Preparing Authority: Carlyn Mathews	**R602 - Conditions for Accreditation for Clinical Testing Laboratories Meeting the CLIA Requirements**	**Publication Date:**

LABORATORY NAME: _____

MASTER ID: _____ CERT NO(s): _____

In order to attain and maintain CLIA accreditation, clinical laboratories must comply with the Conditions for Accreditation published by A2LA, as noted below.

The Laboratory's Director, must agree to the conditions for accreditation and must attest that all statements made on the application are correct to the best of his/her knowledge and belief. An accredited Laboratory's Director is responsible for ensuring that all of the relevant conditions for accreditation are met. During the on-site assessment, the assessor will determine that the Laboratory Director and laboratory management team are knowledgeable about the accreditation requirements and that those requirements will be upheld.

Note: For clinical laboratories, the Authorized Representative is the Laboratory Director, without exceptions. Please note the phrase "Authorized Representative" is interchangeable with "Laboratory Director".

The Conditions for Accreditation include:

1. Afford reasonable accommodation, cooperation, and assistance as is necessary to enable A2LA to verify compliance with the requirements for accreditation including provision for examination of documentation (including documents that provide insight into the level of independence of the applicant from any other related activities undertaken by their laboratory, where applicable) and access to all testing areas, equipment, records and personnel for the purposes of assessment, reassessment, investigation and resolution of complaints;

2. Comply at all times with the criteria, requirements, including R601 - General Requirements: Accreditation for Clinical Testing Laboratories Meeting the CLIA Requirements, and conditions for accreditation; including participation in proficiency testing as required by national, regional, or local regulations. Please see R603 – General Requirements: Proficiency Testing for Clinical Testing Laboratories Meeting the CLIA Requirements for further information regarding these proficiency testing requirements;

3. All such records and information must be provided to A2LA or to national, regional, or local regulators upon request;

4. Comply with 42 CFR 493 and USPHS Section 353 by:

    - Obtaining from the Centers for Medicare and Medicaid Services (CMS), a certificate of accreditation or registration (as appropriate), pay required certificate, accreditation, and validation fees;
    - Authorizing A2LA to release to CMS any correspondence including a copy of the laboratory's assessment records and actions taken by A2LA;
    - Releasing to CMS all records and information required by CMS, or appropriate state authorities;
    - Authorizing A2LA to, upon appropriate written request, release any relevant information to a public requestor, as required by United States Public Health Service Act, Section 353;

- Affirming that the laboratory owner or operator has not owned or operated a laboratory that had its CLIA certificate revoked within the preceding two-year period;

5. Comply with the basic inspection requirements of 42 CFR 493.1773 and allow CMS or A2LA to conduct validation or complaint inspections at any time during its hours of operations as cited in 42 CFR 493.1773(a) and 1780. As part of the inspection process, CMS or A2LA may require the clinical laboratory to do the following:

   - Test samples, including proficiency testing samples, or perform procedures;
   - Permit interviews of all personnel concerning the laboratory's compliance with the applicable inspection requirements of 42 CFR 493;
   - Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic);
   - Permit CMS access to all areas encompassed under the certificate, including but not limited to, the following:
     - Specimen procurement and processing areas;
     - Storage facilities for specimens, reagents, supplies, records, and reports;
     - Testing and reporting areas;
   - Provide CMS or A2LA with copies or exact duplicates of all records and data it requires;
   - A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection;
   - A laboratory must provide, upon request, all information and data needed by CMS or A2LA to make a determination of the laboratory's compliance with the inspection requirements of 42 CFR 493;
   - CMS or A2LA may re-inspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable results;
   - CMS or A2LA may conduct an inspection when there are complaints alleging noncompliance with any requirements of 42 CFR 493;
   - Failure to permit CMS to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of 42 CFR 493;
   - If a validation or complaint inspection results in any deficiencies, an A2LA accredited laboratory is subject to full review and possible follow up by CMS or A2LA;
   - If the laboratory possesses a valid certificate of accreditation, CMS or A2LA shall be authorized to monitor the correction of any deficiencies found through the validation inspection;

6. Retain and have readily available, all quality and technical records supporting reported results throughout the period between A2LA on-site assessments, and in compliance with the guidelines set forth in 42 CFR 493 and A2LA Policy P604- CLIA Program Policy for Record and Material Retention, and bearing in mind that adequate records (e.g., testing, quality control/calibration, proficiency testing, complaint records, etc.) must be available to demonstrate full compliance with the requirements for accreditation (Note: local, regional and state requirements may apply);

