Form Approved
OMB NO. 0938-0650

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) ALTERNATE QUALITY ASSESSMENT SURVEY

CLIA Identification Number____D_____

GENERAL INFORMATION: Please complete the following: *(Please Print or Type)*

Laboratory Name			Name of Director		
Laboratory Owner			Telephone Number (include area code)		
Laboratory Address (No., Street)			Mailing Address (No., Street) *(if different)*		
City	State	Zip Code	City	State	Zip Code
Type of CLIA Certificate Currently Held			Contact Person in Laboratory		

	Yes	No
Have any new testing sites been added under the current CLIA certificate since the last CLIA survey?	☐	☐

PLEASE UPDATE/COMPLETE THE ENCLOSED FORM CMS-209, LABORATORY PERSONNEL REPORT (CLIA). DOCUMENTATION TO SUPPORT THE QUALIFICATIONS FOR ANY NEW DIRECTOR, TECHNICAL SUPERVISOR/CONSULTANT OR CLINICAL CONSULTANT MUST BE RETURNED WITH THIS FORM.

1. a) Has your laboratory added any new test(s) since your last inspection? ☐ ☐

   b) If yes, please list test(s) that you have added.

TEST	MANUFACTURER'S KIT or EQUIPMENT USED
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

2. a) Has your laboratory made any changes in instruments or test methods since your last inspection? ☐ ☐

b) If yes, please list the changes you have made.

_____
_____
_____
_____
_____
_____

3. Put an X by each test that your laboratory currently performs. Indicate your current annual test volume (excluding waived, proficiency tests, quality control, calibration and calculated tests) for each group of tests represented within each box. Include testing in all test sites registered under the certificate listed above. Refer to Appendix B for guidance on how to determine test volumes.

Histocompatibility
_____ HLA Typing
_____ Other

ANNUAL VOLUME: _____

Syphilis Serology
_____ RPR
_____ FTA, MHA-TP
_____ Other

General Immunology
_____ Mononucleosis Assays
_____ Rheumatoid Arthritis
_____ Febrile Agglutinins
_____ Cold Agglutinins
_____ HIV
_____ Antibody Assays (hepatitis, herpes, etc.)
_____ Mycoplasma Pneumoniae Assays
_____ ANA Assays
_____ Other
_____
_____

ANNUAL VOLUME: _____

Bacteriology
_____ Gram Stains
_____ Cultures
_____ Sensitivities
_____ Strep Screens
_____ Antigen Assays (chlamydia, etc.)
_____ H. Pylori
_____ Other

Mycobacteriology
_____ Acid Fast Smears
_____ Mycobacterial Cultures
_____ Sensitivities
_____ Other

Mycology
_____ Fungal Cultures
_____ DTM
_____ KOH Preps
_____ Other

Parasitology
_____ Direct Preps
_____ Ova and Parasite Preps
_____ Wet Preps
_____ Other

Virology-List all procedures performed below (RSV, HPV assays, cell cultures):
_____
_____

ANNUAL VOLUME: _____

Chemistry□

Routine Chemistry

_____ Albumin
_____ Bilirubin, total
_____ Bilirubin, direct
_____ Calcium
_____ Chloride
_____ Cholesterol, total
_____ CO2, total
_____ Creatinine
_____ Glucose
_____ pH
_____ pO2
_____ pCO2
_____ Phosphorus
_____ Potassium
_____ Protein, total
_____ Sodium
_____ Triglycerides
_____ BUN
_____ Uric acid
_____ ALT/SGPT
_____ AST/SGOT
_____ Gamma GGT
_____ Alk phos
_____ Amylase
_____ CPK/CPK isoenzymes
_____ CKMB
_____ HDL Cholesterol
_____ Iron
_____ LDH
_____ LDH isoenzymes
_____ Magnesium
_____ Ferritin
_____ Folic acid
_____ Vitamin B12

Urinalysis

_____ Automated urinalysis
_____ Urinalysis with microscopic analysis
_____ Urine specific gravity by refractometer
_____ Urine specific gravity by urinometer
_____ Urine protein by sulfasalicylic acid
_____ Other

Endocrinology

_____ TSH
_____ Free T4
_____ Total T4
_____ Triiodothyronine (T3)
_____ T3 Uptake
_____ PSA
_____ Serum beta-HCG
_____ Cortisol
_____ Other

