from the same version of the OSCAR file, there was a longer period during which the Phase II laboratories might have ceased operations.

Thus, as further discussed in Section 5.2.2.2, the overall percentage of ineligibles was higher in Phase II than in Phase I, for the various reasons already discussed. However, the Telephone Eligibility Screener improved the detection of ineligibles at the Phase II Telephone Enrollment Stage by detecting a higher proportion of them at the preferable, earlier stage. Notwithstanding this implementation of the Telephone Eligibility Screener, however, nearly half of all ineligibles identified during Phase II were still not detected until the Field Tabulation stage. This seeming anomaly is discussed in Section 5.2.2.2.

Response Rate

The response rate for the Phase II Telephone Enrollment was 86.2 percent:

(1,473 enrolled) / (1,859 sampled - (78 ineligible + 73 out of business))

This was very close to the Phase I Telephone Enrollment response rate reported in Section 5.1.3.1 (85.4%). The complement, the nonresponse rate, was 13.8 percent.

5.2.2.2 Phase II Telephone Tabulation Results

The final outcomes of the Phase II Telephone Tabulation process for the 1,544 enrolled laboratory locations appear in Table 5-11. The categories appearing in this table are the same as those described in Section 5.1.3.2, Phase I Field Tabulation Results. The cases represented in Table 5-11 are laboratory locations, not CLIA ID numbers. Examination of Tables 5-9 and 5-11 shows that the 1,473 CLIA ID numbers enrolled at the Phase II Telephone Enrollment stage became the 1,544 total laboratory locations sent to the Phase II Telephone Tabulation stage. All results presented in Table 5-11 apply to the individual locations.

Table 5-11. Phase II Field Tabulation results

Result	Number of locations	Percent
Tabulated*	1,322	85.6
Ineligible	71	4.6
Refusal	138	8.9
Out of Business	9	0.6
Other	4	0.3
Total	1,544	100.0

* includes 24 locations at multiple-location laboratories collected without separate tabulation: consolidated by respondents on single data form for each laboratory CLIA ID number overall.

Overall, 1,322 (85.6%) of the laboratory locations sent to the Phase II Telephone Tabulation process were tabulated, and 138 (8.9%) refused to respond to the telephone tabulation interview (i.e., after initially agreeing to

be enrolled in the study during the Telephone Enrollment stage). An additional 71 (4.6%) of locations were categorized as ineligible during the Phase II Telephone Tabulation and 9 (0.6%) were determined to be out of business.

The preceding section discussed various reasons why the Phase II Telephone Enrollment had higher percentages of ineligible and out-of-business laboratories than Phase I. Except for issues related to the full implementation of the Telephone Eligibility Screener in Phase II, these reasons apply to all ineligible and out-of-business laboratories discovered in Phase II, regardless of whether they were detected at the Telephone Enrollment stage or the Telephone Tabulation stage. The net effect was that the percentage of ineligible and out-of-business laboratories was higher for Phase II than for Phase I, at each stage and cumulatively. The Telephone Eligibility Screener did show some effect in Phase II, by increasing the proportion of ineligible laboratories that were detected at the Telephone Enrollment stage. In Phase I, about one-third of all ineligibles were detected during Telephone Enrollment. In Phase II, more than half were detected during enrollment (Table 5-10). In contrast, all but two out-of-business laboratories were detected in the Phase I enrollment but, in Phase II, nine enrolled laboratories were ultimately determined to have been out of business at the time of enrollment, after the telephone tabulator discussed the situation in greater detail during the Telephone Tabulation stage. The question that remains is why a fairly high number of ineligible laboratories were initially enrolled in Phase II, and why any out-of-business laboratories were enrolled in either phase.

The second question is easier to answer. As previously discussed, the out-of-business status was not limited to laboratories that simply closed their doors. It included a continuum of situations, such as laboratories that were bought by other laboratories and consolidated their operations at the acquirer's facility. While the CLIA regulations are clear on the matter, a degree of confusion often remained in the minds of the laboratory managers about the status of the CLIA ID number of the merged laboratory. Thus, it was feasible for the enrollment specialists to trace the CLIA ID number to a fully operational laboratory, where staff were quite able to make a connection with the information about the sampled laboratory, by name and CLIA ID number. Since the enrollment protocol employed a chain-of-evidence approach to locating the sampled laboratory when there was instability in the name, address, and so forth, it was a natural outcome for such laboratories to pass successfully through the enrollment process. That process attempted to clarify the situation as much as possible, but the protocol always anticipated that the most confusing and complex situations would require the in-depth investigation that the tabulators or their supervisors would be in a better position to pursue knowledgeably.

Most of the foregoing explanation for the initial enrollment of a few out-of-business laboratories applied as well to the enrollment of ineligible laboratories. Here the issues of ambiguity and confusion about the status of the sampled CLIA ID number came into play with full force. The issues were diverse: multiple simultaneous CLIA ID numbers; accretion of CLIA ID numbers over time; and CLIA ID numbers associated with different providers, locations, or acquired facilities. The enrollment protocol also explicitly sought to enroll a laboratory even when the CLIA ID number confirmation was in doubt, again with the goal of allowing the tabulator to make a final determination after further investigation.

When all of these factors are considered, it becomes clear why a number of ineligibles were encountered at the tabulation stage. The Telephone Eligibility Screener was designed primarily to address the issue of the types of tests being performed, rather than the CLIA ID number issue. It ensured the inclusion of facilities that did not consider themselves as performing any clinical tests, but actually did perform testing. It filtered out those that clearly did not perform any tests in calendar year 1996. It did not exclude a laboratory that could not confirm its CLIA ID number. Absent an enrollment protocol that stringently required positive confirmation of the sampled CLIA ID number and vigorously investigated multiple location/multiple CLIA ID number/multiple provider situations before classifying a laboratory as eligible to proceed to the tabulation stage, a percentage of ineligible cases inevitably passed through enrollment before being detected at the tabulation stage.

Response Rate

For the Telephone Tabulation stage, as for the Telephone Enrollment stage, laboratories identified during NICLTS operations as being ineligible or out of business were excluded from the response rate calculation. This produced a response rate of 90.3 percent:

(1,322 tabulated) / (1,544 sent to telephone tabulation - (9 out of business + 71 ineligible))

While this was considered a successful result, it was somewhat lower than the analogous Phase I Field Tabulation response rate (94.9%). Most of the difference was due to the higher percentage of laboratories that refused to respond at this stage of Phase II (8.9%, versus 4.4% for Phase I). There are several likely explanations for this. In Phase I, the field tabulator's presence may have had a "foot-in-the-door" effect, making it more awkward for the laboratory to decline participation. If laboratory contacts were reticent to turn down someone in

person, in Phase II they may have been less averse to refusing someone on the telephone.

The fact that the Phase I field tabulator did the work of reviewing the records and assembling the test data was presented as an incentive for the Phase I laboratories to participate. In Phase II, the laboratory contact bore the burden of assembling the test data on the mailed Test Inventory Form. This may have had a three-part effect on the comparative rates of refusal between Phase I and Phase II tabulations. First was the simple difference in the burden (work performed by tabulator versus work performed by laboratory). Second, the laboratory had agreed to enrollment after hearing a brief description of the process. When the Phase II laboratory then received the actual tabulation materials in the mail, they may have decided that the process was more involved or time-consuming than they had anticipated. Third, in POL's it was more common than in other types of laboratories that a physician was identified as the only feasible respondent. Given that a physician may have less time or inclination to review and fill out the NICLTS material, and given the high concentration of POL's in the Phase II sample, it is not surprising that more refusals would occur in Phase II after a laboratory initially agreed to be enrolled in the study.

5.2.2.3 Phase II Validation Telephone Enrollment

The final outcomes of the Phase II Validation Telephone Enrollment process for the 204 tabulated laboratory locations released as the validation sample appear in Table 5-12. (Phase II Validation is more fully described in Section 6.2.2.2.) The categories appearing in this table are the same as those defined in Section 5.1.3.1.

Table 5-12. Phase II Validation Telephone Enrollment results

Result	Number of locations	Percent
Enrolled	127	62.3
Ineligible	0	0.0
Refusal	72	35.3
Out of Business	0	0.0
Nonlocatable	0	0.0
Other	5	2.5
Total	204	100.0

Overall, 127 (62.3%) of the Phase II validation sample was enrolled, while 72 (35.3%) refused to participate. As in the Phase I Validation Enrollment, this rate of refusal was still lower than expected.

The 35.3 percent who refused to participate in the Phase II Validation Field Tabulation did, however, represent a substantially higher refusal rate than in the Phase I Validation Field Tabulation (21.6%). This higher rate was likely due to three factors. First, because of a variety of design and operations considerations, more time had elapsed between the original tabulation and the validation request for many of the Phase I sample laboratories as compared to the Phase II sample laboratories. Thus, the Phase II request may have seemed more abrupt or pressing than the Phase I request.

Second, the Phase I laboratories were asked to do nothing more than they had already done in the main study. In contrast, the Phase II laboratories had participated in the primary data collection by telephone, and the request was now for the more intrusive activity of allowing a tabulator to enter their laboratory. Furthermore, most Phase I participants had already surrendered any initial concerns about burden or intrusiveness after experiencing the well-planned protocol and professionalism of the field staff. In contrast, the Phase II sample were asked to agree to an unknown experience, with the potential perception of extra burden or intrusion.

A third possible factor was the higher percentage of physician office laboratories in the Phase II sample. In perception and possibly in reality, physician office operations may have been more affected by the on-site tabulation process or concerned about patient confidentiality issues. In POL's, the physician was often the only feasible contact person, with less time or inclination to accommodate the field tabulator. In some combination, all of these factors were likely to have contributed to the higher percentage of refusals to the Phase II Validation Enrollment.

As in Phase I, the small percentage of the Phase II Validation Telephone Enrollment sample falling into the "Other" result category consisted mainly of laboratories whose staff were not available to respond to the enrollment request or during the period allotted for the Phase II Validation Field Tabulation activity.

Response Rate

The response rate for the Phase II Validation Telephone Enrollment was 62.3 percent:

(127 enrolled) / (204 sampled - (0 ineligible + 0 out of business))

Achieving this high a response rate was attributable to the factors suggested in Section 5.1.3.4 for Phase I: laboratory good will, CDC sponsorship, the positive effect created by the professionalism and courtesy of the telephone tabulators during the original tabulation, and the skill of the telephone tabulators who were given the special assignment of performing as the Phase II validation enrollment.

5.2.2.4 Phase II Validation Field Tabulation Results

The final outcomes of the Phase II Validation Field Tabulation process for the 127 enrolled laboratory locations appear in Table 5-13. For the sake of parallelism, this table presents the same categories as those appearing in the comparable table for the main Phase I Validation Field Tabulation, Table 5-7.

Table 5-13. Phase II Validation Field Tabulation results

Result	Number of locations	Percent
Tabulated	110	86.6
Ineligible	0	0.0
Refusal	4	3.1
Out of Business	0	0.0
Other	13	10.2
Total	127	100.0

Of the 127 laboratories enrolled, 110 (86.6%) were tabulated. There were four refusals (3. 1 %). The 13 laboratories falling into the "Other" result category consisted mainly of ones where it was not feasible to complete a tabulation, because of tabulator time and distance considerations at the end of the Validation Field Tabulation period or because the laboratory staff proved to be unavailable during the field period. Using the same formula as

in preceding sections, the Phase II Validation Field Tabulation response rate was 86.6 percent.

5.2.2.5 Summary of Phase II Response Rates

Table 5-14 is a convenient overview of the response rates for each of the operational stages.

Table 5-14. Summary of Phase II response rates

Operational stage	Total sample (n)	Response rate (percent)
Telephone Enrollment	1,859	86.2
Field Tabulation	1,544	90.3
Validation Telephone Enrollment	204	62.3
Validation Field Tabulation	127	86.6

5.3 Overall Survey Results

Table 5-15 shows the number of distinct clusters by region and group. These data are the distinct clusters over the sampled laboratories in the categories indicated. For example, POL's in the Northeast region tested 148 distinct clusters overall, while POL's as a whole tested a total of 1,604 distinct clusters. The full sample of laboratories that participated in the NICLTS tested 8,164 distinct clusters. Table 5-16 shows the average number of distinct clusters per laboratory. For example, POL's nationally tested an average of nine distinct clusters, though this is somewhat higher for POL's in the Northwest region (13.7 distinct clusters). The average among all laboratories in the NICLTS sample was 15.2 distinct clusters per laboratory.

