R901 - General Requirements:
Accreditation of
Clinical Testing Laboratories
Meeting the
ISO 15189 Requirements

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PART A
INTRODUCTION

The AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA) is a non-profit, non-governmental, public service, membership organization dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Accreditation is defined as a formal recognition of competence that a laboratory can perform specific tests or types of tests. Accreditation is available for many types of testing laboratories, both in the private sector (independent or in-house) and in the government sector.

A2LA was formed in 1978, as a practical and efficient organization to develop and manage a system to verify and recognize competent laboratories.

Under the Clinical Testing Laboratory program A2LA provides a meaningful accreditation process that combines the Quality Management strengths of the ISO 15189 Standard, Section 4 with the technical detail of Section 5 of ISO 15189. A2LA provides accreditation to any clinical laboratory performing non-waived testing (as defined in CLIA). Laboratories that provide only waived or Provider Performed Microscopy (PPM) are not eligible for accreditation through A2LA. If the laboratory does perform non-waived testing along with waived testing and/or PPM, A2LA will accredit for all of this testing and microscopy.

This integration of standards and regulations forms a complete framework for a laboratory to plan and operate a clinical testing laboratory with an effective Management System (MS) that has strong elements of Quality Assurance, Quality Control and Quality Improvement. When clinical testing laboratories effectively implement this MS they have continuous assurance that they are meeting their customers’ needs and expectations for consistent, accurate and timely test results.

The A2LA clinical testing accreditation program, as described in Part B of this document, ensures the competence and reliability of clinical testing laboratories:

- To protect all individuals served by laboratories against substandard testing of specimens;
- To safeguard the general public against health and safety hazards that might result from laboratory activities; and
- To motivate laboratories to comply with these accreditation requirements so that they can provide accurate and reliable test results.

The A2LA program offers accreditation in the following Specialties and Subspecialties:

- Histocompatibility
- Microbiology
  - Bacteriology
  - Mycobacteriology
  - Mycology
  - Parasitology
  - Virology
- Hematology
  - General Hematology
  - Coagulation
  - Flow Cytometry*
  - Immunohematology
  - ABO Group & Rh type
  - Antibody Detection (transfusion)
Diagnostic Immunology – - Antibody Detection (non-transfusion)
- Syphilis Serology - Antibody Identification
- General Immunology - Compatibility Testing
Chemistry - Pathology
- Routine Chemistry - Histopathology
- Urinalysis - Oral Pathology
- Endocrinology - Cytology
- Toxicology - Molecular Pathology*
Clinical Cytogenetics - Radiobiology

* A2LA recognizes that Molecular Pathology testing and Flow Cytometry testing may be considered by a laboratory to apply to a different Specialty or Subspecialty than how they are categorized here. The laboratory can decide, with the assessor’s input, how best to describe Molecular Pathology and Flow Cytometry on their scope of accreditation.

All clinical testing laboratories are not alike and do not offer the same combinations of testing in the same facility configuration and staff organization. A2LA can customize the assessment process to match a laboratory’s combination of specialties and subspecialties, whether a single application for multiple sites within a hospital campus and under a common director or multiple applications for laboratory sites within the same physical location A2LA can design a special program in response to the user needs.

In order to be accredited by A2LA and to maintain accreditation as a clinical testing laboratory, located domestically or foreign based and meeting the requirements of ISO 15189, the laboratory must comply with the requirements of this document and the following additional requirements:

- ISO 15189 (2012), Medical laboratories – Requirements for quality and competence;
- A2LA R902 - Conditions for Accreditation for Clinical Testing Laboratories Meeting the ISO 15189 Requirements;
- A2LA R903 – General Requirements: Proficiency Testing for Clinical Testing Laboratories Meeting the ISO 15189 Requirements;
- A2LA F901 - Application for Accreditation: ISO 15189 Testing Laboratories;
- A2LA P905 – A2LA Metrological Traceability Policy for ISO 15189 Laboratory Testing;

A2LA will follow §493.25 (Laboratories performing tests of high complexity) where the applicant laboratories for accreditation will be those performing both Moderate and High
Complexity testing. A2LA accreditation requirements apply to all moderate and high complexity testing that a laboratory seeks to include on their scope of accreditation.