Toxicology

_____ Acetaminophen
_____ Blood alcohol
_____ Carbamazephine
_____ Digoxin
_____ Ethosuximide
_____ Gentamycin
_____ Lithium
_____ Phenobarbitol
_____ Phenytoin
_____ Primidone
_____ Procainamide
_____ NAPA
_____ Quinidine
_____ Salicylates
_____ Theophylline
_____ Tobramycin
_____ Valproic acid
_____ Other

ANNUAL VOLUME FOR ALL CHEMISTRY TESTS: _____

Hematology
_____ WBC count
_____ RBC count
_____ Hemoglobin
_____ Hematocrit (Other than spun micro)
_____ Platelet
_____ Differential
_____ MCV
_____ Activated clotting time
_____ Prothrombin time
_____ Partial thromboplastin time
_____ Fibrinogen
_____ Reticulocyte count
_____ Manual WBC by hemocytometer
_____ Manual platelet by hemocytometer
_____ Manual RBC by hemocytometer
_____ Sperm count
_____ Other
_____
_____
_____
_____

ANNUAL VOLUME: _____

Immunohematology
_____ ABO group
_____ Rh(D) type
_____ Antibody screen
_____ Antibody identification
_____ Compatibility testing
_____ Other
_____
_____
_____

ANNUAL VOLUME: _____

Pathology
_____ Dermatopathology
_____ Oral pathology
_____ PAP smear interpretations
_____ Other cytology tests
_____ Histopathology
_____ Other
_____

ANNUAL VOLUME: _____

Radiobioassay
_____ Red cell volume
_____ Schilling's test
_____ Other

ANNUAL VOLUME: _____

Cytogenetics
_____ Fragile X
_____ Buccal smear
_____ Other

ANNUAL VOLUME: _____

TOTAL ANNUAL VOLUME FOR ALL TESTING PERFORMED: _____

LABORATORY ASSESSMENT:	**Yes**	**No**
PATIENT TEST MANAGEMENT		
4. Does your laboratory—		
a) review policies and procedures for specimen collection, labeling, preservation, and handling for completeness and accuracy?	☐	☐
b) verify that these policies are available and followed?	☐	☐
5. Does your laboratory—		
a) evaluate specimen processing for accuracy (e.g., specimen identification, tests ordered, correct specimen type), appropriate handling, and storage?	☐	☐

	Yes	No	N/A
b) review specimen rejection criteria and procedures for actions to be taken if criteria are met?	☐	☐	
c) investigate the cause of the specimen rejection or other specimen processing problems and take action to prevent recurrences?	☐	☐	
6. Does your laboratory review a number of test requisitions or patient medical charts to ensure—			
a) completeness relevant to the testing performed and information requested?	☐	☐	
b) information on the requisitions has been accurately transferred to the test report? (if a separate test requisition is used)	☐	☐	
c) tests ordered were performed?	☐	☐	
d) test results were reported to the authorized person?	☐	☐	
7. Does your laboratory review—			
a) a number of test reports or medical charts to ensure that test results from worksheets, instrument printouts or electronic transmissions were accurately reported?	☐	☐	
b) its reporting system to ensure that panic values have been promptly brought to the attention of the authorized person?	☐	☐	
8. Does your laboratory's process for reporting results include a mechanism to—			
a) detect and document reporting errors?	☐	☐	
b) prevent recurrences of reporting errors?	☐	☐	
c) ensure that corrected reports are issued, documented and maintained?			
9. Does your laboratory maintain and have the capability to retrieve—			
a) patient test results or reports?	☐	☐	
b) requisitions or test orders?	☐	☐	
c) instrument printouts, work records, etc.?	☐	☐	
d) quality control records, instrument maintenance records, corrective actions records?	☐	☐	

NOTE: ***A patient chart or medical record may meet the requirements for test requisition, test record and test report***.□

10. Does your laboratory maintain records for a minimum of—			
a) 2 years for test requisitions, worksheets, quality control and patient test reports?	☐	☐	
b) 5 years for immunohematology (blood bank) records, quality control records and reports?	☐	☐	

	Yes	No	N/A
c) 10 years for pathology reports?	☐	☐	
11. Does your laboratory's specimen processing system allow your laboratory to track a specimen from collection to test reporting?	☐	☐	

QUALITY CONTROL (QC)

12. Are current written procedures available for each test the laboratory performs to ensure accurate and reliable test results including quality control, preventative maintenance, calibrations (if applicable), normal values and test reporting?	☐	☐	

NOTE: ***Manufacturers' package inserts are sufficient if the instructions meet CLIA's requirements for frequency, number and type of control material and, when applicable, they are supplemented with specific instructions reflecting laboratory practice and are approved by the current laboratory director***.