The estimated mean number of distinct clusters per laboratory is given in Table 5-16. Nationally, the estimated mean number of distinct clusters tested per laboratory is 15.2 (95% CI 13.9 to 16.4).

Table 5-15: Number of distinct clusters by region and group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	148	105	29	818	127	49	1,075
2. New York, New Jersey	348	79	79	976	231	183	1,582
3. Mid-Atlantic	433	197	30	1,361	171	224	1,968
4. Southeast	650	209	31	1,168	484	333	2,124
5. Midwest (North)	602	114	46	2,118	508	416	3,130
6. South (Central)	264	231	30	2,052	180	846	2,883
7. Midwest (Central)	204	174	25	970	90	387	1,474
8. Mountain	142	117	13	867	49	393	1,323
9. West	327	115	19	834	410	471	1,708
10. Northwest	209	52	14	223	208	217	733
Total	1,604	822	151	5,698	1,679	2,322	8,164

NOTE: This table shows the number of distinct clusters in the sample in each cell. For example, data collected from sampled POL's in the Northeast region had a total of 148 distinct clusters.

Table 5-16: Estimated mean number of distinct clusters per laboratory by region and group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	7.0	7.9	2.2	148.2	29.5	4.3	13.3
2. New York, New Jersey	7.6	7.9	6.6	131.4	55.5	9.9	14.2
3. Mid-Atlantic	10.4	13.4	2.2	113.4	27.7	7.9	16.7
4. Southeast	10.4	7.6	1.6	64.7	45.7	7.3	13.3
5. Midwest (North)	9.0	5.0	1.7	126.9	50.0	9.0	15.6
6. South (Central)	7.7	5.9	1.4	104.9	24.2	19.5	16.6
7. Midwest (Central)	9.6	12.7	1.3	104.0	24.2	17.9	17.8
8. Mountain	10.0	11.4	1.6	139.6	14.1	33.1	22.5
9. West	7.6	5.6	1.4	56.5	40.0	15.6	12.3
10. Northwest	13.7	7.5	3.0	64.9	73.7	19.2	18.0
Total	9.0	7.5	1.9	100.6	39.0	12.4	15.2

Based on NICLTS data, the estimated total national volume of testing performed in calendar year 1996 is 7,250,519,342 (7.25 billion) tests; the 95 percent confidence interval around this point estimate is 5.12 to 9.38 billion tests. The average volume per laboratory for all laboratories is 51,114 tests; the 95 percent confidence interval ranges from 36,119 to 66,109 annual tests per laboratory.

Table 5-17 gives estimates of volume by DHHS region and laboratory group. The greatest volume of testing is performed in Region 4 (Southeast); across the six major laboratory groups, the greatest volume of testing is performed by hospitals. Table 5-18 gives the estimated mean volume per laboratory. The Northeast (Region 1) has the highest average volume per laboratory. As might be expected, hospitals show the highest average volume per laboratory. Table 5-19 gives estimates for total volume and mean volume per laboratory by more detailed categories of laboratory type.

Table 5-17. Estimated volume of tests by region and group (000,000)

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	24	24	6	441	91	10	596
2. New York, New Jersey	68	5	8	551	38	44	715
3. Mid-Atlantic	71	14	6	543	30	41	705
4. Southeast	167	21	12	302	351	912	1,765
5. Midwest (North)	115	6	19	672	126	53	991
6. South (Central)	44	21	8	507	26	295	901
7. Midwest (Central)	36	12	3	154	36	39	279
8. Mountain	25	9	3	123	2	37	199
9. West	113	12	6	212	347	175	865
10. Northwest	70	1	2	13	133	16	236
Total	732	126	73	3,518	1,181	1,621	7,251

Table 5-18. Estimated mean volume per laboratory by region and group

	Laboratory Group						
Region	POL	Other Ambulatory	Hospice, Nursing home	Hospital	Independent, Blood bank	Specialty	Total
1. Northeast	5,456	29,255	4,927	1,258,852	280,753	11,413	74,880
2. New York, New Jersey	7,623	7,828	10,922	1,070,788	123,187	38,786	58,580
3. Mid-Atlantic	8,492	13,618	5,168	616,823	66,559	21,298	51,080
4. Southeast	10,105	8,767	5,639	186,939	404,811	229,760	64,123
5. Midwest (North)	7,753	2,845	5,843	435,960	176,862	12,310	36,818
6. South (Central)	5,097	6,480	4,336	352,093	39,329	101,682	47,924
7. Midwest (Central)	9,639	12,541	2,050	230,110	139,630	26,803	32,851
8. Mountain	11,388	14,523	3,976	336,312	9,879	55,598	42,227
9. West	11,214	6,635	5,367	223,065	404,990	90,048	51,392
10. Northwest	26,111	2,561	4,857	66,691	643,829	22,305	50,960
Total	9,118	8,815	5,173	412,762	243,192	81,612	51,114

Table 5-19. Estimated distinct clusters and volume by laboratory type

Laboratory type	Distinct clusters	Mean distinct clusters per laboratory	Total volume (000,000)	Mean Volume per laboratory
1. Ambulatory surgery center	452	20.6	243.54	188,618
2. Community clinic	675	14.2	66.04	12,850
3. Comprehensive outpatient rehab.	44	44.0	11.50	207,853
4. Ancillary test site	394	14.0	71.31	35,347
5. End stage renal disease dialysis	29	2.1	7.00	4,154
6. Health fair	5	2.0	0.08	501
7. Health Maintenance Organization (HMO)	215	20.2	44.45	51,714
8. Home health agency	52	1.5	13.24	1,862
9. Hospice	6	1.3	0.01	20
10. Hospital	5,698	100.6	3,517.66	412,762
11. Independent	1,656	41.6	1,159.37	258,384
12. Industrial	89	4.7	8.31	7,173
13. Insurance	2	2.0	0.02	402
14. Interm. care facil. mentally retarded	52	6.0	1.97	3,210
15. Mobile unit	21	1.7	0.23	341
16. Pharmacy	9	3.3	0.02	158
17. School/student health service	65	4.5	1.91	1,675
18. Skilled nursing/nursing facility	151	2.0	72.78	5,293
19. Physician office	1,604	9.0	732.02	9,118
20. Other practitioner	496	19.7	57.04	30,106
22. Blood banks	33	6.9	21.64	58,608
23. Other	1,490	13.6	1,220.38	120,218

NOTE: "Distinct clusters" gives the number of distinct clusters in the sample for each laboratory type. "Mean distinct clusters" gives the mean number of distinct clusters per laboratory "Total volume" represents the estimated national volume for each laboratory type. "Mean volume" represents the estimated mean per laboratory.

6. DATA TABULATION PROTOCOL QUALITY ASSURANCE

In addition to the specific operational quality control procedures described throughout this report, two formal quality assurance programs were implemented for each phase of the study. The first of these monitored the tabulators' adherence to the data collection protocol. The second involved retabulation of a sample of the locations. Since these activities differed between the two phases of the study, the quality assurance programs for each phase are discussed separately below.

6.1 Phase I Quality Assurance

The formal quality assurance programs for the Phase I data tabulation protocol consisted of Telephone Verification and Field Validation. Each of these programs is described in detail in a separate section below.

6.1.1 Telephone Verification

The telephone verification quality assurance program consisted of a brief followup telephone interview with all of the tabulated laboratories by home office staff, to verify that the tabulator had visited the laboratory and performed the data tabulation in conformity with the on-site protocol. While of limited size and complexity, this was nevertheless a formal telephone interviewing effort that required the typical survey components of survey materials, interviewer training, an operational protocol, and outcome reporting. Telephone verifications were carried out only at laboratories where a tabulation took place.

6.1.1.1 Verification Materials

Verification Questionnaire. The principal verification document was a short paper questionnaire containing questions that a home office telephone interviewer asked the laboratory's field contact. The questions were designed to confirm that the tabulator had visited the laboratory, explained the purpose of the visit, performed the laboratory tour, asked to review the available laboratory records for 1996 or discuss the number of tests performed in 1996 with lab staff (i.e., estimate volumes), did not ask to take laboratory records out of the facility, and conducted himself or herself in a professional manner. The interviewer concluded by thanking the laboratory once again for its participation. The strategy was to

intermix informal courtesy questions (explaining the visit, professional conduct) with formal questions whose answers pointed directly to correct or incorrect performance of the protocol, without indicating to the respondent the explicit reason for asking a given question.

On each of the four questions that related to the tabulator's performance of the formal protocol, one of the possible responses indicated potential deviation from protocol. This response category was flagged on the paper form. At the end of the interview, each interviewer determined if any of the four questions resulted in undesired responses. The interviewer then marked the case with a result code indicating that no problems were identified or that a potential exception to the protocol was determined. The very few cases with an undesired response were carefully reviewed. (The verification protocol also allowed for another code for the extreme case that the respondent denied that the tabulator visited the laboratory; predictably, this situation never occurred.)

Verification Respondent Information Sheet (VRIS). The VRIS was an informational and sample control sheet containing each laboratory's enrollment information and NICLTS ID number, name and telephone number of each person with whom formal contact was made during the enrollment call, the final field contact, the concluding date of the visit (as uploaded from the Tabulation Device), and the name of the tabulator who visited the laboratory.

If a laboratory had multiple locations, a separate verification was carried out for each location. Because it was preferable to coordinate telephone attempts to verify visits at different locations of laboratories that had more than one location, the VRIS consolidated the information for all locations sequentially on a printed VRIS output form. Consolidating the information for all locations on one VRIS made the process more efficient, especially when the same field contact was responsible for more than one location. Even in the latter situation, the verification interview was repeated for each location. In multiple-location laboratories, it was possible for one location to be tabulated while one or more others were not. To allow the verification interviewer to sort out any confusion, the nontabulated locations were printed out on the VRIS along with the tabulated locations. The result code for each location also was printed on the VRIS. The verification procedures instructed the interviewer to initiate verifications only for locations that showed a result code indicating that a completed tabulation had occurred.

6.1.1.2 Verification Interviewer Training

The verification interviewer training consisted of a 2-hour session in which the operations manager trained the interviewers in the protocol, forms, and procedures. Because the verification interviewers were the same staff who conducted the telephone enrollment, they were already familiar with the issues and procedures surrounding the contacting of the labs and the conduct of the study. Therefore, it was possible to conduct the training by means of a short lecture about the protocol and forms, a group read-through of the forms and

materials, a read-through of specific forms documentation in a Verification Interviewer Manual, and a question-and-answer session.

6.1.1.3 Verification Outcome Summary

As discussed in Section 5.1.3.3, the verification interview was conducted with 753 of the 757 tabulated locations. Of these 753, all but 9 received perfect scores on the verification questionnaire (i.e., every protocol-related question was answered with the desired response). For the other nine cases, only one question on each questionnaire was answered with an undesired response. NICLTS project managers reviewed all nine cases and determined that, in each case, the preponderance of the evidence was that the basic protocol was followed. Since the responses to all the other protocol-related questions demonstrated correct performance of the protocol, it was reasonable to conclude that the protocol was followed in such a way as to achieve the ultimate goal, which was the consistent collection of valid data.

In interpreting the implications of a single question yielding an undesirable response, the reviewers considered the possibility of recall error on the part of the laboratory respondent, the possibility that the respondent may not have given full attention to the process of the visit, and the possibility that the respondent may have understood the meaning of a given verification question differently than intended. For example, if the response to the question "Did [the tabulator] ask to review your available laboratory records for 1996?" was negative, it is possible this response meant that the tabulator acquired the records without formally asking for them. The laboratory staff could have simply handed the records to the tabulator before being asked, since they had been informed of the need to provide records at several points in the process before the tabulator arrived. The tabulator could also have acquired the records from someone other than the respondent. The laboratory could have informed the respondent that there were no records before he or she had a chance to formally ask for them. Beyond such possible explanations for these nine anomalous responses, the very small number is further mitigated by their context: in each case, all the other protocol-related questions yielded the desired response.

