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

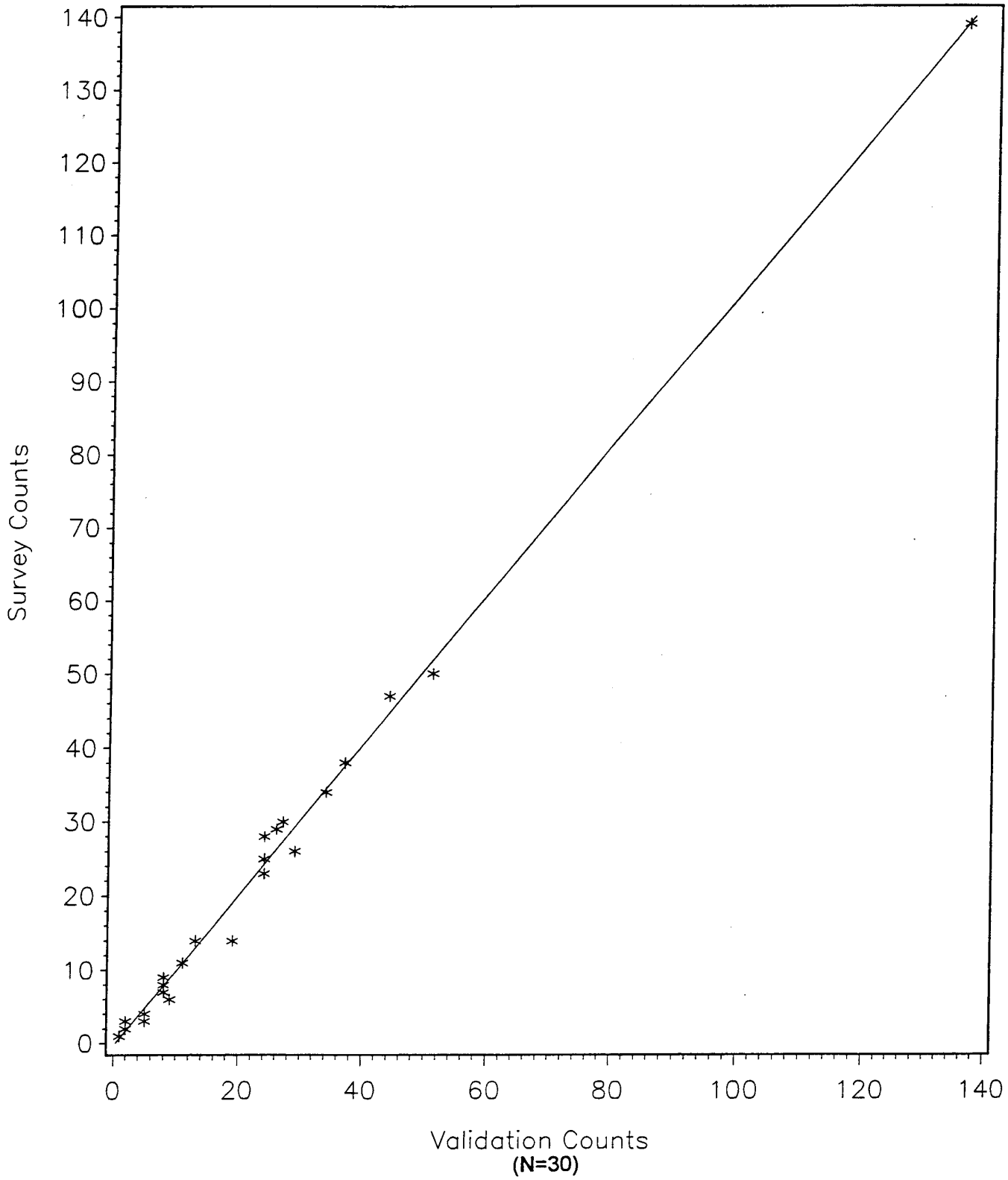

Figure 6-1. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the 30 Phase I validation locations