A2LA provides accreditation to any clinical laboratory performing moderate or high complexity testing (as defined in CLIA). Laboratories that provide only waived or Provider Performed Microscopy (PPM) are not eligible for accreditation through A2LA. If the laboratory does perform moderate or high complexity testing along with waived testing and/or PPM, A2LA will accredit for all of this testing and microscopy.

In effect, A2LA accreditation attests that a laboratory has demonstrated that:

a) it is competent to perform specific clinical laboratory tests on samples from humans in the specialties and subspecialties, listed on its Scope of Accreditation;

b) its management system addresses and conforms to all elements of ISO 15189, and is documented in accordance with those requirements and is fully operational;

c) it is operating the Preanalytic, Analytic and Postanalytic systems in accordance with its management system; and

d) it conforms to any additional requirements of A2LA or specific fields or programs necessary to meet particular user needs.

A2LA will not accredit or renew accreditation of a laboratory that fails to meet the A2LA criteria (see R902: Conditions for Accreditation for Clinical Testing Laboratories Meeting ISO 15189 Requirements, and Part B of this document - Accreditation Process, sections on deficiencies, accreditation decisions and suspension or withdrawal of accreditation).
PART B

A2LA ACCREDITATION PROCESS

I. Application

A clinical laboratory applies for accreditation by obtaining the application package (available from A2LA headquarters or the A2LA website www.A2LA.org) and completing appropriate application sheets and relevant checklists. All clinical laboratory applicants must agree to a set of conditions for accreditation (see R902: Conditions for Accreditation for Clinical Testing Laboratories Meeting ISO 15189 Requirements), pay the appropriate fees, and provide detailed supporting information, including:

- Proposed scope of testing in terms of specialties/subspecialties, test methodologies and test systems;
- Quality manual;
- Organization structure;
- Key staff qualifications (including copies of verifiable credentialing documents)
- Proficiency testing plan and results
- Facilities description
- List of major equipment (including laboratory information systems)
- List of tests
- Hours of operation

A2LA has defined the following clinical laboratory types as follows:

**Main Laboratory:** A clinical laboratory (organization) that maintains a single location only.

**Permanent Laboratory:** A clinical laboratory erected on a fixed location. This is the laboratory location (address) denoted on the clinical scope of accreditation.

**Branch Laboratory** [multi-location system]: A clinical laboratory system that consists of two or more laboratories owned and operated by the same organization, utilizing the same management system and managed by a Corporate Representative. If you are applying as a multi-laboratory system, a separate application must be completed for each clinical laboratory. The conditions for applying as a branch of another laboratory are as follows:

- All application, renewal of accreditation and annual review processes must be coordinated through one central person, the Corporate Representative;
- All fee payments and invoices must be coordinated through the Corporate Representative;
- All laboratories within a single branch system are given related certificate numbers (e.g., 301.01, 301.02, 301.03, etc.);
• All laboratories within a single branch system must be visited, assessed and accredited regardless if they are performing the exact same testing as the main laboratory.

This central coordination and arrangement within our database allows for greater efficiency in handling various processes, therefore a discount on fees is offered to all branch laboratories.

Please consider these issues carefully as you decide whether or not to apply as a branch laboratory system. If you have any questions concerning this arrangement, please contact A2LA.

**Hospital Satellite Laboratory:** A Hospital Satellite laboratory is allowed to place their clinical testing on the main laboratory’s scope (with a footnote to reference their location) as long as the hospital satellite laboratory is on the same campus or in the same contiguous building as the main laboratory, operates under the same management system as the main laboratory, can have prompt supervisory oversight from the main laboratory, when necessary, and has appropriate oversight from the same laboratory director that represents the main laboratory.

As accreditation is ‘site specific’, only the main laboratory address can be listed in the heading information contained on the Scope of Accreditation. The satellite location(s) address(es) will be listed at the end of the scope content of the main laboratory and will contain all of the scope content that coincides with that satellite location. If there is more than one satellite location, this information is repeated for each separate satellite location. No clinical scope of accreditation can contain more than four hospital satellite laboratories.

As the satellite location(s) operate under the same management system as the main location, A2LA will assign the same assessor(s) and the satellite laboratories will be assessed in their entirety and concurrently with the main location assessment.