In light of all these considerations, it was not necessary to pursue the quality assurance verification any further. Any potential effect on data validity would have been minimal and likely undetectable. The overall finding of the verification study was that the tabulators visited every site in person and carried out the study according to protocol. The success of the NICLTS Phase I Verification study is even more convincing in the context of standard field study practice, which is to verify only a small sample of completed work, typically under

10 percent. The 100 percent verification performed for NICLTS Phase I was much more rigorous and was still unable to find exceptions to cause undue concern.

6.1.2 Validation

The design and conduct of NICLTS Phase I employed many proven, standard survey research techniques and procedures. In some instances, it was necessary to modify standard tools and methods to meet the unique requirements of NICLTS. This was the case in such areas as the development and use of a purpose-built, portable, computerized Tabulation Device, the collection of test volume data on site in laboratories, and the use of medical technologists as field data collectors for large-scale, national data collection. For these and other reasons, a validation test of the NICLTS protocol was conducted.

The validation design was straightforward. A sample of laboratories was selected from the set of those tabulated as of the date that the validation process began. A second tabulator was assigned to revisit the laboratory to carry out a duplicate but independent tabulation, using the same protocol used for all the primary tabulations. Other than being aware that the laboratory was a validation point, the second tabulator knew nothing that occurred at or resulted from the original tabulation. Similarly, the validation sample laboratories were aware only that they were participating in a quality assurance check of the NICLTS project. After the data were retabulated, the NICLTS staff analyzed the results from the two tabulations, both at the level of individual laboratories and in the aggregate for the whole validation sample.

The protocol and methodology for the validation process were identical to those used for the original tabulations, except for special handling of enrollment. In fact, the handling of the validation cases took place transparently within the same operational processes as the main sample. This section, therefore, describes only three aspects of the validation study: validation sample, laboratory enrollment, and results.

6.1.2.1 Validation Sample

The validation sample was targeted to allow 30 complete retabulations of laboratory locations. These locations were selected purposively to represent all types of laboratories; in addition, all field interviewers had at least one laboratory in the initial validation sample. An initial sample of 60 laboratories was selected manually from a two-way grid of laboratory type by interviewer. Only one location was selected for retabulation from each participating laboratory.

A total of 51 locations which had previously been tabulated were released for enrollment. Overall, 31 (60.8%) locations were enrolled, 9 (17.6%) agreed to enrollment but could not accommodate the short period of time allotted for the validation visit, and 11 (21.6%) refused to participate. The refusal rate was extremely low, given that laboratories had recently completed the process they were now being asked to repeat, and the fact that no refusal conversion was attempted.

6.1.2.2 Validation Enrollment and Tabulation

A selected group of the enrollment specialists carried out the enrollment of the laboratories selected for the validation sample.

NICLTS staff prepared a brief explanation of the reason and process for the validation study. This explanation stressed that the validation represented quality assurance of the NICLTS protocol and not of the laboratory's own role in the original tabulation, nor was it an enforcement visit. It acknowledged the appreciation for extra burden that participation in the validation study placed on the laboratories. The enrollment specialists used this explanation to enroll the laboratories.

Because of the small size of the validation sample, the enrollment materials were produced by manual rather than automated methods. The enrollment specialists were given a photocopy of the Call Record from the field tabulator's visit to use as a source of contact information. They placed the enrollment call to the person named on this Call Record as the final field contact.

The enrollment specialists completed a new laboratory enrollment form (LEF) for each enrolled laboratory. From this point on, the field tabulation, home office procedures, and automated case management system handled the case according to the overall NICLTS operational process.

All 31 locations enrolled for validation were visited by a second data tabulator. Thirty field cases were tabulated; the other location was visited, but tabulation could not be completed because of Tabulation Device problem. Overall, for Phase I validation field tabulation, a primary sample of 31 locations was visited for tabulation and the response rate was 97 percent.

6.1.2.3 Results of the Phase I Validation Study

The purpose of the validation study was to evaluate the reliability of data tabulated in the field during the NICLTS. This section compares the original field tabulation with the data collected during validation. In the remainder of this discussion, the former will be called survey data, survey totals, survey counts, and so on, as compared with validation data, validation totals, validation counts, and so forth. The analysis has several parts: tabulation of analytes, tabulation of cluster counts, and tabulation of total volume. Each type of tabulation is discussed in a separate section.

Tabulation of Analytes

Table 6-1 lists the total number of analytes for each laboratory. Figure 6-1 is a scatter plot of survey analyte counts (vertical axis) versus validation analyte counts (horizontal axis) at each location. One laboratory was significantly larger than others. In this case, the number of analytes agreed very closely (139 survey analytes versus 136 validation analytes). Figure 6-2 shows the scatter plot without this laboratory; no outliers are evident from this scatter plot. The regression analysis demonstrated a close one-to-one association between the survey and validation volume data. The slope coefficient was 1.03, slightly greater than 1.0 ($p = 0.0533$) and the intercept term of -0.363 was not significantly different from zero ($p = 0.4003$). No constant or systematic errors were detected.

Tabulation of Cluster Counts

Table 6-2 lists the cluster counts (i.e., counts of distinct triples of analytes, test systems, and biological specimens) for each laboratory.

Table 6-1 Summary of analyte counts tabulated during the original survey and the validation survey at 30 Phase I validation locations

NICLTS ID	Analyte Counts	
	Original survey	Validation survey
03159-01	14	19
03225-01	2	2
04419-01	139	136
07924-01	1	1
10728-04	8	8
15385-01	9	8
18685-01	14	13
19691-01	7	8
19954-01	50	51
20062-01	4	5
21180-01	38	37
24547-01	25	24
24949-01	29	26
25843-01	4	5
26019-01	2	2
27744-02	6	9
31826-01	28	24
35329-01	1	1
37994-01	11	11
38393-01	3	2
39783-01	2	2
40145-01	47	44
42859-01	30	27
49036-01	23	24
50498-01	26	29
51486-01	3	5
52867-01	8	8
54272-01	2	2
58391-01	34	34
58953-01	14	13

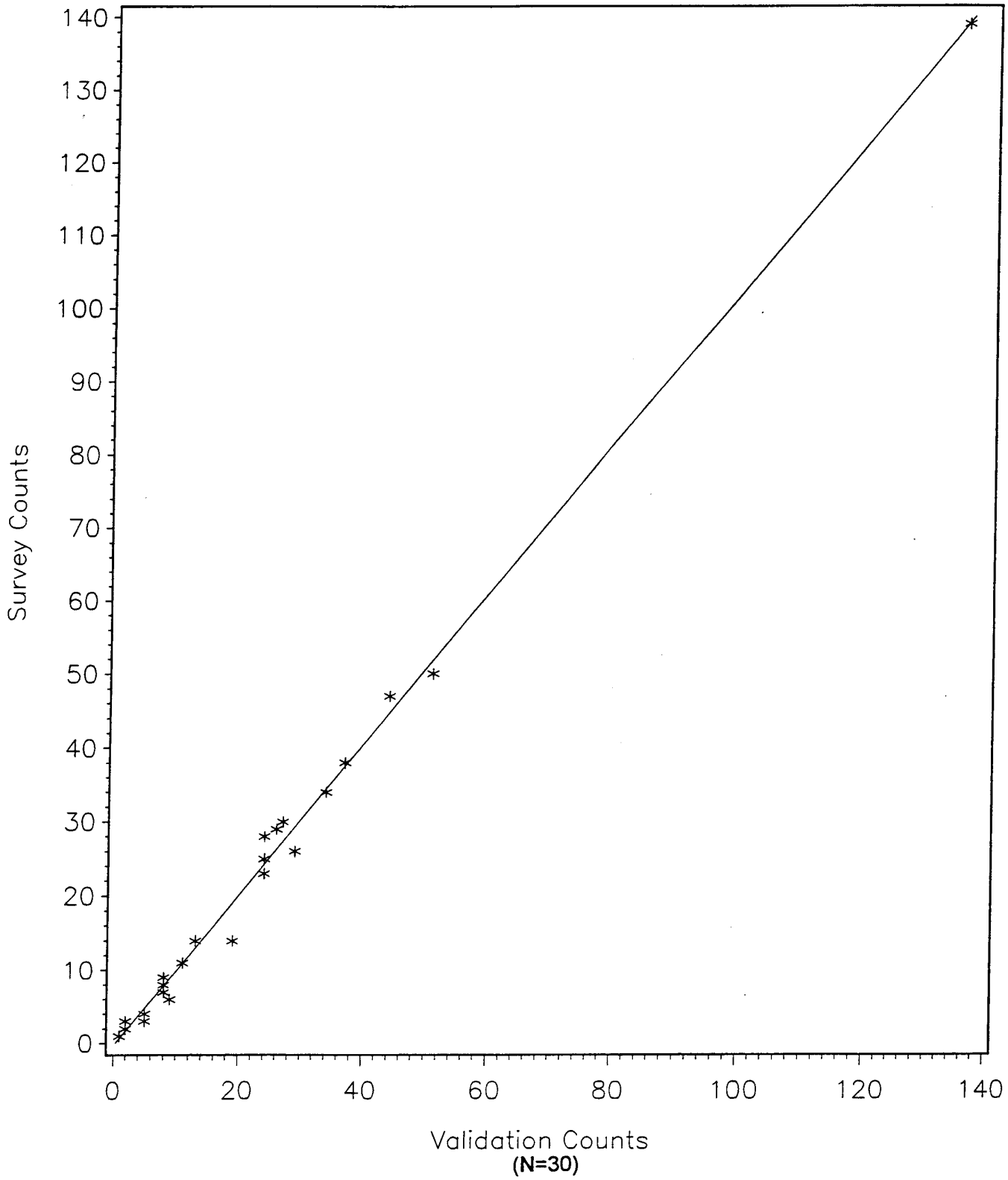

Figure 6-1. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the 30 Phase I validation locations