13. Are all of your laboratory procedures current and approved by the present laboratory director?	☐	☐	
14. Are all test modifications in practice in your laboratory included in the written test procedure and approved by the laboratory director?	☐	☐	
15. For new tests or test systems added since the last CLIA survey, did your laboratory verify—			
a) the accuracy of the method?	☐	☐	☐
b) that the method met the manufacturer's performance specifications?	☐	☐	☐
16. Does your laboratory follow manufacturers' instructions regarding operation, maintenance and test performance for instruments or test systems?	☐	☐	
17. a) Does your laboratory routinely review a sample of records for all instruments requiring calibration to ensure that calibration and/or calibration verification is performed at least every 6 months?	☐	☐	
b) Are calibrations performed in accordance with manufacturers' recommendations and/or in accordance with the laboratory's QC policies?	☐	☐	
c) If calibration fails, does the laboratory follow its policy for corrective action and document it?	☐	☐	
18. Does your laboratory review a sample of tests performed to ensure that—			
a) controls are run at the appropriate level and frequency as specified in the CLIA regulations?	☐	☐	

	Yes	No	N/A
b) controls are within the acceptable range and met your criteria for acceptability?	☐	☐	
19. Does your laboratory ensure that—			
a) patient results are not reported when QC values fail to meet your criteria for acceptability?	☐	☐	
b) your remedial and corrective action policies and procedures are followed?	☐	☐	
c) your review of remedial and corrective actions are documented?	☐	☐	
d) any ineffective policies and procedures are revised and approved by the laboratory director?	☐	☐	

PROFICIENCY TESTING (PT)

20. Is your laboratory continually enrolled in a CMS approved proficiency testing (PT) program(s), and performing PT for all regulated analytes tested in your laboratory? [see Appendix — for list of regulated PT analytes under CLIA]	☐	☐	
21. Are PT samples tested in the same manner as patient samples, for example—			
a) the same number of times?	☐	☐	
b) using personnel who routinely perform testing?	☐	☐	
c) using the laboratory's routine procedure for testing?	☐	☐	
d) with routine workload?	☐	☐	
22. In the past 2 years has your laboratory received a report of less than 100% for any PT results?	☐	☐	
a) If yes, does your laboratory have a plan that includes a mechanism to conduct and document an investigation identifying the cause?	☐	☐	☐
b) If yes, did your laboratory take and document corrective action(s) to avoid recurrence?	☐	☐	☐

Please submit a copy of your laboratory's corrective action for a PT event in which your laboratory did not receive 100%.

23. Does your laboratory review patient testing performed at the time of the PT testing event to determine any negative impact such testing errors had on the accuracy of patient testing?	☐	☐	
a) Is corrective action taken?	☐	☐	

COMPARISON OF TEST RESULTS	Yes	No	N/A
24. a) If your laboratory performs the same test by more than one method or instrument, is there a system that, twice a year, compares test results between the instruments or methods?	☐	☐	
b) For tests where PT is not required or is not available, does your laboratory have a mechanism to verify and document, at least twice a year, that test results are accurate?	☐	☐	
RELATIONSHIP OF PATIENT INFORMATION TO TEST RESULTS			
25. Does your laboratory have a mechanism to identify and evaluate patient test results that appear inconsistent with known patient data?	☐	☐	
PERSONNEL ASSESSMENT			
26. Does your laboratory monitor and document employee competence, at least annually, for the tasks they perform?	☐	☐	
27. Does your laboratory ensure that testing personnel have a working knowledge of and can perform new tasks required to obtain accurate and reliable test results?	☐	☐	
COMMUNICATIONS AND COMPLAINT INVESTIGATIONS			
28. Does your laboratory have a system in place to monitor, document and resolve communication problems and complaints? (e.g., incorrect test(s) performed, patient name, test results, unacceptable specimens, etc.)	☐	☐	
29. Does your laboratory have a system to monitor and document problems that may occur with the reference laboratory used, including specimen handling, test results and reporting?	☐	☐	☐
30. Does your laboratory investigate complaints to determine the cause, take timely actions to remedy the problem and notify the appropriate people?	☐	☐	
QUALITY ASSURANCE (QA)			
31. Does your laboratory—			
a) have a mechanism to assess the findings of all quality assurance activities?	☐	☐	
b) document problems identified and corrective actions taken during QA activities?	☐	☐	
c) document communication of QA findings with staff (i.e., via memos, meeting agendas, meeting minutes, newsletters)?	☐	☐	
d) assess whether the corrective actions taken to prevent recurrences are effective?	☐	☐	