**Mobile Laboratory:** Fully equipped, self-contained, transportable clinical testing laboratory capable of performing clinical tests under controlled environmental conditions. A mobile laboratory may perform testing only when the laboratory is stationary. (Note: Wherever they are located, mobile clinical laboratories are subject to the same terms of accreditation as a hospital satellite laboratory. However, mobile clinical laboratories left at one location for three years or more will be subject to the same terms of accreditation as a permanent laboratory.)

**Point of Care Testing:** A2LA will accredit for moderate or high complexity Point of Care Testing (POCT) as part of the assessment of the applicant clinical laboratory, if request by the laboratory. The POCT requirements are based on ISO 22870, – *Point of Care Testing (POCT) – Requirements for quality and competence* and the ISO 15189:2012 standard. Point of care testing is defined as tests done at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside of the physical facilities of the clinical laboratory. A sampling of the applicant laboratory’s POCT services is assessed, if the clinical laboratory requests accreditation for POCT.
Specimen Collection Sites: Any specimen collection sites that support the activities of the applicant laboratory are assessed as part of the accreditation process for the laboratory. A sampling plan is used to ensure that all collection sites are eventually assessed over a span of accreditation periods. A specimen collection assessor checklist (available as part of the application process) is used to assess specimen collection sites.

In order to use both the assessor’s and the laboratory staff time effectively, A2LA requires that the following information be accessible and retrievable at the time of the on site visit:

- Standard operating procedures with all test procedures (package inserts and supplemental information, as necessary)
- Records of tests referred to other laboratories*
- Records that support personnel qualifications, training, experience, competency assessment**, responsibilities and authority*
- Quality Control records: with remedial actions, calibration and calibration verification, statistical limits, instrument maintenance and function checks*
- Proficiency testing (PT) reports including the test runs and results, printouts, report forms, reviews, attestation signatures, and performance summary data.
- Records that support validation of test methods*
- Management system assessment plans and records: policies and procedures directed towards monitoring, assessing and correcting identified problems*
- Documentation of ongoing assessment activities including corrective action effectiveness reviews, policy and procedure revisions made to prevent recurrence of a problem, discussion of assessment reviews with staff.
- Patient test records including requisitions, instrument printouts and test reports.*
- Access to any specimen collection sites that A2LA may wish to assess as part of the accreditation process using the C916: A2LA Collection Site Assessor Checklist
- Accommodation records: facility (environmental monitoring, water system, etc.) and Laboratory Information Management System (LIMS)*

* Please see Part C for additional requirements for record and material retention.

All documentation must be provided in English and the assessment conducted in English. An appropriate English translation of pertinent documentation must be provided as well as a translator, if needed, to facilitate the assessment.

All the testing is subject to full assessment by A2LA assessors.

Accreditation of non-standard tests may be granted and shall be referenced in the scope by unambiguous identification.
If a clinical laboratory wishes accreditation for the use of its own methods (i.e., laboratory-developed methods and/or modified FDA-approved tests), then it must provide the following information to the assessor(s) before assessment:

- Origin of method;
- Comparison with the standard methods they replace including any departures from the standard (if applicable);
- Reasons for and effects of departures;
- Validation data (per Section 5.5 of ISO 15189).

Where an A2LA accreditation requirement states “laboratory management” this means the same thing as “the Laboratory Director”. A2LA requires the Laboratory Director to sign the Conditions for Accreditation attestation in the Application for A2LA Accreditation for Clinical Laboratories. The laboratory’s director has overall responsibility for all accreditation requirements.

The Laboratory Director’s responsibilities include the design, implementation, maintenance and improvement of the Quality System (ISO 15189, 4.1.5) as well as ensuring that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-examination, examination and post examination processes.

II. Assessment Process

The objective of an assessment is to establish whether or not a clinical laboratory complies with the A2LA requirements for accreditation and can competently perform the types of tests for which accreditation is sought. However, when accreditation is required to demonstrate compliance with additional criteria which may be imposed by other authorities, such as in the case of CLIA, the A2LA assessment will include such additional criteria.