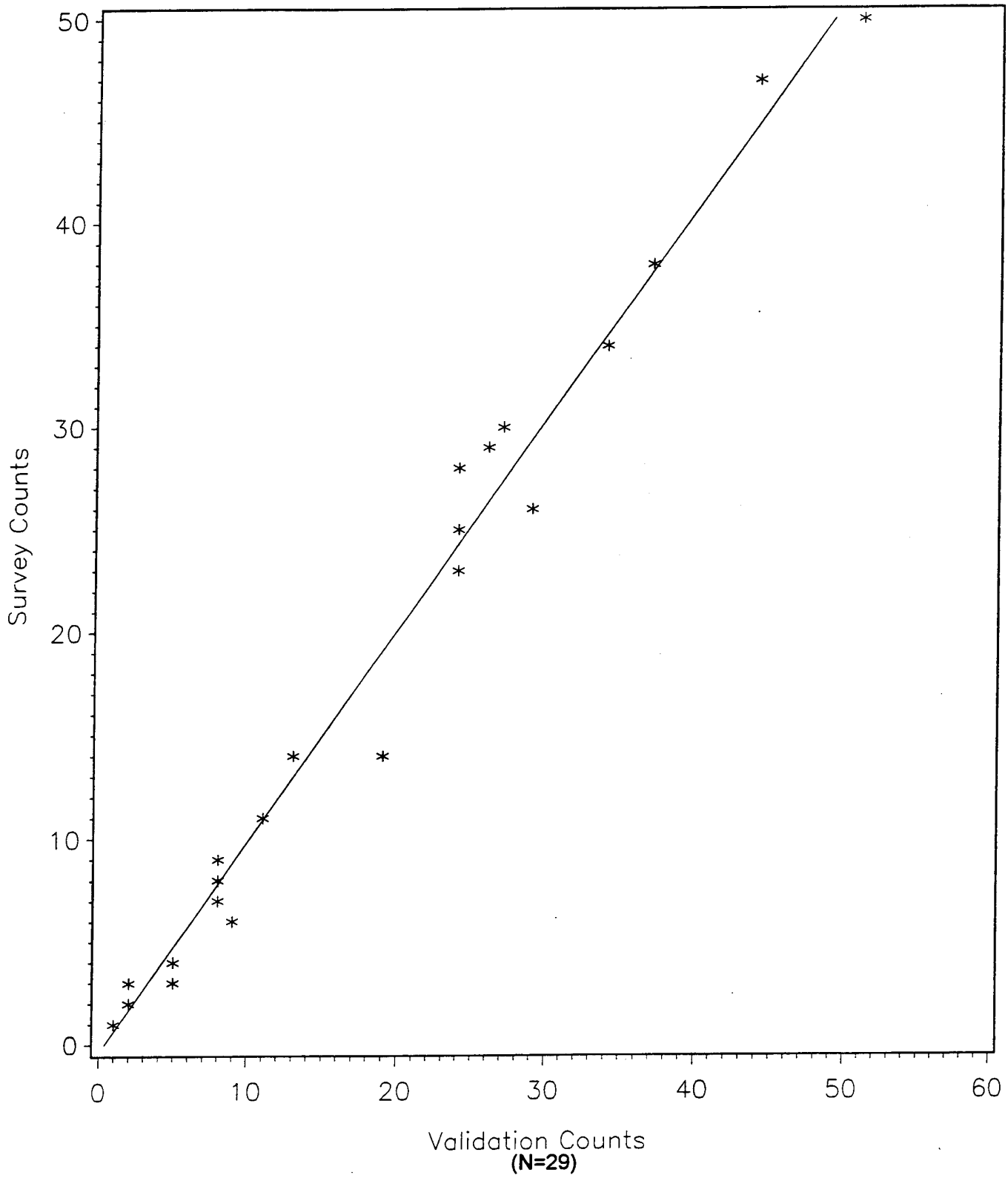

Figure 6-2. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the Phase I validation locations with largest laboratory removed

Table 6-2. Summary of cluster counts tabulated during the original survey and the validation survey at 30 Phase I validation locations

NICLTS ID	Cluster Counts	
	Original survey	Validation survey
03159-01	14	22
03225-01	2	2
04419-01	237	193
07924-01	2	2
		9
10728-04	8	
15385-01	15	13
18685-01	14	14
19691-01	7	9
19954-01	60	58
20062-01	5	6
21180-01	40	37
24547-01	30	30
24949-01	58	34
25843-01	4	5
26019-01	3	2
27744-02	6	9
31826-01	37	26
35329-01	1	1
37994-01	14	12
38393-01	3	2
39783-01	2	2
40145-01	55	52
42859-01	31	27
49036-01	29	28
50498-01	31	30
51486-01	3	5
52867-01	9	9
54272-01	2	2
58391-01	24	34
58953-01	14	13

Figure 6-3 is a scatter plot of survey clusters (vertical axis) versus validation clusters (horizontal axis). Again this plot indicates that one laboratory is particularly large, with more than twice as many clusters as the next largest laboratory. This laboratory's number of clusters is about 22.8 percent higher than that for validation clusters (237 versus 193); a review of the clusters for this laboratory revealed no obvious patterns of discrepancy.

In order to see the relationship between survey and validation clusters for the smaller laboratories more clearly, the largest laboratory was dropped from the scatter plot. The result is shown in Figure 6-4. From this plot, it is evident that there is one other laboratory for which the number of survey clusters (58) was substantially greater than the number of validation clusters (34).

The regression analysis gave a slope coefficient of approximately 1.219 (P = 0.0001), with an intercept coefficient of -2.3 (p = 0.0543). These values reflect the 'influence of the largest laboratory, which had many more survey clusters than validation clusters. When this outlier was dropped from the regression, the slope coefficient was 1. 12, slightly greater than 1 (p = 0.050), and the intercept coefficient (-0.7) was not significantly different from zero (p = 0.61). No constant or systematic errors were detected.

Tabulation of Total Volume

Table 6-3 lists the original survey and validation survey "total volume" for each location in the validation study. The total volume is the aggregate volume for all tests performed during calendar year 1996 for all clusters for a given laboratory location.

Figure 6-5 is a scatter plot of survey total volume (vertical axis) versus validation total volume (horizontal axis). As the plot indicates, one laboratory was particularly large, with a total volume of approximately 900,000 tests. The survey and validation volumes for this laboratory appeared to match fairly closely, with survey volume being about 6.7 percent greater than validation volume (938,074 versus 878,833). In the second largest laboratory, however, the survey volume was about 15 percent smaller than the validation volume.

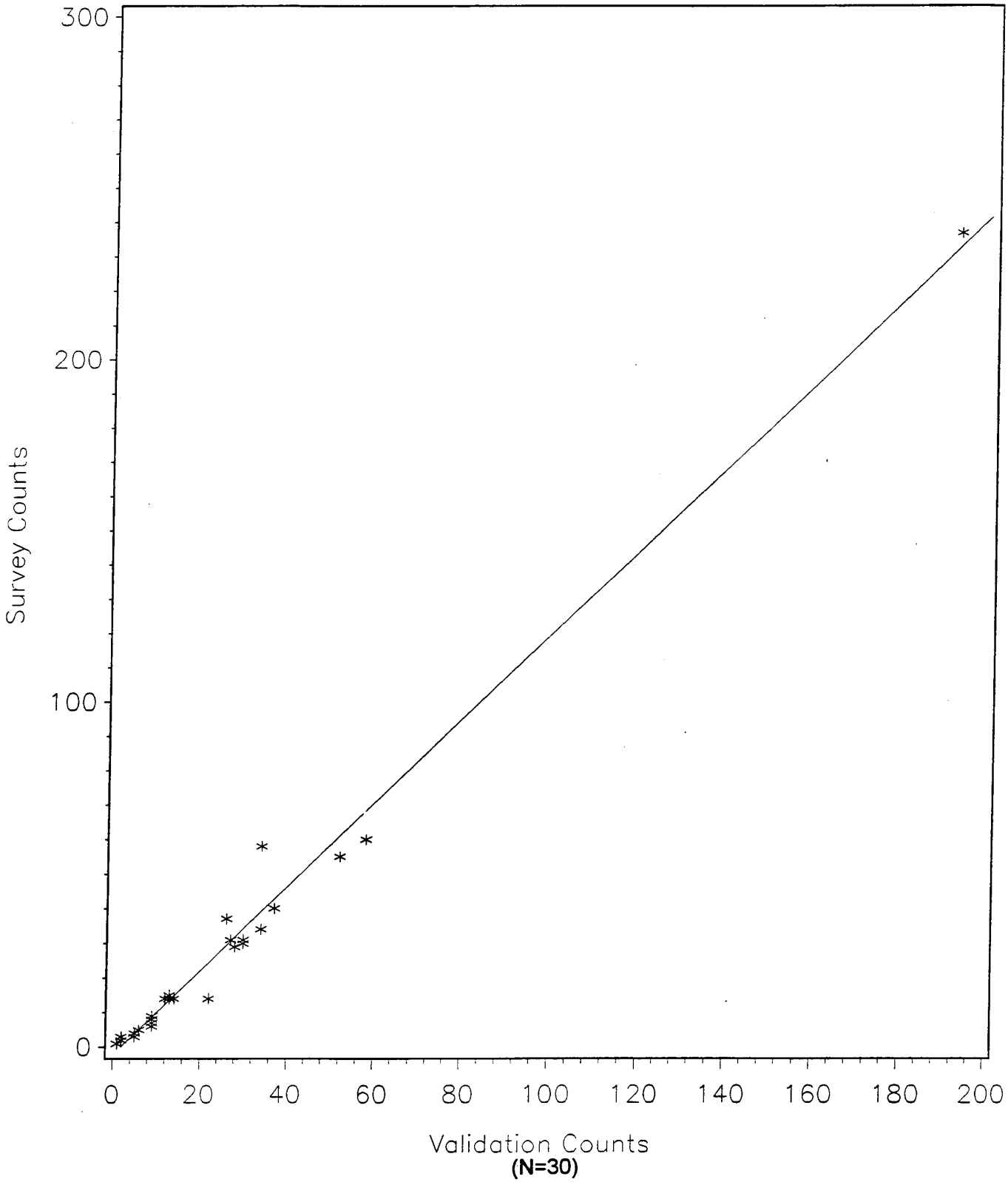

Figure 6-3. Scatter plot of distinct cluster counts tabulated during original survey and validation survey at the 30 Phase I validation locations

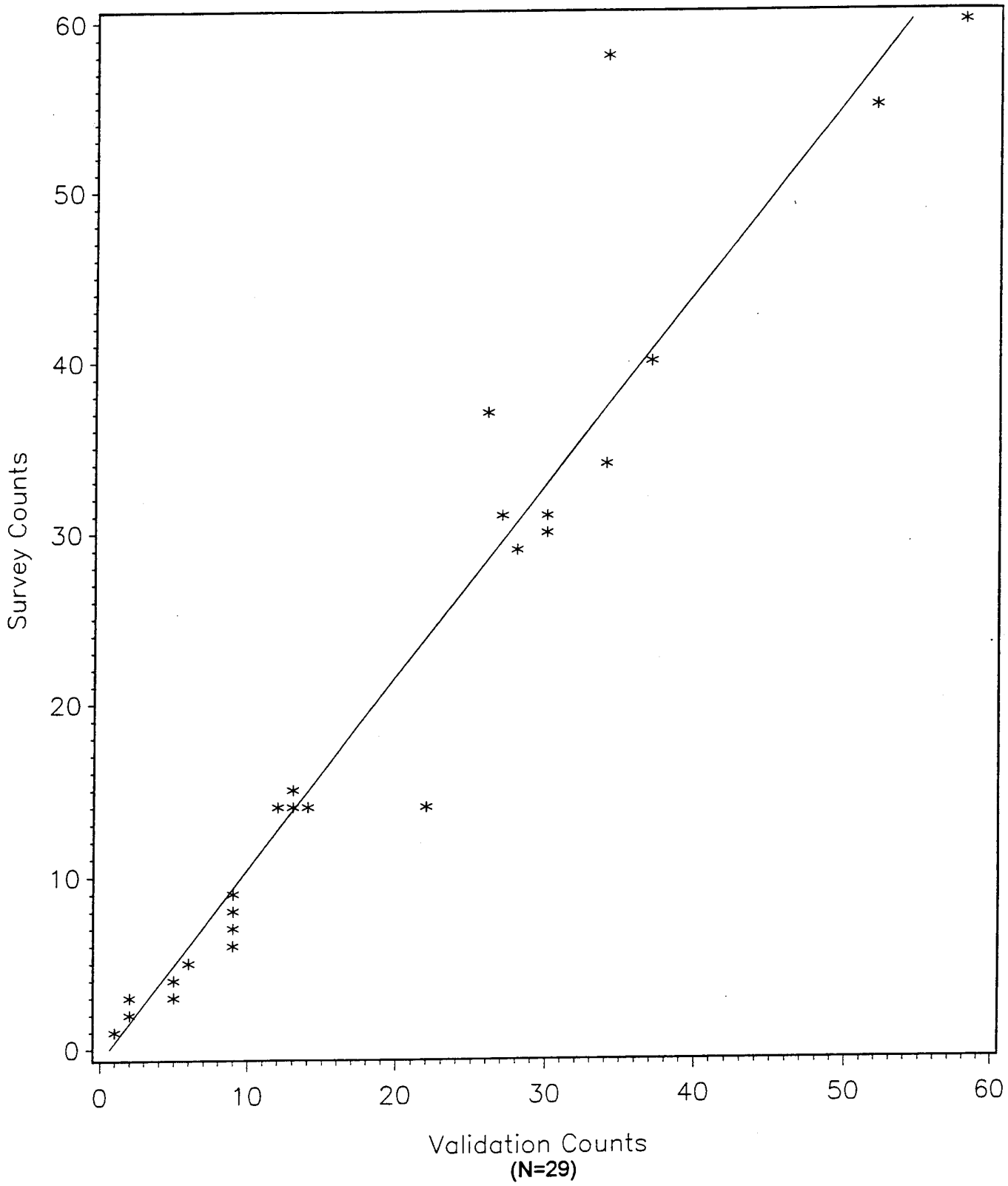

Figure 6-4. Scatter plot of distinct cluster counts tabulated during original survey and validation survey at the Phase I validation locations with largest laboratory removed