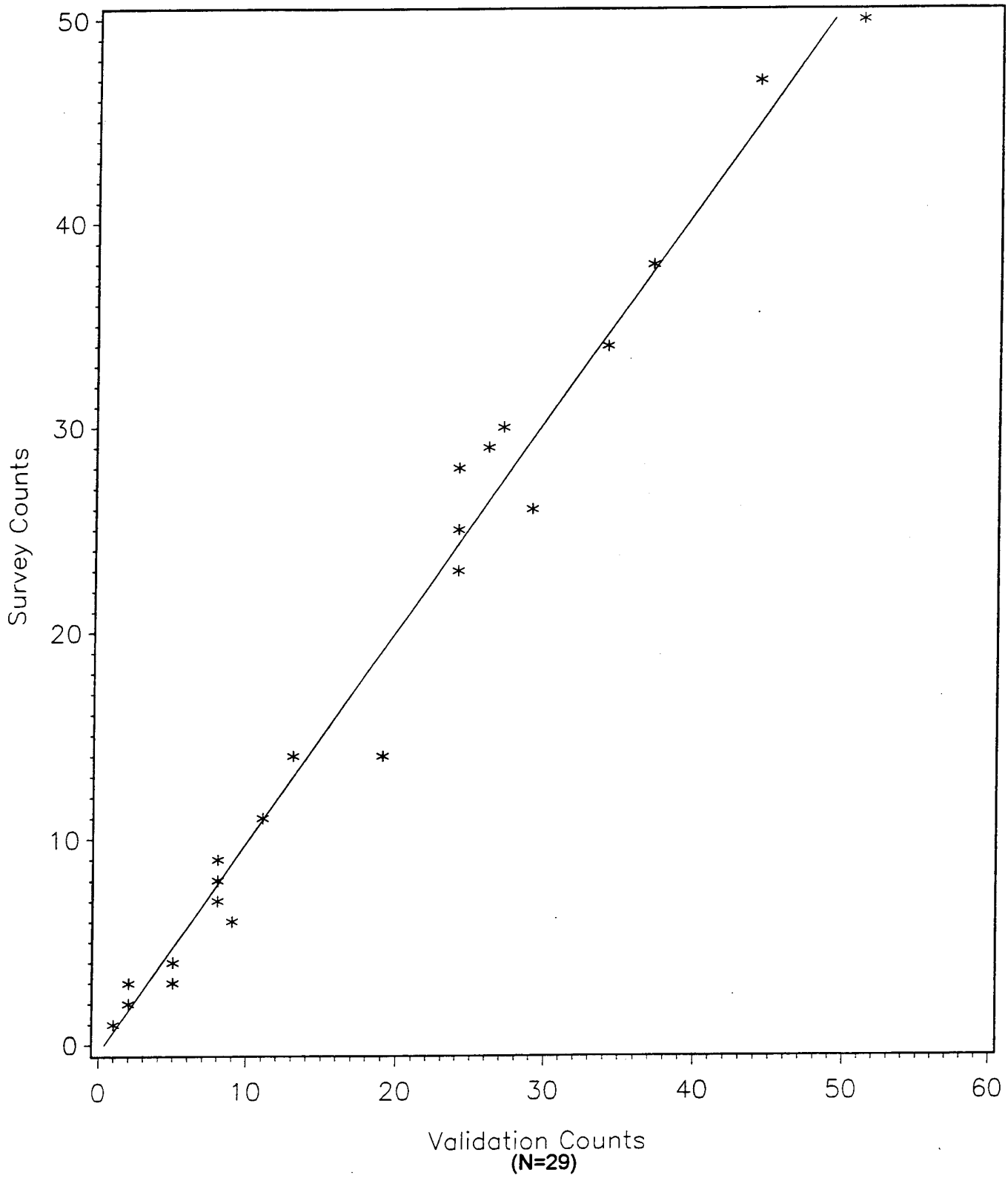

Figure 6-2. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the Phase I validation locations with largest laboratory removed

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.