Pre-assessment and Pre-assessment visit

Once the application information is completed and the appropriate fees are paid, A2LA headquarters staff identifies and tentatively assigns one or more medical assessors to conduct an assessment at the laboratory’s site. Assessors are selected on the basis of their testing expertise so as to be better able to provide guidance to the laboratories. They do not represent their employers (if so affiliated) while conducting assessments for A2LA. The medical laboratory has the right to ask for another assessor if it objects to the original assignment. A2LA medical assessors are drawn from industry, academia, government agencies, consultants, and from the laboratory community. Assessors work under contract to A2LA. Assessments may last from one to several days depending on the extent of the desired scope and the size of laboratory. More than one assessor may be required.

Medical assessors are given a Medical Assessor Instruction Manual and checklists to follow in performing an assessment. These documents are intended to ensure that assessments are
conducted as uniformly and completely as possible among the assessors and from laboratory to laboratory.

Before the assessment is conducted, the assessment team will perform a review against the requirements of ISO 15189 and A2LA policies of documents provided by the applicant or renewal clinical laboratory. These documents may include but are not limited to the Quality Manual and test procedures. The team leader will provide the applicant or renewal laboratory with the gap analysis from the document review prior to the assessment date in order to give the laboratory an opportunity to address the documentation gaps and provide the revisions to the assessment team prior to the assessment. Any gaps not addressed prior to the assessment will be carried over to the deficiency report resulting from the assessment. The laboratory cannot provide revised documents resulting from the document review to the assessors during the assessment.

A pre-assessment visit may be requested by the laboratory or suggested by the assessor as an option at this point to enhance the success of the full assessment.

Prior to scheduling the full assessment, the assessor reviews the draft scope to determine the tests to possibly witness and checks on the availability of the technical personnel who perform the tests. An assessment agenda is provided by the assessor.

On-Site Assessment

The clinical testing laboratory:

- An entry briefing with laboratory management;
- Interviews with technical staff; (including health care providers outside the laboratory in hospital based laboratories);
- Observation of staff performing assigned tasks in all three areas of the workflow process (pre-analytical, analytical and post-analytical);
- Demonstration of selected tests including, as applicable, including tests performed at other sites within the scope of the accreditation;
- Examination of equipment and calibration records; test records, supplies and reagents and PT records;
- Audit of the management system to verify that it is fully operational and that it conforms to all sections of ISO 15189, including documentation;
- Review of training records and competency assessments;
- A written report of assessor findings; and
- An exit briefing including the specific written identification of any deficiencies.

The clinical laboratory is expected to meet every individual requirement however the assessor seeks to determine the laboratory’s overall compliance. The assessors use an outcome-oriented approach that emphasizes the provisions that have a direct impact on the laboratory’s overall test performance and ask the question, “Is the laboratory producing quality results (accurate, reliable and timely)?”
The assessor is looking for effective processes (pre-analytic, analytic and post-analytic) that function well together. The assessor will also look at the processes that the laboratory uses to detect, prevent and control non-conformances and assure quality testing and services. The assessor focuses on the effectiveness of the management system in all aspects of the clinical laboratory.

**Immediate Jeopardy**

Immediate Jeopardy (IJ) is defined as a situation in which immediate corrective action is necessary because the laboratory’s noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

During the assessment, if any deficiency is identified in an A2LA accredited laboratory that poses an immediate jeopardy to the laboratory’s patients or a hazard to the general public, or is identified as an illegal activity, immediate action to address the deficiency is expected. If the deficiency is not immediately corrected, A2LA will take appropriate enforcement actions in accordance with section XV of these requirements. A2LA may confirm effective implementation of corrective action for every IJ deficiency with a follow up assessment of the laboratory at the laboratory’s expense.

**III. Deficiencies**

During the assessment, assessors may observe condition level or non-condition level deficiencies.

**Condition Level Deficiencies:** These are serious, system wide non compliances with the requirements of ISO 15189 or A2LA policies.

**Non-Condition Level Deficiencies:** These are any other deficiencies that do not qualify as IJ, illegal activities or condition level deficiencies.

A deficiency to accreditation requirements may include:

- a clinical laboratory’s inability to perform a test, or type of test, for which it seeks accreditation;
- a clinical laboratory’s management system does not conform to a clause or section of ISO 15189, is not adequately documented, or is not completely implemented in accordance with that documentation; or
- a clinical laboratory does not conform to any additional requirements of A2LA or the clinical field of testing requirements necessary to meet particular needs.