Table 6-3. Summary of volumes tabulated during the original survey and the validation survey at the 30 Phase I validation locations

NICLTS ID	Total Volumes	
	Original survey	Validation survey
03159-01	4,541	7,753
03225-01	467	936
04419-01	938,074	878,833
07924-01	97,263	113,826
10728-04	1,409	1,457
15385-01	25,940	25,123
18685-01	9,085	9,103
19691-01	395	409
19954-01	83,087	73,118
20062-01	4,817	3,233
21180-01	23,168	25,540
24547-01	78,624	77,765
24949-01	27,081	20,000
25843-01	98	122
26019-01	54	33
27744-02	1,081	1,283
31826-01	4,188	1,936
35329-01	28	30
37994-01	2,487	2,560
38393-01	3,143	728
39783-01	26	26
40145-01	73,967	71,896
42859-01	923	972
49036-01	18,369	8,770
50498-01	23,004	25,726
51486-01	2,129	2,049
52867-01	3,274	3,266
54272-01	184	24
58391-01	19,446	15,787
58953-01	43,439	12,094

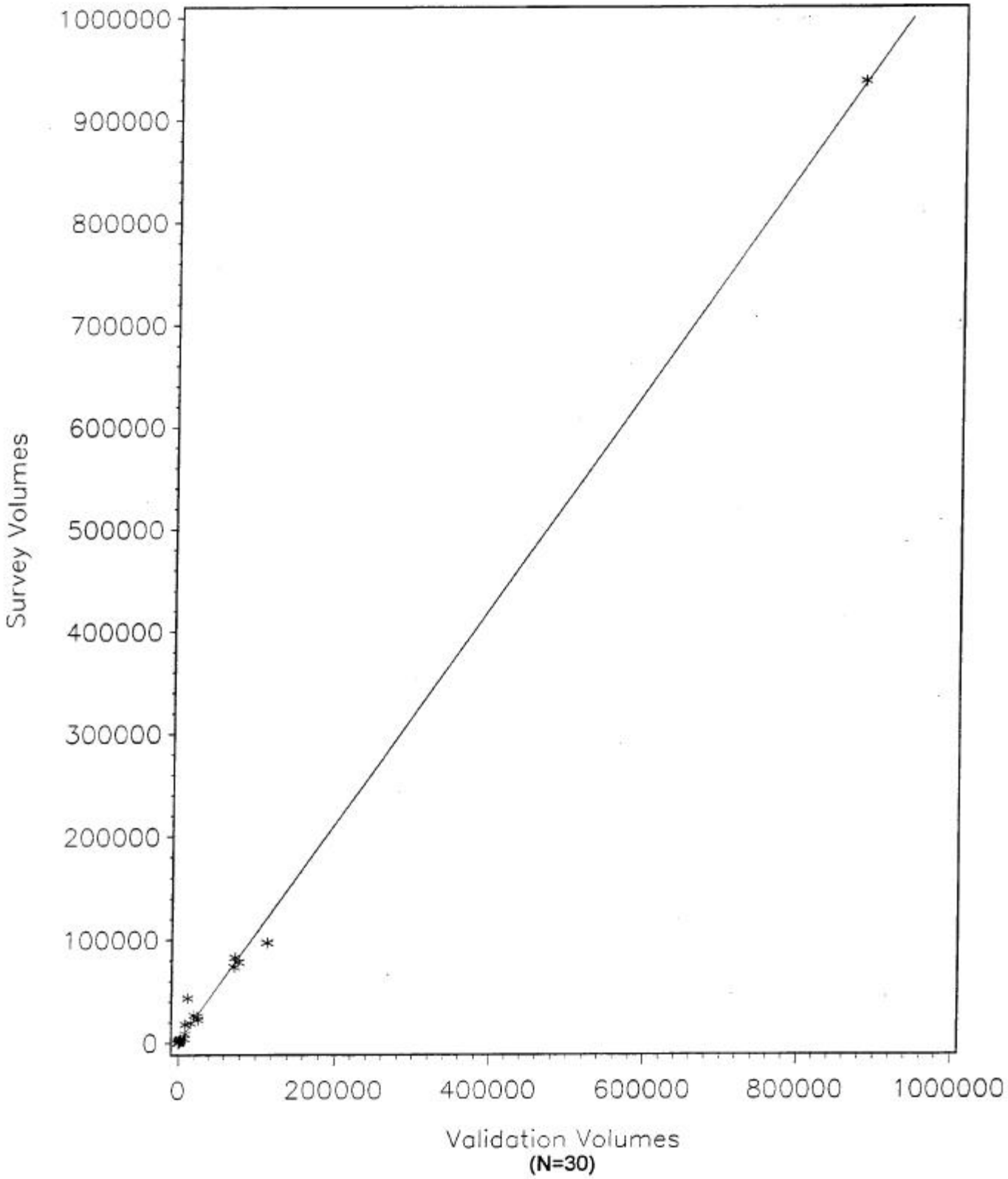

Figure 6-5. Scatter plot of total volumes tabulated during original survey and validation survey at the 30 Phase I validation locations

In order to see the relationship between survey and validation volume for the smaller laboratories more clearly, the largest laboratory was dropped from the scatter plot. The results are shown in Figure 6-6. From this plot, it is evident that there was one laboratory for which the survey volume (43,439 tests) was substantially greater than the validation volume (12,094 tests). More detailed listings revealed that a portion of this discrepancy resulted from mismatching counts of several tests performed on whole blood, where 6,181 tests were counted by the survey tabulator but only 1,169 were counted in the validation.

It should be remembered that the data collection protocol did not allow for missing data. If records were not available for a given analyte, test system, specimen, or volume, the participating laboratory was asked to estimate these data using a standard protocol to assist memory. While the validation protocol called for contacting the original laboratory respondent, scheduling difficulties sometimes made this impractical. It may be that different respondents had differing knowledge of available records and/or differing recollections of procedures performed.

Despite the sharp disagreement for the one laboratory, a regression analysis showed a fairly close one-to-one correspondence between the survey and validation volumes. In the regression analysis, the slope coefficient was 1.06, reflecting the close one-to-one relationship. The intercept term (598.7) was not significantly different from zero ($p = 0.6927$). When the extreme outlier was removed, the regression analysis had a slope coefficient of 1.04, again reflecting a close one-to-one relationship; again the intercept term was not significantly different from zero ($p = 0.2713$). No constant or systematic errors were detected.

Table 6-4 lists survey and validation data for test volume by tabulator's source of volume data. The discrepancy discussed earlier is not accounted for by use of either testers' estimates or daily log sampling. It appears from this listing that discrepancies in testers' estimates versus other sources tend to balance out when all sources are summed.

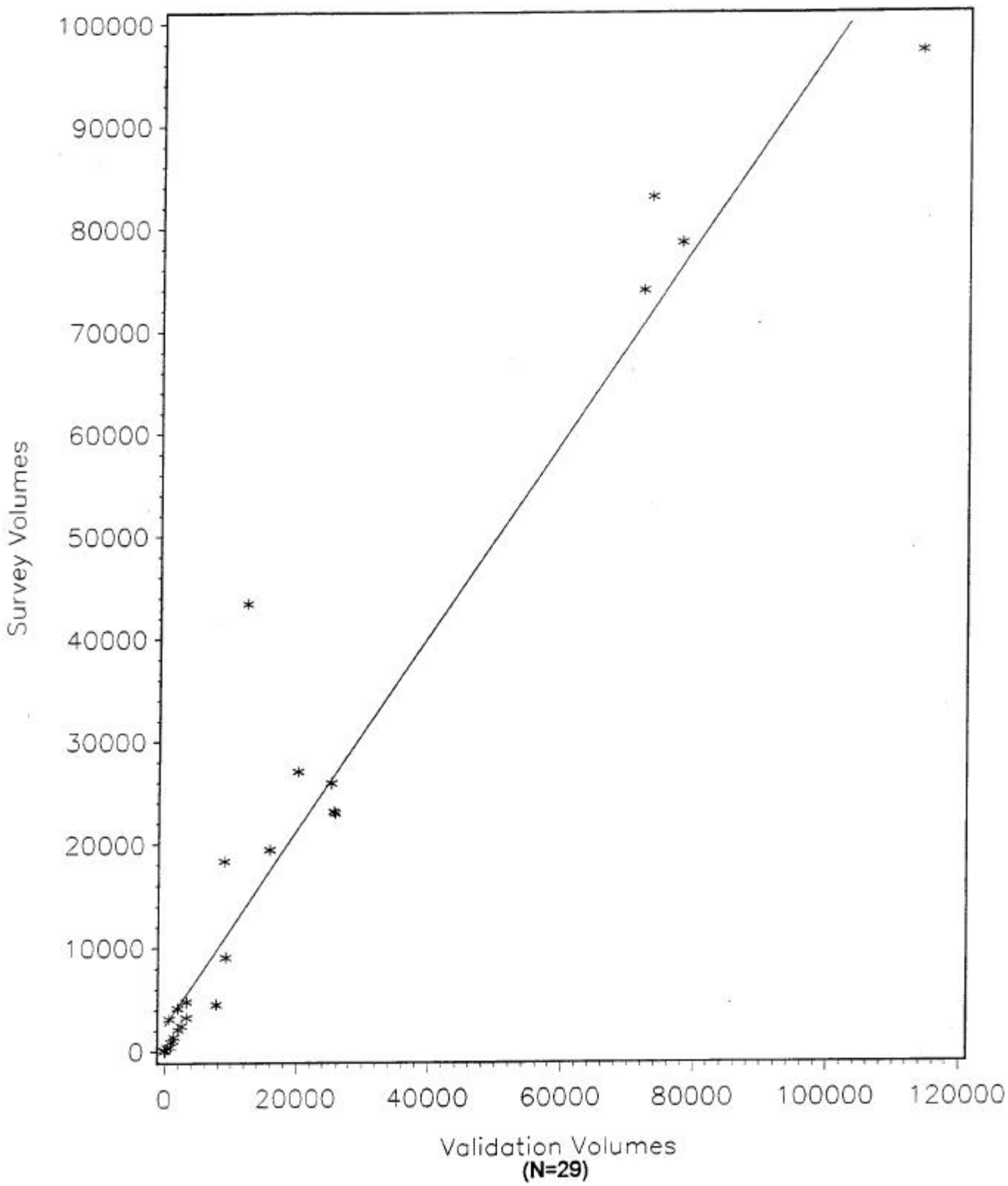

Figure 6-6. Scatter plot of total volumes tabulated during original survey and validation survey of the Phase I validation locations with largest laboratory removed

Table 6-4. Volumes tabulated during original survey and validation survey at the 30 Phase I validation locations, broken out by tabulator's source of volume data

	Total Volumes		Tester's Estimates		Daily Logs		Volume or Billing Records	
NICLTS ID	Original Survey	Validation Survey	Original Survey	Validation Survey	Original Survey	Validation Survey	Original Survey	Validation Survey
03159-01	4,541	7,753	0	3,662	0	0	4,541	4,091
03225-01	467	936	0	0	0	0	467	936
04419-01	938,074	878,833	195,417	42,144	0	0	742,657	836,689
07924-01	97,263	113,826	0	0	0	0	97,263	113,826
10728-04	1,409	1,457	0	556	0	0	1,409	901
15385-01	25,940	25,123	1,786	0	0	245	24,154	24,878
18685-01	9,085	9,103	0	13	0	0	9,085	9,090
19691-01	395	409	288	222	107	125	0	62
19954-01	83,087	73,118	22,265	13,826	0	0	60,822	59,292
20062-01	4,817	3,233	394	0	0	0	4,423	3,233
21180-01	23,168	25,540	0	970	0	0	23,168	24,570
24547-01	78,624	77,765	24	6	0	0	78,600	77,759
24949-01	27,081	20,000	27,081	0	0	0	0	20,000
25843-01	98	122	0	0	0	0	98	122
26019-01	54	33	0	0	0	0	54	33
27744-02	1,081	1,283	0	10	0	0	1,081	1,273
31826-01	4,188	1,936	1,081	0	3,107	0	0	1,936
35329-01	28	30	0	0	0	0	28	30
37994-01	2,487	2,560	0	285	0	0	2,487	2,275
38393-01	3,143	728	2,400	0	0	728	743	0
39783-01	26	26	0	0	0	0	26	26
40145-01	73,967	71,896	19,417	43,276	0	0	54,550	28,620
42859-01	923	972	25	0	0	0	898	972
49036-01	18,369	8,770	18,369	8,644	0	0	0	126
50498-01	23,004	25,726	392	1,617	0	0	22,612	24,109
51486-01	2,129	2,049	0	132	0	0	2,129	1,917
52867-01	3,274	3,266	0	0	0	0	3,274	3,266
54272-01	184	24	184	6	0	0	0	18
58391-01	19,446	15,787	6,134	2,086	0	0	13,312	13,701
58953-01	43,439	12,094	0	10	0	0	43,439	12,084
TOTAL	1,489,791	1,384,398	295,257	117,465	3,214	1,098	1,191,320	1,265,835

Adjustments to Data

No adjustments to the estimates were made based on the validation study results. While there were a few discrepant cases, the validation study did not reveal any systematic bias in the tabulation of analytes, clusters, or volumes. Since there does not appear to be a systematic bias, Westat concluded that there was no need for corrections or adjustments.