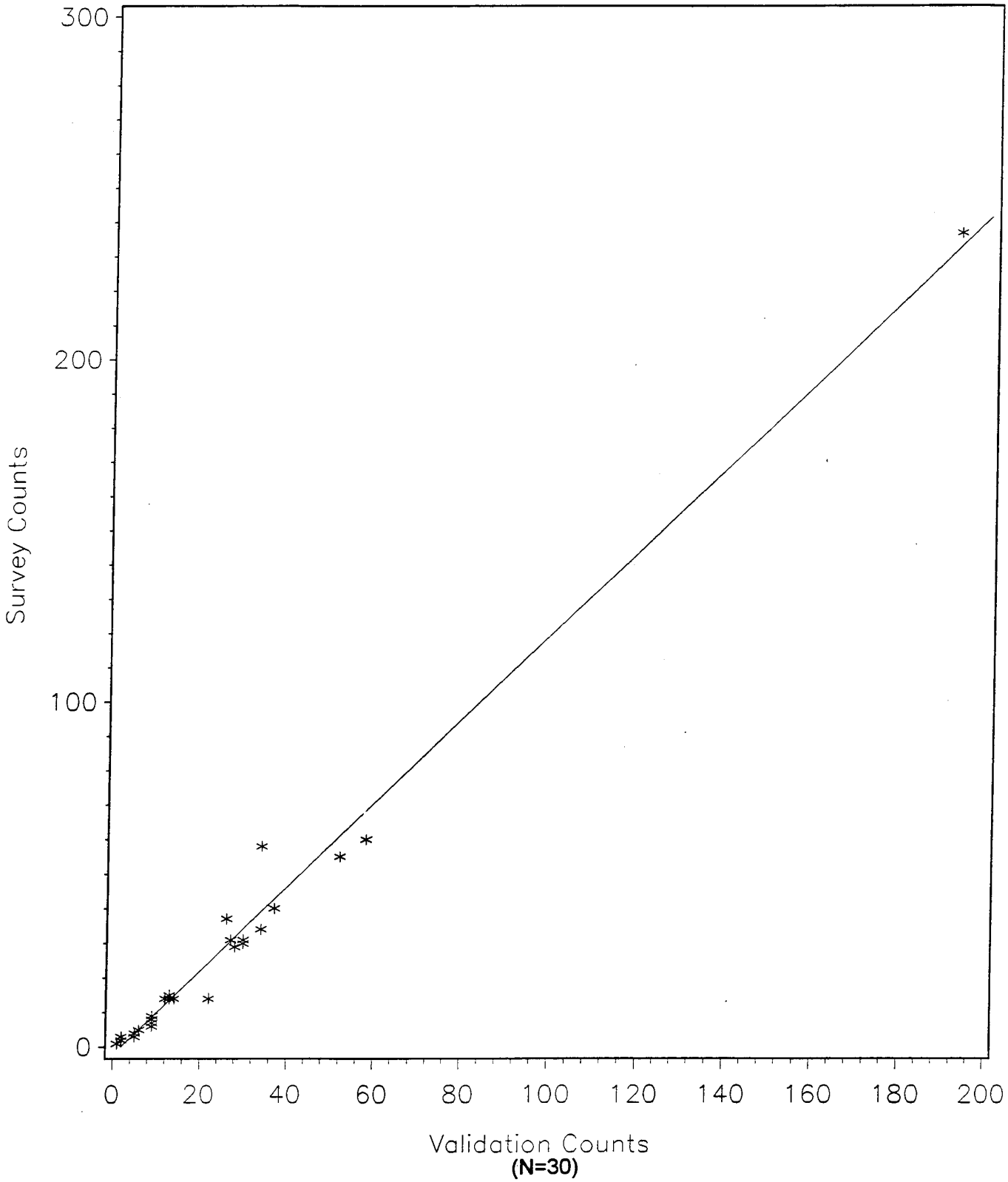

Figure 6-3. Scatter plot of distinct cluster counts tabulated during original survey and validation survey at the 30 Phase I validation locations