At the conclusion of an assessment, the assessor prepares a report of findings, identifying deficiencies which, in the assessor's judgment, the clinical laboratory must resolve in order to be
accredited. The deficiencies are categorized as condition level or non-condition level deficiencies.

For renewal laboratories, any repeat deficiencies will be identified as such in the assessor’s deficiency report. In these cases, the laboratory is required to correct the repeat deficiencies quickly and thoroughly. Otherwise and depending on the nature of the repeat finding, revocation of a portion of or suspension of the full scope of accreditation will be considered.

The assessor holds an exit briefing with top management of the organization and the clinical laboratory, going over the findings and presenting the list of deficiencies (deficiency report). The Laboratory Director of the clinical laboratory is required to sign the assessor report to attest that the full assessor report (including the deficiency report) has been reviewed with the assessor. The signature does not imply that the laboratory representative concurs that the individual item(s) constitute a deficiency.

Assessors may also write an ‘observation’ when they question the practice or competence of the clinical laboratory but there is not enough supporting objective evidence to justify a deficiency or the issue cannot be tied to the accreditation requirements. If this occurs, the clinical laboratory does not have to respond to observations in order for accreditation to be granted. However, the observations are part of the assessment record and will be followed up by the next assessor to visit the clinical laboratory who will check to see if that observation was addressed by the clinical laboratory, resulting in an improvement, or possibly may have progressed into a deficiency.

IV. Corrective Action Process

Immediately following the assessment or reassessment of a clinical laboratory, A2LA staff will review the resulting deficiencies; if there is one or more deficiencies (condition level or non-condition level) that cannot be adequately responded to via a documentary exchange, this would automatically result in a follow up assessment.

Upon receipt of the assessor’s deficiency report, A2LA may also decide that due to:

- the nature, incidence, severity, duration of the non-condition level deficiencies;
- whether the non-condition level deficiencies have been identified repeatedly;
- the accuracy and extent of the laboratory’s efforts and records to address the non-condition level deficiencies;
- the relationship between one deficiency or group of deficiencies to another; and
- the overall compliance history of the laboratory (including any periods of non-compliance, the outcome of previous corrective actions or levels of continuous improvement following correction of condition level or non-condition level deficiencies);

it may be necessary to re-classify one or more of the non-condition level deficiencies as conditional level deficiencies. A2LA would then take appropriate action (pursuit of corrective action response from the laboratory, follow up assessment at the laboratory’s expense, suspension of all or revocation of a part of the scope of accreditation) as is warranted by the findings.
Every clinical laboratory (new or renewal) is requested to respond, in writing, within 30 days after the date of the exit briefing detailing either its preliminary corrective action response or why it does not believe that a deficiency exists. This response and all other corrective action responses must be signed by the laboratory director. If the laboratory fails to respond within 30 days, A2LA sends a letter prompting a response and reminding the laboratory of the relevant deadline for a complete corrective action response.

If any repeat deficiencies from the last assessment are cited, the clinical laboratory must respond within 30 days with a complete corrective action response including root cause analysis. Failure to respond within 30 days will result in suspension of the laboratory’s accreditation until the issue(s) relating to the repeat deficiency is fully resolved to A2LA’s satisfaction.

The clinical laboratory is required to provide a corrective action response for every deficiency (condition and non-condition level) cited, along with root cause analysis and objective evidence (e.g., policies, lab procedures, instrument/test data, equipment maintenance documents, and/or training records) to effectively close the deficiency. A2LA does not close any deficiencies based only on a plan of correction. The corrective action response must also detail any corrective actions taken for patients found to have been affected, or have the potential of being affected, by the deficient practice.

Note: It is entirely possible that the laboratory will disagree with the findings that one or more items are deficiencies. In that case, the clinical laboratory is requested to explain in its response why it disagrees with the assessor.

If the corrective action response is not complete (lacking objective evidence of compliance or lacking root cause analysis), A2LA will request additional information in order to close each deficiency or request a follow-up visit to the laboratory to confirm compliance, always keeping relevant deadlines in mind.