7. Maintain impartiality and integrity;

8. Claim that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

9. Pay such fees as established by A2LA by the due date identified on the invoice (Note: Any taxes levied by the applicant's taxing authority are to be paid by the applicant in addition to the amounts billed by A2LA for services and expenses);

10. Not use its accreditation in such a manner as to bring A2LA into disrepute and not make any statement relevant to its accreditation, which A2LA may consider misleading or unauthorized;

11. Upon suspension, withdrawal, or expiration of its accreditation (however determined) discontinue its use of all advertising matter that contains reference thereto, return any certificates and scopes of accreditation to A2LA;

12. Not use its accreditation to imply product approval by A2LA;

13. Endeavor to ensure that no report, nor any part thereof, is used in a misleading manner;

14. In making reference to its accreditation status in communication media such as advertising (R105 – Requirements When Making Reference to A2LA Accredited Status), brochures or other documents, comply with the requirements of A2LA;

15. Inform A2LA headquarters and CMS within 30 days and in writing of changes or pending changes in any aspect of the laboratory's status or operation that affects the laboratory's legal, commercial or organizational status; ownership, organization or management (e.g., managerial staff or directorship); policies or procedures, where appropriate; premises or location; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation;

16. Carry out any adjustments to its procedures in response to due notice (by A2LA newsletter, website or email) of any intended changes by A2LA to the criteria, requirements, or conditions for accreditation, in such time as in the opinion of A2LA is reasonable;

17. Comply with 42 CFR 493.61(a)(1)-(2) by committing to these Conditions for Accreditation;

18. Notify A2LA not later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation so that the A2LA can determine compliance and a new certificate of accreditation can be issued;

19. Notify A2LA not later than 6 months following any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation;

20. Notify A2LA within 2 business days of any sanctions taken against the laboratory by CMS, the Regional Office or the State Agency, as well as any adverse media attention involving the laboratory; and

21. Once accredited, post in a prominent place within the laboratory a copy of the A2LA G603 – CLIA Program Whistleblower Poster.

Indemnity and Limitation of Liability:

The Applicant agrees to hold harmless and indemnify A2LA against any and all claims, liabilities, suits, losses, damages, and actions arising directly or indirectly out of the Applicant/accredited organization's application to or accreditation by A2LA, as well as any actual or alleged breach of these Conditions for Accreditation by Applicant including without limitation, costs and expenses (including but not limited to attorneys' fees), judgments, fines, settlements and any other amounts actually and reasonably incurred by A2LA in connection therewith. The above indemnification does not include indemnification of A2LA against a claim caused by the gross negligence or fault of A2LA, its agent or employee, or any third party under the control or supervision of or acting in concert with A2LA, other than the Applicant/accredited organization or its agent, employee or subcontractor.

The Applicant further acknowledges that A2LA and its representatives do not warrant the services provided and have no liability or responsibility for any loss or damage arising out of or relating to its accreditation services, except if such loss or damage results from gross negligence by A2LA.

In order to apply, the Applicant's AUTHORIZED REPRESENTATIVE must agree to the above conditions for accreditation and statements of indemnity and limitation of liability and must attest that all statements made on the application are correct to the best of his/her knowledge and belief. An accredited organization's AUTHORIZED REPRESENTATIVE is an official who represents the organization in all matters related to maintaining A2LA accreditation. This official is A2LA's primary point of contact with the organization. An Accredited Organization's Authorized Representative shall have binding authority to ensure that the Applicant complies with the A2LA criteria. Furthermore, this representative is responsible for ensuring that all of the relevant conditions for accreditation are maintained. The Applicant shall be held liable and responsible for any breach of these Conditions for Accreditation or any acts or omission, including but not limited to, negligence by the Authorized Representative or any other employee, agent or independent contractor of the Applicant.

As the organization's AUTHORIZED REPRESENTATIVE, I agree to the above conditions for accreditation. I attest that all statements made on this application are correct to the best of my knowledge and belief.

_____	_____	_____
AUTHORIZED REP. NAME (PRINTED)	AUTHORIZED REP. SIGNATURE	DATE

DOCUMENT REVISION HISTORY

Date	Description
03/07/20	➢ Integrated into Qualtrax ➢ Updated Header/Footer to current version ➢ Updated format and font for consistency ➢ Added Qualtrax hyperlinks
05/07/21	➢ Added Qualtrax hyperlinks ➢ Minor editorial and grammatic changes ➢ Updated document to align with relevant sections of R102 ➢ Added clarification that laboratory directors are the authorized representative ➢ Updated condition 5 ➢ Removed signature block and added signature lines ➢ Update "medical" to "clinical" ➢ Updated part 4, bullet 1