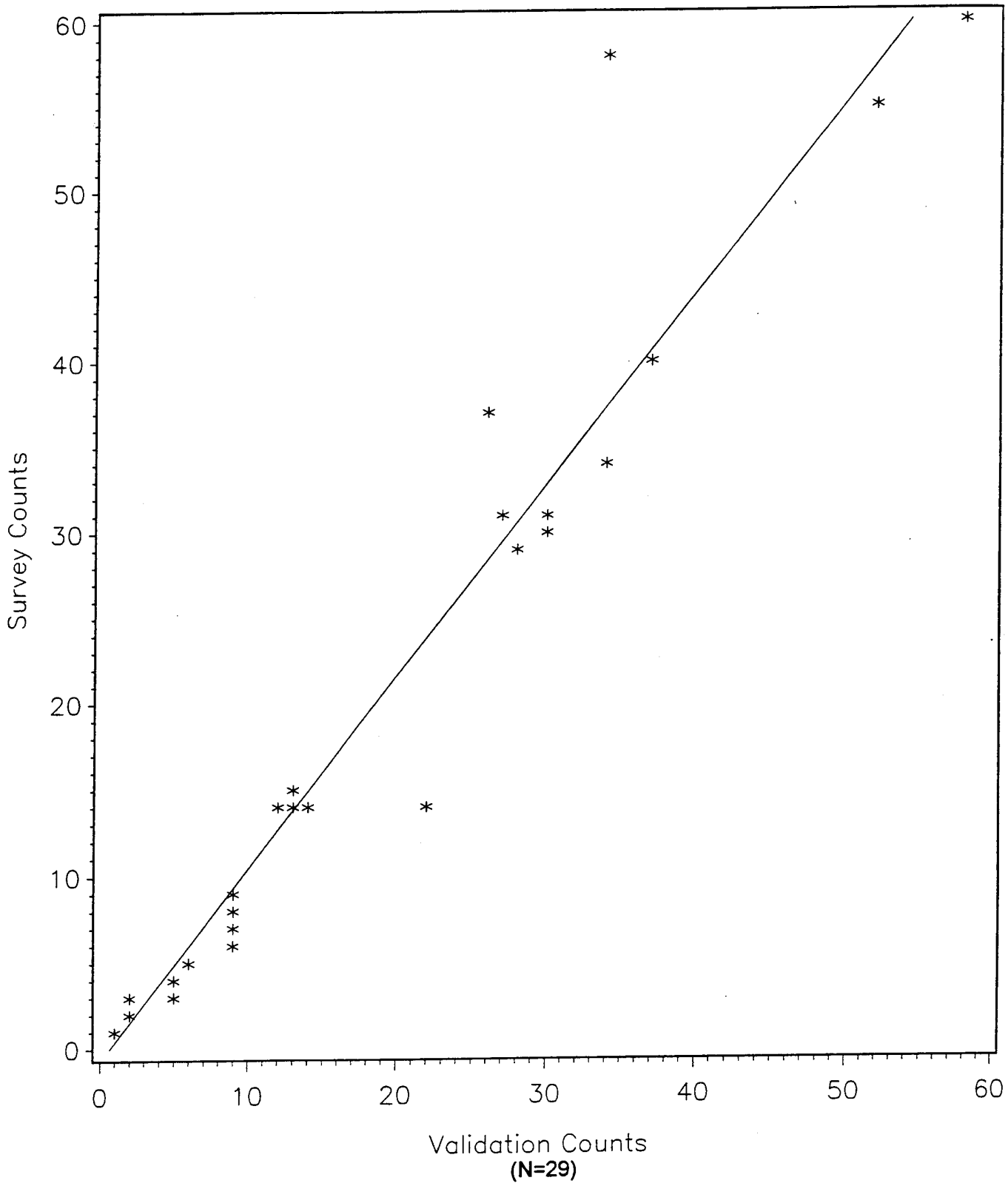

Figure 6-4. Scatter plot of distinct cluster counts tabulated during original survey and validation survey at the Phase I validation locations with largest laboratory removed

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

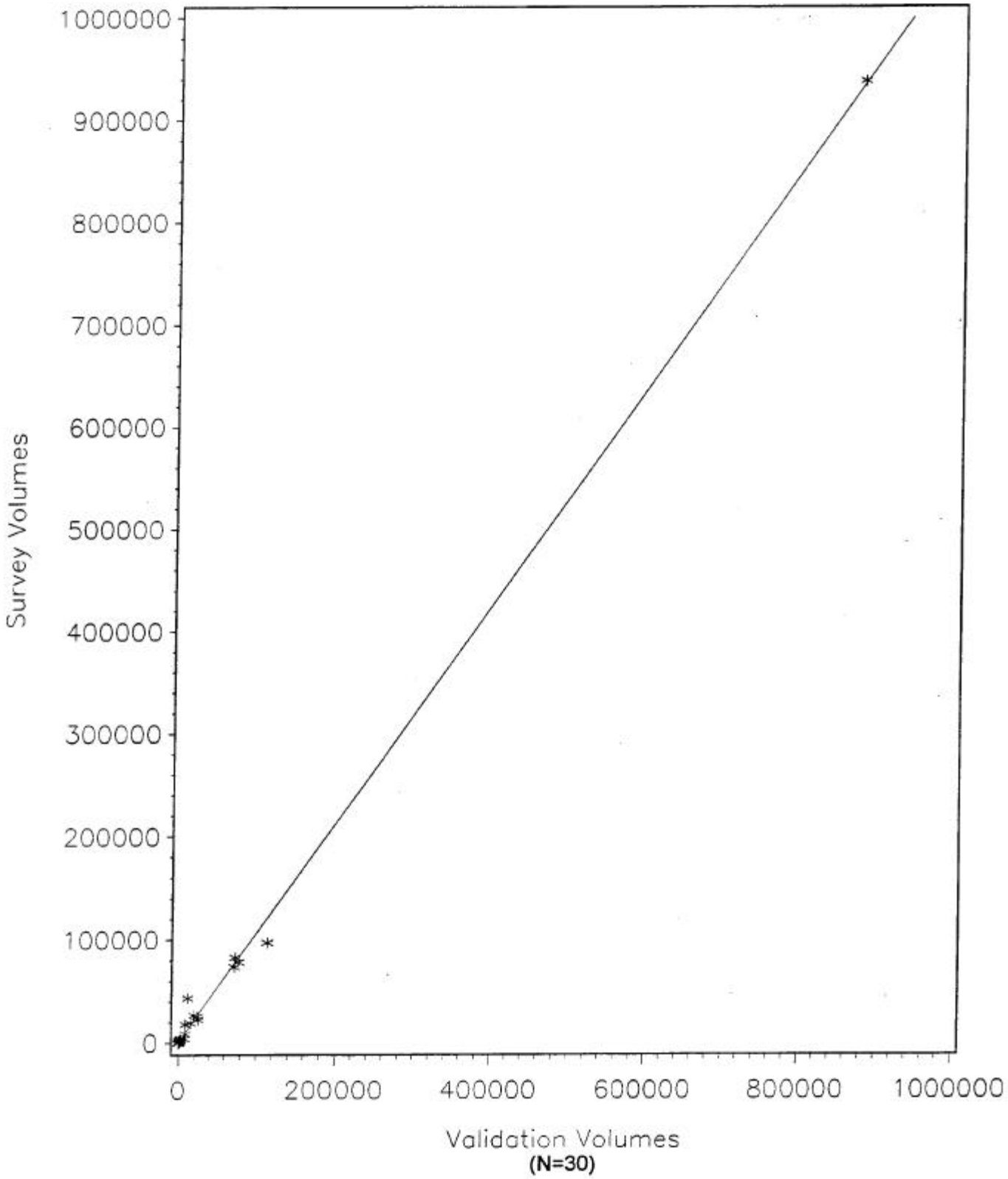

Figure 6-5. Scatter plot of total volumes tabulated during original survey and validation survey at the 30 Phase I validation locations

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.