Summary and Conclusions

In summary, there were two cases of discrepant results. One laboratory showed 58 survey clusters versus 34 validation clusters. The same laboratory had a survey volume of 43,439 tests when the validation volume was 12,094 tests. Aside from these individual discrepancies, the validation study indicated good agreement between the survey and validation data. Thus we conclude that there were no systematic errors or bias in the data tabulation process.

6.2 Phase II Quality Assurance

The formal quality assurance programs for the Phase II data tabulation protocol consisted of Telephone Monitoring and Field Validation. Each of these programs is described in a separate section below.

6.2.1 Telephone Tabulation Monitoring

Since Phase II utilized a mail-telephone methodology, no telephone verification was performed with participating laboratories. The standard quality assurance tool for telephone data collection operations was real-time monitoring of the live telephone interviews by supervisory and management staff. This procedure was comparable to verification calls made to respondents in field interviews, since it served as a way of confirming that the interview actually took place and adhered to the approved protocol. Telephone monitoring was performed at random times continually throughout the data collection process, and the telephone monitoring equipment did not create any interference that would alert the telephone data collector to the fact that the monitoring session was taking place. Thus, the knowledge that monitoring might occur at any time served as an incentive and admonition

to the telephone data collector to follow the protocol.

As described in Section 4.2.4.4, the NICLTS telephone operations supervisory staff monitored a selection of each tabulator's telephone contacts, especially at the beginning of the process. This monitoring was designed both to ensure that the tabulator followed the protocol and to identify any individual or generic difficulties encountered in administering the forms or otherwise following the protocol. The telephone supervisors used the findings of monitoring calls to provide feedback to specific tabulators on individual issues, and to provide general advice to the tabulators on ways to correct minor problems in following the protocol or recording the data, or to improve their data collection telephone techniques. There were no individual or generic problems that affected the validity of the NICLTS protocol and resulting data. Each tabulator's performance of the telephone protocol fulfilled all operational and data validity goals of the NICLTS Phase II.

6.2.2 Field Validation

The design and conduct of NICLTS Phase II employed standard survey research mail and telephone data collection methodologies. Because it collected data from laboratories through a combination of self-administered forms and telephone data collection, a validation test of the telephone protocol was performed to ensure consistency with data collected in Phase I.

6.2.2.1 Validation Study Design

The validation design was straightforward and shared many features with the validation of the field tabulations in Phase I. The validation sample was targeted to consist of 100 laboratory locations. An initial sample of 204 locations was selected from the set of those already tabulated by telephone. A nationally distributed team of validation field tabulators was selected from among those who had worked on Phase I. Team members were individually assigned to visit the Phase II validation sample in their area to carry out a duplicate but independent on-site tabulation. Other than being aware that the visit was a validation site visit, the validation field tabulator had no knowledge of anything that occurred during the original telephone tabulation. Similarly, the validation sample laboratories were aware only that they were participating in a quality assurance check of the NICLTS project. After the data were retabulated, the NICLTS staff analyzed the results from the two tabulations, at the

level of individual laboratories and in the aggregate for the whole validation sample.

The protocol and methodology for the validation process shared many of the elements of the Phase I and Phase II tabulations. The remainder of this section, therefore, discusses only the two significant points of difference-laboratory enrollment and field protocol and operations-then concludes with a discussion of the results.

6.2.2.2 Validation Enrollment

The enrollment of the Phase II validation sample was carried out using the same procedures as the Phase I enrollment. For the sake of efficiency, the telephone validation enrollment was performed by a selected group of the telephone tabulators who evidenced superior telephone and interpersonal skills. Even though the validation assessed the product of the telephone tabulation, there was no possibility that the recruitment of validation laboratories by the tabulators would confound or contaminate the validation findings. The reasons for this include the following:

- Tabulators who did the re-enrollment of the validation sample were not informed of the specifics of the validation protocol;
- They had no contact with the validation tabulators and were not even informed of their names;
- They could have no effect on the validation tabulations that ultimately took place in the field; and
- The procedure was intended as a validation of the general mail/telephone protocol itself, rather than as a check of specific laboratories or telephone tabulators.

Because of the relatively small size of the validation sample, the enrollment materials were produced by manual rather than automated methods. The enrollment tabulators were given a photocopy of the Call Record from the original telephone tabulation to use as a source of contact information. They placed the enrollment call to the person named on this Call Record as the final mail/telephone contact.

A new laboratory enrollment form was completed for each enrolled laboratory. From this point on, the field procedures, home office procedures, and automated case management system handled the case according to the overall NICLTS Phase I field operations processes.

The validation sample was targeted to allow 100 complete on-site retabulations by the end of the mail-telephone data collection phase. Laboratories were purposively chosen from a two-way grid of telephone data tabulator by laboratory type (waived, PPM). All telephone tabulators in the mail-telephone data collection effort were represented in the sample.

A total of 204 laboratories which had previously been tabulated by mail and telephone were released for enrollment, and Westat was able to contact all of the sampled laboratories. Of these, 127 (62.3%) were enrolled, 5 (2.5%) agreed to participate but could not schedule a visit during the short time allotted for validation visits, and 72 (35.3%) refused to participate. The refusal rate was low and the enrollment rate high, given that laboratories had recently completed the mail/telephone-assisted interview and they were now being asked to accommodate a data tabulator for a more intrusive on-site visit to repeat the tabulation, and given the fact that no refusal conversion was utilized.

6.2.2.3 Field Protocol and Operations

For the validation effort, the Phase I (field) version of the survey management system was reactivated to manage the Phase II field validations, with only minor modifications. The Phase II telephone operations supervisors fulfilled the functional role that had been played by the three field monitors for the full-scale Phase I field study, in terms of guiding the field tabulators, overseeing their efforts, and responding to their inquiries. The case distribution and management was handled with essentially the same systems, materials, and methods as for Phase I, except for changes dictated by the actual validation tabulation protocol, as described below.

The validation tabulators visited waived and PPM laboratories and tabulated the test data using forms the same as or similar to those used by the mail-telephone data collectors. It was a deliberate aspect of the Phase II validation design that they would not use the computerized Tabulation Device used in Phase I; the NICLTS Telephone Data Tabulation Form replaced the Tabulation Device. A case folder containing all materials necessary for completing a validation site visit was sent to the assigned tabulator. Each case folder included the following:

- Laboratory-specific Call Record;
- NICLTS Telephone Data Tabulation Form;

- Generic copies of the 1996 Test Inventory Form and the Test System Reference List that had been mailed to all laboratories in the main Phase II survey;
- Modified version of the Phase I On-Site Protocol;
- Laboratory tour form;
- Volume estimation script;
- Coded biological specimen list; and
- Appointment form.

The validators also received a binder containing a hard-copy version of the expanded Complexity Model for use when coding any moderate or high complexity analytes or test systems encountered at the laboratory.

Since the validators were previously trained Phase I field tabulators, training was simply a refresher course. The materials used for telephone tabulator training were sent to the validator staff to study. Westat staff arranged a telephone conference call to answer any questions about the data collection process and administrative issues and to reiterate protocol and confidentiality requirements. The differences between tabulating using the computerized Tabulation Device and recording on the paper Telephone Data Tabulation Form were emphasized.

The validation tabulators used a protocol that combined the paper NICLTS Telephone Data Tabulation Form to collect and record the data with the main elements of the on-site protocol from the Phase I field study. Three significant Phase I elements were incorporated into the Phase II validation study:

- Use of an On-Site Protocol (this combined the function of the Phase I On-Site Protocol with some of the structuring and probing functions of the Phase II Telephone Data Tabulation Guide);
- Laboratory tour; and
- Tabulation of the test volume data from laboratory records by the tabulator.

These components permitted the Phase II validation study to compare data collected by methods that differed in several key elements from those used in the mail-telephone protocol. These elements and the different approaches are presented in Table 6-5.

Table 6-5. Comparison of Phase II validation methods with Phase II primary mail-telephone methods

Protocol element	Phase II mail-phone method	Phase II validation method
Identification of tests performed	Self-report by laboratory Representative	Self-report by laboratory representative
	Probing by telephone tabulator	Probing by field tabulator
		Tabulator tour of laboratory to identify test systems
		Tabulator review of test records, if available
Test volume data	Assembled/calculated by laboratory representative according to instructions/definitions printed in Test Inventory Form; laboratory representative could interpret differentially or ignore	Tests identified and volumes counted by NICLTS tabulator trained in specific definitions and volume counting methods
	Request for laboratory to use available source records to assemble data; laboratory representative could ignore available records as a convenience or time saver	Volumes always assembled from source records, if available
Reporting/recording of data	Recommended use of mailed Test Inventory Form to record data and read to telephone tabulator; laboratory representative could ignore request and report data from memory or estimates	Tabulator recorded data directly on Data Tabulation Form from records
	Spoken by respondent over telephone and recorded by second party (tabulator) on Data Tabulation Form	Assembled and recorded by first party (tabulator), if records available; or spoken by laboratory representative in person to second party (tabulator) and recorded by second party on Data Tabulation Form

An essential element of the validation protocol was the establishment of a preference hierarchy for the sources and methods for identifying tests and calculating volumes. This hierarchy was designed, in particular, to maximize the collection of data as independently as possible of the processes that underlay its collection in the main telephone study. The highest priority was primary collection of the test data from written records by the field

tabulators. The second priority was the use of an in-person interview of the laboratory contact by way of the same protocol used for the telephone data collection, but without recourse to the information that the contact had assembled for the initial telephone data collection. The lowest priority was accepting from the laboratory contact the actual filled-out copy of the mailed Test Inventory Form that he or she used to respond to the telephone data collection interview.

6.2.2.4 Results of the Phase II Validation Study

The purpose of the Phase II validation study was to evaluate the reliability of telephone versus on-site data collection in waived/PPM laboratories. The study consisted of 110 laboratories that were tabulated on site as well as by the mail-telephone methodology. This section compares the original mail-telephone data with the data collected on site. In the remainder of this discussion, the latter will be called survey data, survey totals, survey counts, and so forth as contrasted with validation data, validation totals, validation counts, and so forth. Table 6-6 lists the original survey and validation survey values for the analyte counts, cluster counts, and total volumes for each laboratory.

The analysis has several parts: tabulation of analytes, tabulation of cluster counts, and tabulation of total volume. Each type of tabulation is discussed in a separate section below.

Tabulation of Analytes

A scatter plot of survey total analytes (vertical axis) versus validation total analytes (horizontal axis) is shown in Figure 6-7. One laboratory had 11 analytes by validation but only 7 reported by the mail-telephone respondents. Another laboratory had 17 analytes by validation but only 12 reported by the mail-telephone respondents. Otherwise, the scatter plot indicates good agreement between the survey data and the validation data.