**Corrective Action Response for a New Applicant Clinical Laboratory**

* A new applicant clinical laboratory must complete the accreditation process, including addressing any/all cited condition and non-condition level deficiencies with objective evidence of implementation. This period shall not exceed 90 days from the conclusion of the on-site assessment. Laboratories not completing the assessment process within the cited time frames may be required to undergo a follow up on-site assessment visit at the laboratory’s expense. If deficiencies remain after the follow up assessment, laboratories are given 30 days to provide a complete and effective corrective action response. If a full corrective action response is not received within 30 days, the laboratory is denied A2LA accreditation and must complete a new application for accreditation.

If the new applicant clinical laboratory does not respond in writing at all with a corrective action response addressing each deficiency within 90 days after the date of the exit briefing, it may be denied accreditation and required to submit a new application and be subject to new fees and another full assessment at its expense, should it wish to pursue accreditation after that time. Even
if the laboratory responds within 90 days, A2LA staff still has the option to ask for a follow up assessment of a laboratory before an initial accreditation vote is taken based on the number, extent and nature of the deficiencies. The follow up assessment must take place within 30 days to allow the rest of the accreditation process to be completed and a decision on accreditation reached. If deficiencies remain after the follow up assessment, laboratories are given thirty days to provide a complete and effective corrective action response. If a full corrective action response is not received within 30 days, the laboratory is denied A2LA accreditation and must complete a new application for accreditation.

Corrective Action Response for a Clinical Laboratory Renewing Accreditation

A clinical laboratory seeking renewal of A2LA accreditation must complete the assessment process, including addressing any/all cited condition and non-condition level deficiencies. This period cannot exceed 60 days from the conclusion of the on-site assessment.

Renewal laboratories must fully resolve all condition level and non-condition level deficiencies with objective evidence of implementation and root cause analysis within 60 days of the exit briefing. Renewal Clinical laboratories not meeting this time-frame, or a reassessment resulting in one or more condition level or non-condition level deficiency that cannot be adequately responded to via a documentary exchange within the 60 day timeframe may result in an adverse accreditation action (e.g. a follow up assessment at the laboratory’s expense, or suspension or enforced withdrawal of accreditation). The follow up assessment must take place within 30 days to allow the rest of the accreditation process to be completed and a decision on accreditation reached. Renewal laboratories that fail to address all of the deficiencies after the follow up assessment are subject to suspension of all or revocation of a portion of their scope of accreditation until such time as the laboratory can present evidence that the remaining open deficiencies have been satisfactorily resolved.

If the follow up assessment is not completed within the specified deadline, suspension of the laboratory’s accreditation is invoked. This suspension can only be lifted when the laboratory has satisfactorily responded to all deficiencies through follow up assessment.

The Accreditation Council (AC) panel also has the option to require a follow-up assessment of any clinical laboratory (new or renewal) at the laboratory’s expense, before an affirmative accreditation decision can be rendered.

If at any time it becomes apparent that the laboratory’s director or authorized representative is not being effective in correcting deficiencies (particularly if deficiencies remain after a required follow-up assessment), A2LA will communicate directly with the laboratory’s owner, governing body or other responsible party.

It is possible that the assessor’s review of the corrective action response may be needed to determine if the response is satisfactory. If this review is expected to take more than two hours, A2LA may invoice the clinical laboratory for this time at the prevailing assessor rate. The assessor will discuss the possibility of this review with the laboratory during the exit briefing and obtain the laboratory’s concurrence.
V. Accreditation Anniversary Date

The anniversary date of a clinical laboratory’s accreditation is established at 105-135 days from the initial assessment (e.g., a laboratory with an initial assessment concluding on April 30, 2013 would typically be given an accreditation anniversary date of August 31, 2015). This date normally remains the same throughout the clinical laboratory’s accreditation.

VI. Extensions to the Accreditation Anniversary Date

If a clinical laboratory is in their renewal process and is making good faith efforts with A2LA when approaching their accreditation anniversary date, A2LA may extend their accreditation for up to an additional 90 days to complete the renewal of accreditation process. When condition level deficiencies are identified during an assessment, extensions of accreditation are not considered until the laboratory submits objective evidence demonstrating that the non-conformances have been addressed. Likewise, extensions are not granted when delays are due to the laboratory’s failure to respond to requests within established deadlines such as:

- receipt of complete renewal application after imposed due date;
- assessment not performed within assessor availability;
- receipt of response to assessor deficiency report beyond 30 days of assessment exit briefing;
- closure of all deficiencies beyond 60 days of assessment exit briefing.