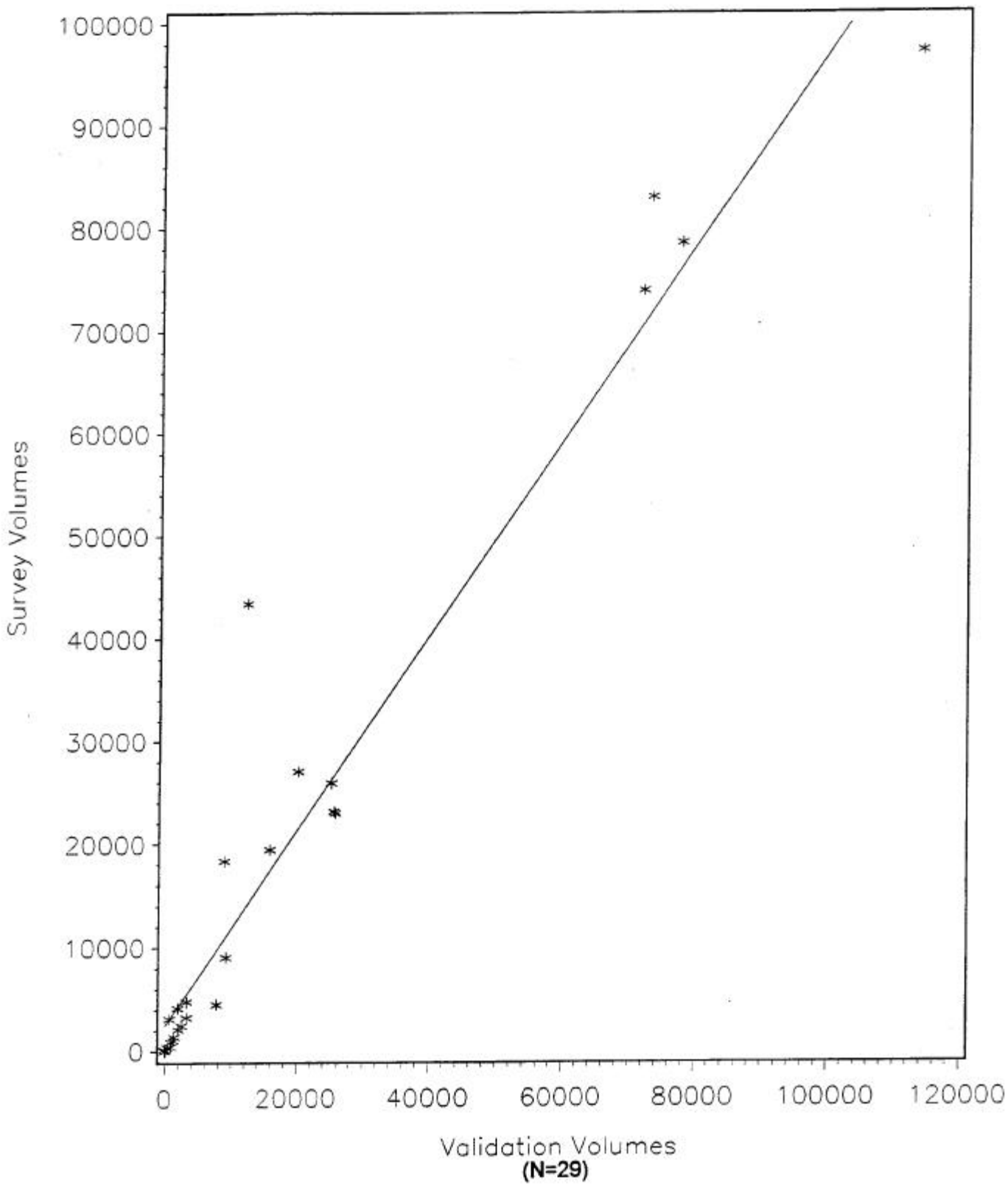

Figure 6-6. Scatter plot of total volumes tabulated during original survey and validation survey of the Phase I validation locations with largest laboratory removed

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 ($p = 0.019$).