A regression analysis demonstrated a slope of 0.80, smaller than one ($p < 0.0001$), and the intercept of 0.350 was statistically significantly different from zero ($p = 0.0006$). This shows underreporting by mail-telephone respondents, but the result is strongly influenced by the outliers described above. If the outliers are removed, the slope is 0.876 ($p = 0.0003$) with an intercept of 0.270 ($p = 0.019$).

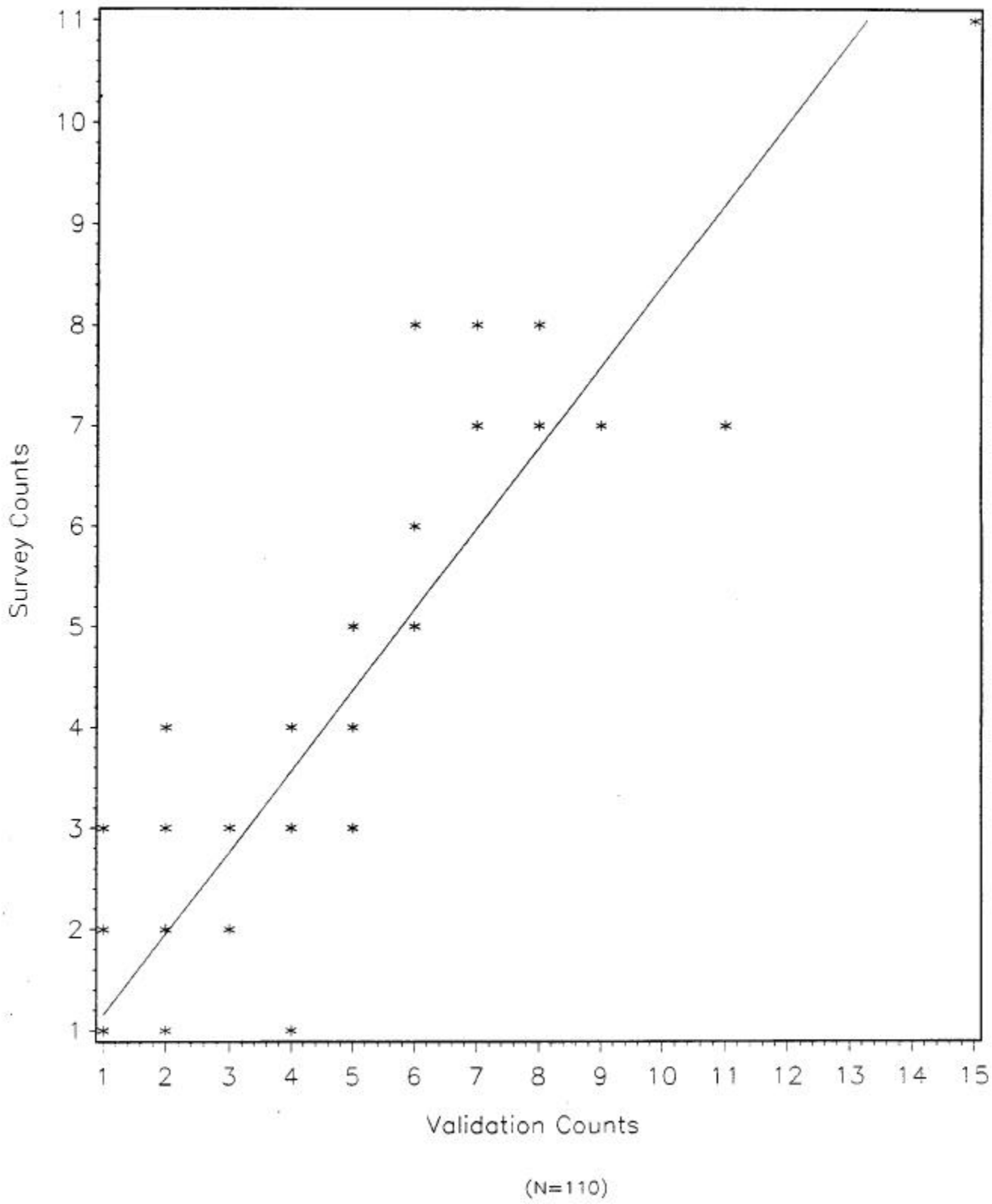

Figure 6-7. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the Phase II validation locations with largest laboratory removed

Tabulation of Clusters (Analyte, Test System, Specimen)

A scatter plot of survey clusters (triples of analyte, test system, and specimen) versus validation clusters (horizontal axis) is shown in Figure 6-8. One laboratory in the validation study had a differing number of clusters, reporting 8 by mail/telephone and 15 by the validation data. Except for this and one other outlier, there was excellent agreement between the two data sources.

A regression analysis demonstrated a slope of 0.74, substantially less than one ($p < 0.0001$), and the intercept of 0.567 was statistically significantly different from zero ($p = 0.0001$). This shows a tendency of the mail-telephone respondents to report fewer clusters than the validators, but this result is strongly influenced by the two outliers mentioned earlier. With the two outliers removed, the slope is 0.897, still less than 1.0 ($p = 0.00\ 15$), with an intercept of 0. 16 ($p = 0.\ 105$).

Tabulation of Total Volume

The total volume is the aggregate volume for all tests performed for all clusters in a given laboratory. Figure 6-9 is a scatter plot of survey total volume (vertical axis) versus validation total volume (horizontal axis). There is one extreme outlier, with a survey volume of about 300,000 tests versus a validation volume of about 200,000 tests. Figure 6-10 shows the data with the largest outlier removed.

A regression analysis (with the largest outlier removed) indicated that there was a tendency for the survey data to be underreported as compared with the validation data. The slope of the regression line is 0.89 ($p = 0.0001$), suggesting that the volume reported in the survey was about 90 percent of that reported in the validation. While this difference is within the range of sampling error for estimated national total volume (see Section 5.3), it is consistent across laboratories in the validation study. The intercept in the regression analysis (-120.8) is not significantly different from zero ($p=0.618$). Results were similar with both the first and second outliers removed.

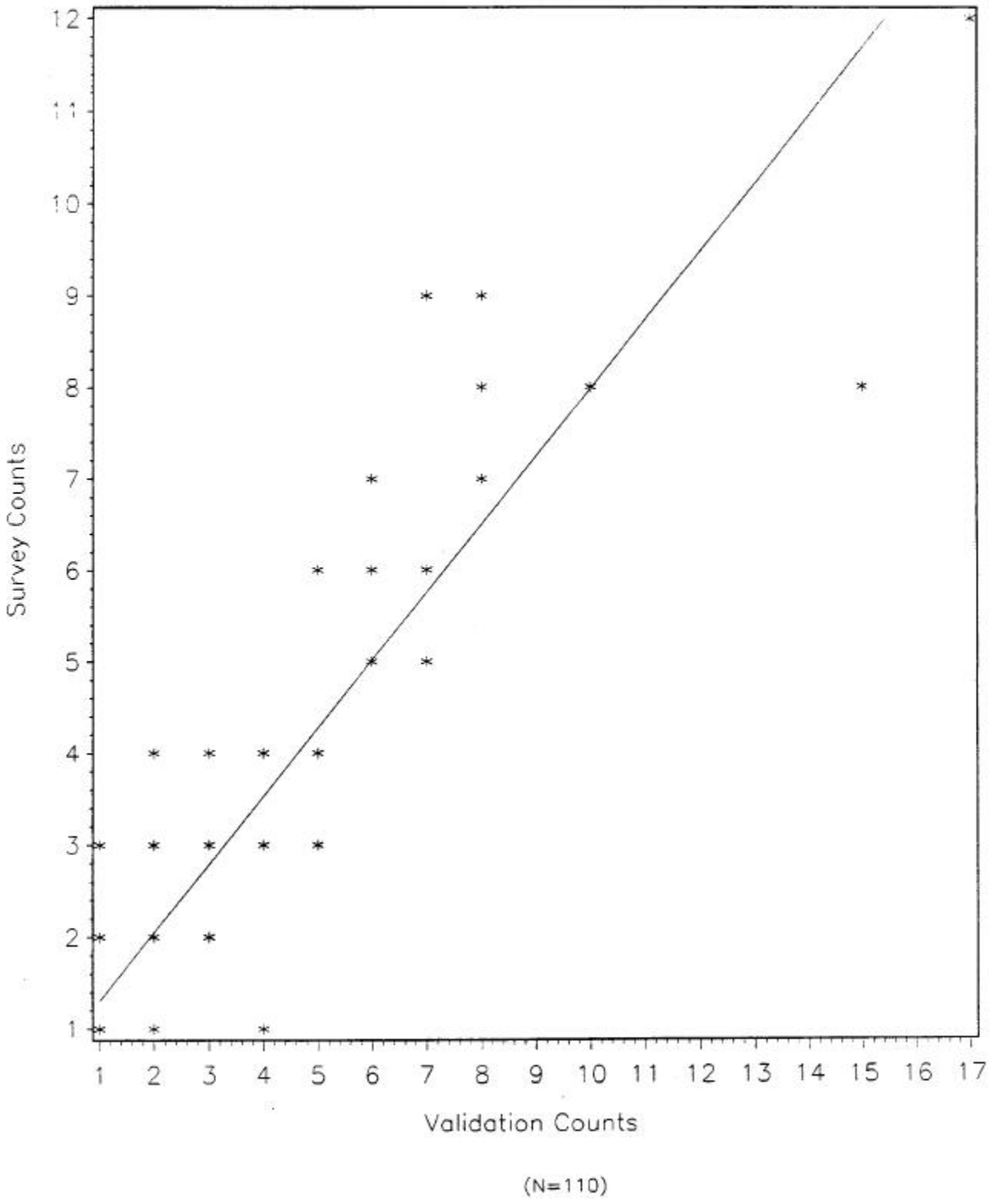

Figure 6-8. Scatter plot of distinct cluster counts tabulated during original survey and validation survey at the 110 Phase II validation locations

Table 6-6. Comparison of survey and validation data for Phase II laboratories

	Analyte Counts		Cluster Counts		Total Volumes	
NICLTS ID	Original Survey	Validation Survey	Original Survey	Validation Survey	Original Survey	Validation Survey
00680-01	2	2	2	1	812	4,278
01119-01	9	8	8	7	2,310	2,178
02938-01	2	2	2	2	11,300	12,300
03494-01	3	3	3	3	300	12,000
03654-01	2	2	2	2	4,036	385
03702-01	2	2	2	2	19	17
03878-01	5	6	5	5	902	907
04428-01	1	1	1	1	52,000	52,100
04660-01	4	5	4	5	670	2,460
04802-01	3	1	2	1	1,210	15
05612-01	1	1	1	1	20	12
06039-01	1	1	1	1	6,720	5,460
06413-01	1	1	1	1	11	11
06691-01	4	3	3	3	30	26
07232-01	1	1	1	1	12	12
07241-01	1	1	1	1	3,029	3,029
08499-01	1	1	1	1	5,400	5,400
09218-01	2	2	2	2	402	321
10540-01	1	1	1	1	4,015	4,015
11903-01	1	1	1	1	2,016	13,000
12441-01	3	3	3	3	2,565	2,120
12722-01	6	6	6	6	1,268	858
13206-01	2	2	1	1	6,950	6,950
13215-01	2	1	2	1	32	18
13372-01	1	1	1	1	513	143
13662-01	1	2	1	2	672	696
14146-01	3	3	3	3	871	1,117
14379-01	2	2	2	2	480	480
14472-01	1	1	1	1	2,200	7,300
14520-01	2	2	2	2	1,157	1,157
14874-01	1	1	1	1	1,800	1,800
15303-01	6	6	6	6	3,304	3,304
15545-01	2	3	2	3	225	610
16850-01	4	5	4	5	190	1,024
18443-01	2	2	2	2	7,380	7,440
19178-01	1	1	1	1	500	1,200
21199-01	3	3	3	3	604	225
21201-01	2	2	2	2	210	210
21564-01	1	1	1	1	1,150	1,150
21966-01	1	1	1	1	9	1,946
22150-01	6	5	5	5	10,760	8,364