	Yes	No
32. Are all QA records maintained for a minimum of 2 years?	☐	☐

PLEASE NOTE:

42 CFR 493.51

Laboratories issued a certificate of compliance must meet the following regulatory conditions:

(a) Notify HHS or its designee within 30 days of any changes in (1) ownership (2) name (3) location (4) director or (5) technical supervisor.

(b) Notify HHS no later than 6 months after instituting any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty for which the laboratory has been issued a certificate of compliance.

ATTESTATION:

I attest that I (or my designee) have truthfully completed and/or verify that this Alternate Quality Assessment Survey accurately reflects the current operations of this laboratory.

_____ _____

Signature of Laboratory Director *(sign in ink please)* Date

Thank you for completing this form. We suggest that you make a copy of your submission for your records.

Comments:_____

AQAS CHECKLIST

PLEASE RETURN THE FOLLOWING MATERIALS IN ONE ENVELOPE TO THE STATE AGENCY (see cover letter for address) WITHIN 15 DAYS OF RECEIPT:

____ THE COMPLETED, SIGNED AND DATED ALTERNATE QUALITY ASSESSMENT SURVEY (AQAS) FORM.

____ PERSONNEL QUALIFICATIONS: Please submit a **copy** of the documentation demonstrating the qualifications of any new director, technical supervisor or clinical consultant WITH THE FORM CMS-209, Laboratory Personnel Report (CLIA).

____ PT-RELATED CORRECTIVE ACTION(S): Please submit a copy of the laboratory's corrective action(s) as requested under question number 22.

____ ATTESTATION: The AQAS form must be signed and dated by the laboratory director. (Page 9 of the AQAS)

Appendix A

PROFICIENCY TESTING (PT)

If you are performing testing for any of the analytes or tests listed below, you must be enrolled in PT for those analytes or tests:

Hematology:
Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin (excluding HemaCue)
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

Diagnostic Immunology
General Immunology
Alpha-1-antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella
Syphilis Serology
Qualitative or quantitative

Chemistry
Routine Chemistry (serum, plasma or blood)
Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose (excluding measurements on devices cleared by FDA specifically for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

Chemistry
Endocrinology (serum, plasma, blood or urine)
Cortisol
Free Thyroxine
Human chorionic gonadotropin (excluding color comparison tests for urine specimens)
T3 Uptake
Triiodothyronine
Thyroid Stimulating Hormone
Thyroxine

Chemistry
Toxicology
Alcohol (blood)
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide (and metabolites)
Quinidine
Theophylline
Tobramycin
Valproic Acid

Immunohematology:
ABO group (excluding subgroups)
D(Rho) typing
Unexpected antibody detection
Compatibility testing
Antibody identification

Microbiology:
Bacteriology
Mycobacteriology
Mycology
Parasitology
Virology

Note: You must be enrolled in PT for the full extent of testing being performed (e.g., gram stain, acid fast stain, direct antigen testing, isolation, identification and susceptibility)

Appendix B

GUIDELINES FOR COUNTING TESTS

- For histocompatibility, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.

- For microbiology, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.

- Testing for allergens should be counted as one test per individual allergen.

- For chemistry profiles, each individual analyte is counted separately.

- For urinalysis, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

- For complete blood counts, each **measured** individual analyte that is ordered **and reported** is counted separately. Differentials are counted as one test.

- Do not count calculations (i.e., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays.

- For immunohematology each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.

- For histopathology, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.

- For cytology, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.

- For cytogenetics, the number of tests is determined by the number of specimen types processed on each patient; i.e., a bone marrow and a venous blood specimen received on one patient is counted as two tests.