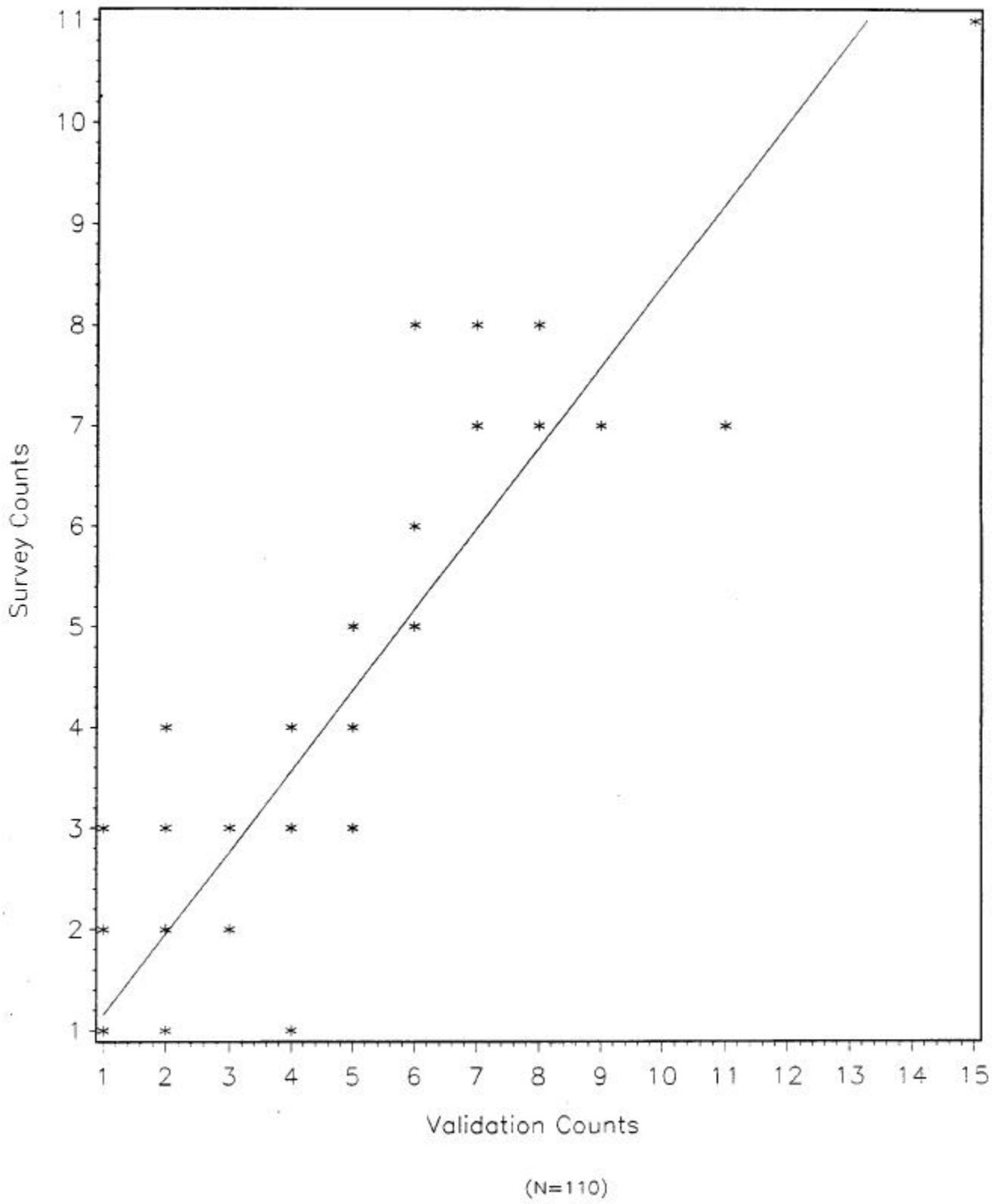

Figure 6-7. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the Phase II validation locations with largest laboratory removed

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.