Table 6-6. Comparison of survey and validation data for Phase II laboratories (continued)

	Analyte Counts		Cluster Counts		Total Volumes	
NICLTS ID	Original Survey	Validation Survey	Original Survey	Validation Survey	Original Survey	Validation Survey
22196-01	4	3	2	2	1,884	1,450
22271-01	2	1	1	1	6,720	2,520
22459-01	1	1	1	1	10	24
23175-01	3	2	1	1	1,080	700
23429-01	4	3	3	3	644	230
23531-01	1	1	1	1	1,296	1,296
24976-01	4	4	4	4	3,235	4,186
25339-01	1	1	1	1	7,200	5,040
25432-01	4	5	4	5	3,154	4,354
26466-01	3	4	3	4	163	179
27490-01	1	2	1	2	12	708
27810-01	1	1	1	1	4,311	4,311
28219-01	1	1	1	1	500	7,150
28291-01	5	7	5	6	1,235	2,532
28956-01	1	1	1	1	2,688	2,920
29243-01	5	6	2	2	2,419	2,635
29627-01	3	3	3	3	658	718
30258-01	2	2	2	2	79	108
30931-01	7	8	7	7	3,105	7,415
33008-01	1	1	1	1	3,600	360
33398-01	7	8	7	8	2,576	3,440
34087-01	8	10	7	9	493	2,036
34582-01	1	1	1	1	3,000	1,488
34993-01	1	2	1	2	20	8
35187-01	2	1	1	1	45	15
35842-01	1	1	1	1	300	300
35897-01	1	1	1	1	58	58
37426-01	2	3	2	3	1,680	7,230
38526-01	1	1	1	1	295,000	200,095
39019-01	12	17	11	15	298	1,671
39439-01	1	1	1	1	1,037	1,749
39756-01	1	4	1	4	260	765
40079-01	3	4	3	4	18	504
41544-01	8	8	8	8	1,562	1,920
41704-01	1	1	1	1	42	36
41861-01	1	2	1	2	6,048	5,870
41889-01	3	5	3	5	9,592	8,290
42224-01	2	2	2	2	271	225
43276-01	2	2	1	1	16,556	16,556
45935-01	1	1	1	1	1,564	1,570
46138-01	3	3	3	3	2,640	9,060

Table 6-6. Comparison of survey and validation data for Phase II laboratories (continued)

	Analyte Counts		Cluster Counts		Total Volumes	
NICLTS ID	Original Survey	Validation Survey	Original Survey	Validation Survey	Original Survey	Validation Survey
46521-01	8	15	7	11	370	2,704
46772-01	1	1	1	1	150	260
47470-01	1	1	1	1	50	50
48749-01	3	1	3	1	5,200	6,000
48758-01	1	1	1	1	1,662	1,662
49960-01	6	6	6	6	175	178
50005-01	1	1	1	1	1,728	120
50573-01	2	2	2	2	4,050	4,050
50788-01	1	1	1	1	260	260
50809-01	7	6	6	6	2,262	6,935
51226-01	3	2	3	2	915	265
51280-01	1	1	1	1	2,912	381
51338-01	2	1	2	1	436	416
51703-01	3	3	2	2	3,128	3,158
51824-01	2	1	1	1	50	252
52009-01	1	1	1	1	35	35
52782-01	1	1	1	1	950	930
53707-01	4	2	4	2	2,303	607
53994-01	9	7	8	6	1,893	3,800
54571-01	1	1	1	1	1,344	1,344
55484-01	6	7	5	5	560	3,168
55578-01	3	3	3	3	3,645	4,179
55831-01	2	2	2	2	2,823	2,923
56418-01	1	1	1	1	112	112
56762-01	1	1	1	1	10,220	4,745
56986-01	2	2	2	2	5,510	5,140
58159-01	1	2	1	2	20	579
58234-01	1	1	1	1	6	6

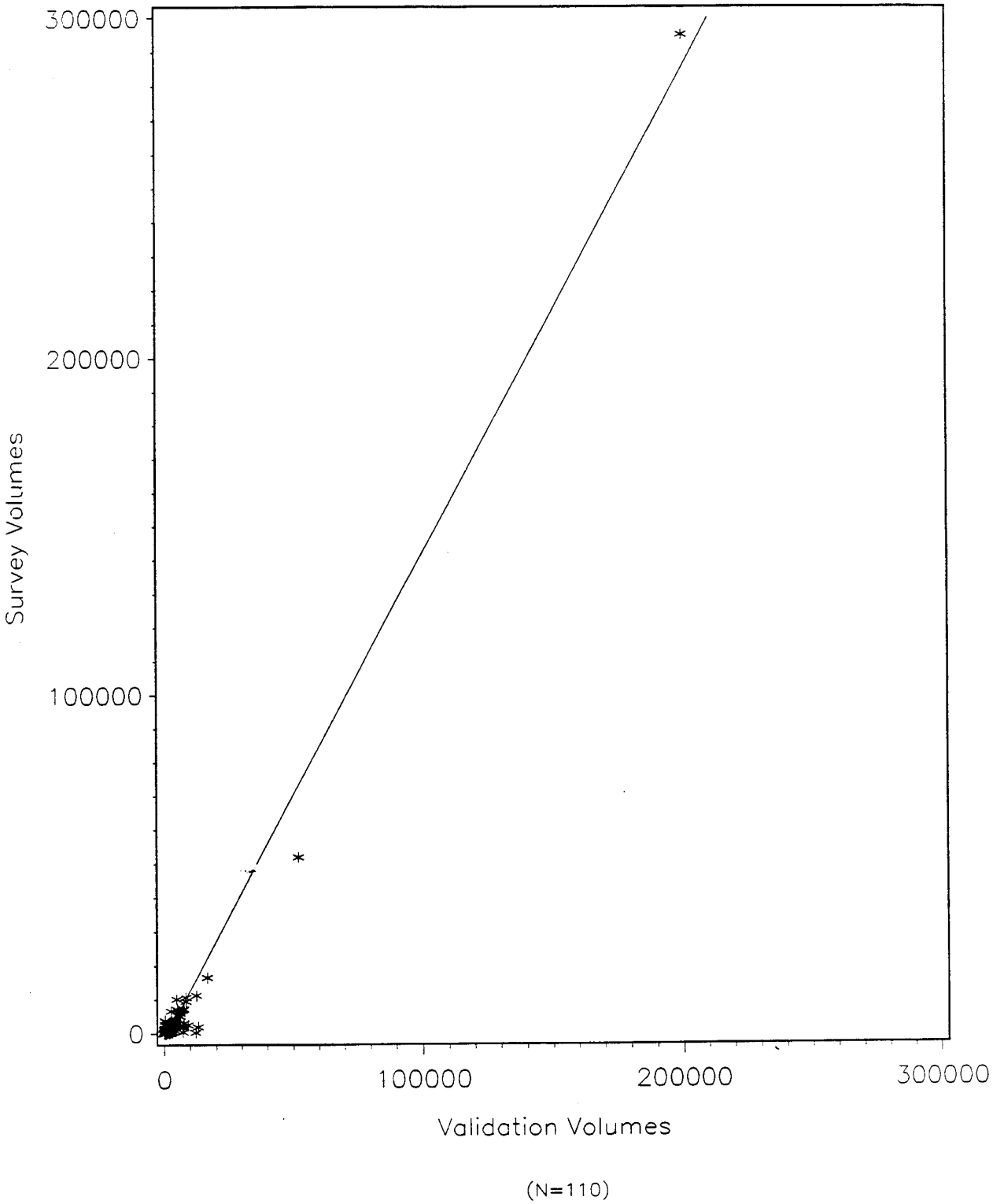

Figure 6-9. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the 110 Phase II validation locations

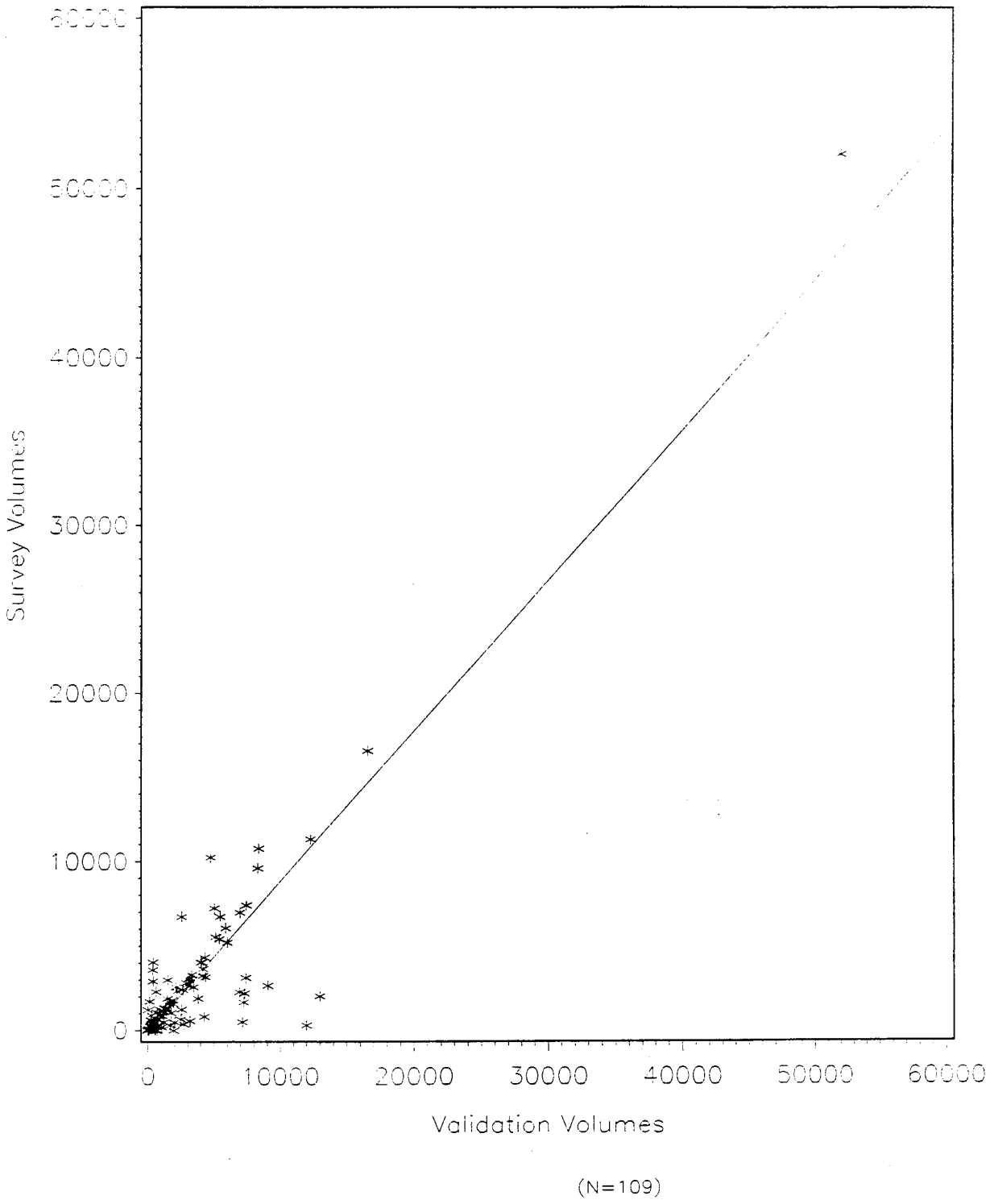

Figure 6-10. Scatter plot of total volume tabulated during original survey and validation survey at the Phase II validation locations with the largest laboratory removed

Phase II Adjustments to Data

No adjustments were made to the data obtained from the NICLTS Phase II telephone data collection effort.

Phase II Summary and Conclusions

In summary the Phase II validation study revealed consistent underreporting of mail/telephone compared to the on-site visit. This underreporting was, however, only about 10 percent, an amount well within sampling error. This degree of underreporting is even less significant when it is realized that it is for waived and PPM testing only, which represents only about 4 percent of the total estimated volume of tests (309 million of 7.25 billion).