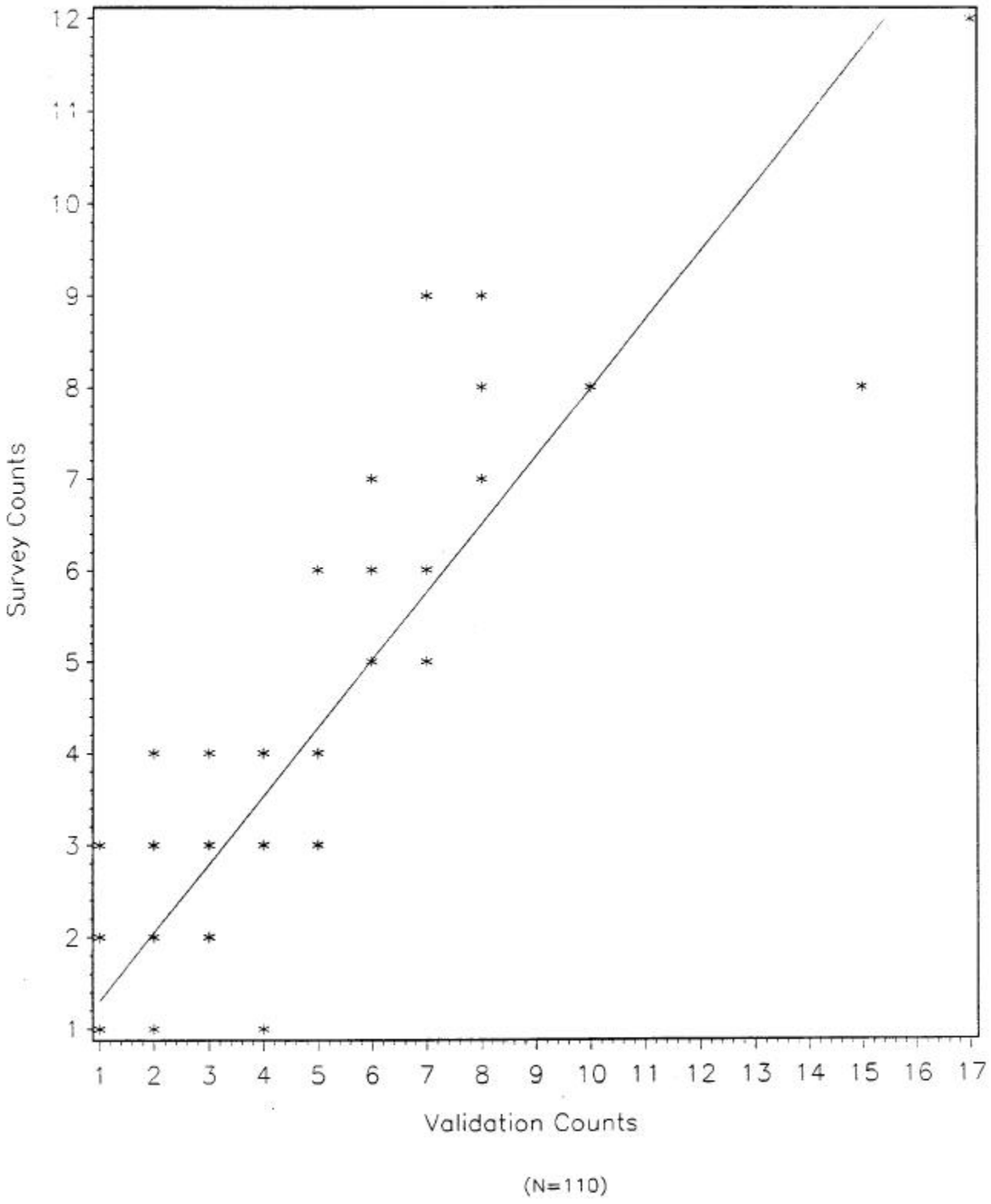

Figure 6-8. Scatter plot of distinct cluster counts tabulated during original survey and validation survey at the 110 Phase II validation locations

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

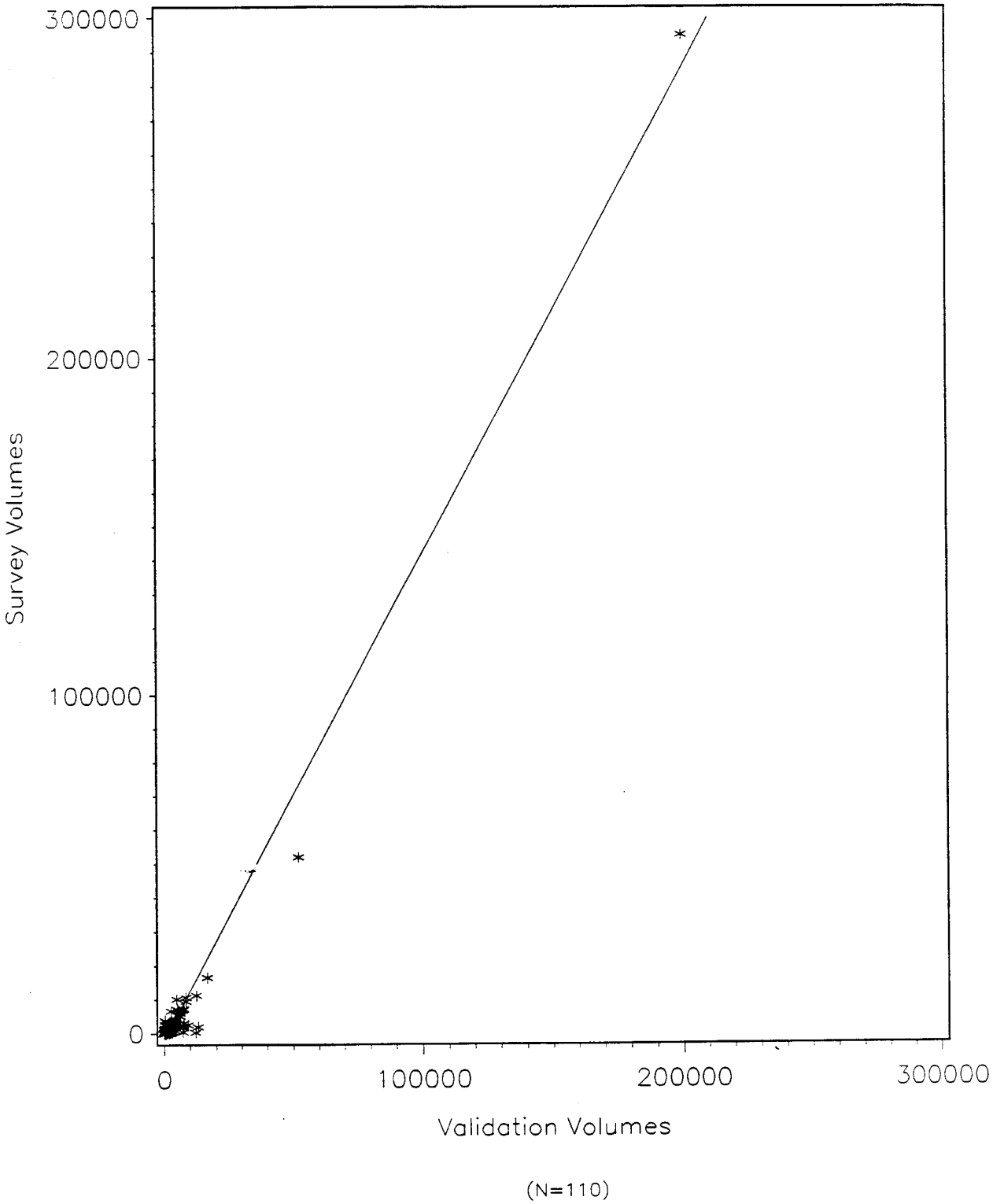

Figure 6-9. Scatter plot of distinct analyte counts tabulated during original survey and validation survey at the 110 Phase II validation locations

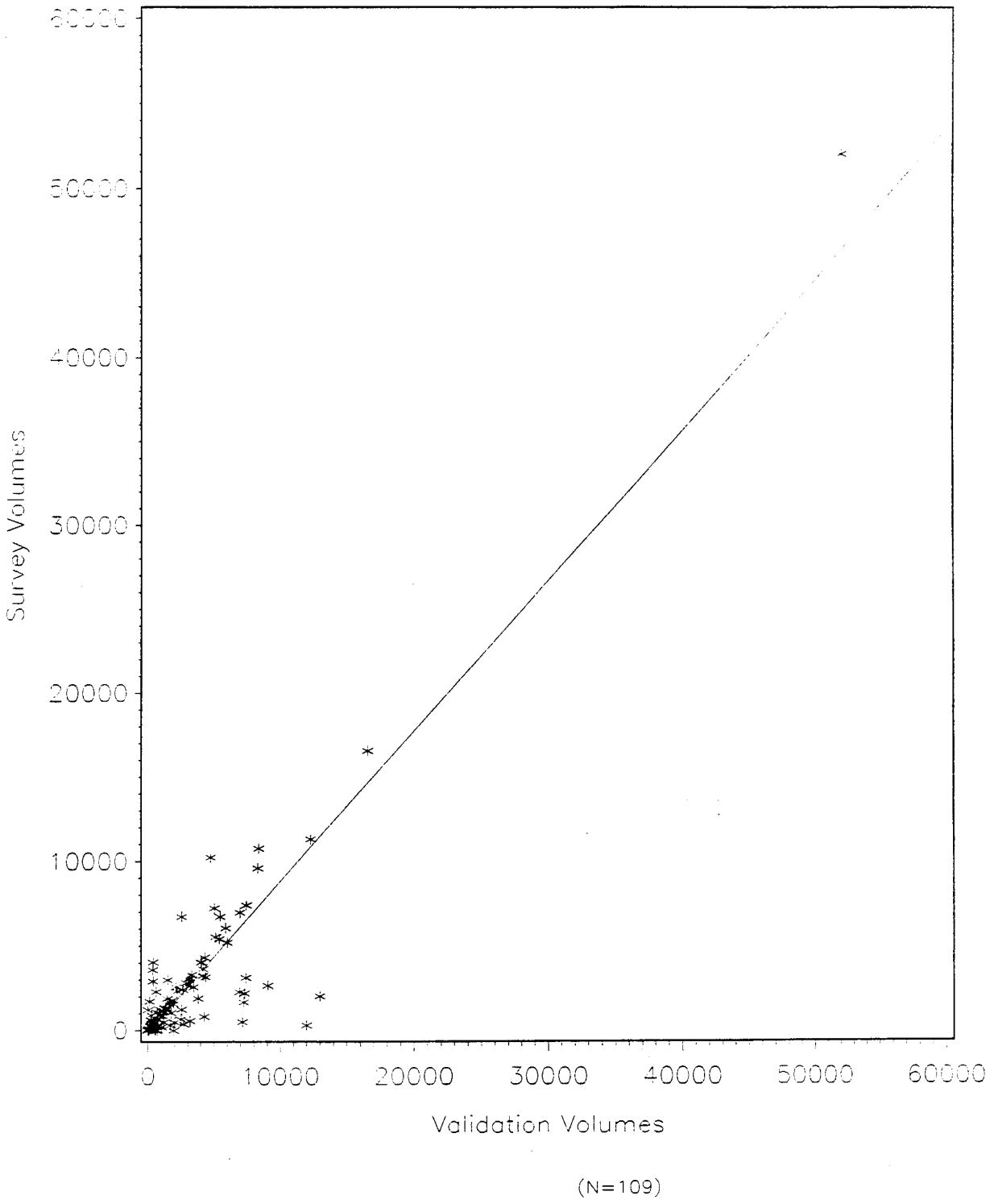

Figure 6-10. Scatter plot of total volume tabulated during original survey and validation survey at the Phase II validation locations with the largest laboratory removed

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).