When a laboratory is granted an extension to their accreditation, a revised Certificate and Scope of Accreditation are posted to the A2LA website which reflects the extended anniversary date. Hard copies of these documents will be made available only upon request. Upon completion of the renewal process, both documents are reissued, reflecting the renewed anniversary date.

When an extension of accreditation is not considered, upon expiration, laboratories will be removed from the A2LA Accredited list on the A2LA website and placed on a separate website list called “Laboratories in the Renewal Process”. Laboratories on this list are currently considered not accredited but are somewhere in renewal process.

VII. Proficiency Testing

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of inter-laboratory test data comparisons. The laboratory must either enroll in a proficiency program or programs approved by The Centers for Medicare and Medicaid Services (CMS), or enroll with an ISO/IEC 17043 accredited Proficiency Testing Provider for each of the specialties and subspecialties for which it seeks accreditation. For details on the requirements for proficiency testing, please refer to the R903 – General Requirements: Proficiency Testing for Clinical Testing Laboratories Meeting the ISO 15189 Requirements.

Clinical laboratories are responsible for ensuring that their PT results and the summary data are provided to both A2LA.
While every unsuccessful PT event is not reason to cite immediate jeopardy, each occurrence of intentional PT referral is cited as immediate jeopardy and there exists no acceptable path to corrective action. When a laboratory intentionally sends its PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory, this is called PT referral. Laboratories that are cited for PT referral are subject to the immediate enforced withdrawal of their A2LA Accreditation for one year. At that time the laboratory will be eligible to reapply to A2LA for accreditation.

VIII. Accreditation Decisions

Before an accreditation decision ballot is sent to Accreditation Council members, staff shall review the deficiency response, including the clinical laboratory’s root cause analysis and objective evidence of completed corrective action, for adequacy and completeness. If staff has any doubt about the adequacy or completeness of any part of the deficiency response, the response is submitted to the assessor(s). Since all deficiencies must be resolved before accreditation can be granted, staff shall ask the clinical laboratory for further written response in those cases where staff recognizes that an affirmative vote is not likely because of incomplete corrective action in response to deficiencies or obvious lack of supporting evidence that corrective action has been completely implemented.

Staff selects a panel of at least three Accreditation Council members for voting. The panel is chosen so that the full range of the clinical laboratory’s testing capabilities is adequately covered by the Accreditation Council review. The laboratory is consulted about any potential conflicts of interest with the Accreditation Council membership prior to sending their package to the Accreditation Council. Generally, at least two affirmative ballots (with no unresolved negative ballots) of the three ballots distributed must be received before accreditation can be granted. If three or more AC members are required in order to ensure a full review of the clinical laboratory’s testing activities, (re)accreditation may not be granted until all of these votes have been received and any negative votes resolved.

It is the primary responsibility of assessors to judge whether the observed evidence is serious enough to warrant a deficiency. However, the panel members that are asked to vote on an accreditation decision are required to make a judgment whether or not cited deficiencies still exist based on information contained in the ballot package. Accordingly, panel members can differ with assessor judgments, based upon their interpretation of the criteria for the specific case under question and the supporting evidence available whether a deficiency does or does not exist. Staff attempts to resolve these differences as they arise, but it remains for the panel to make the initial decision.

Staff shall notify the clinical laboratory asking for further written response based on the specific justification for one or more negative votes received from the panel. If further written response still does not satisfy the negative voter(s), a reassessment may be proposed or required. If a reassessment is requested by more than one voter, the laboratory is asked to accept a reassessment. If the laboratory refuses the proposed reassessment, a nine-member Accreditation Council appeals panel is balloted (see Sections XIV. Adverse Accreditation Decisions and XVII. Appeals Procedures below).
If accreditation is granted, the A2LA staff prepares and forwards a certificate and scope of accreditation to the laboratory for the Clinical field of testing. The laboratory should keep its scope of accreditation available to show clients or potential clients the specialties, subspecialties, analytes and services for which it is accredited. A2LA staff also uses the scope of accreditation to respond to inquiries and to prepare the A2LA online directory.

IX. Annual Review

Accreditation is granted for two years. However, after the initial year of accreditation, each clinical laboratory must pay annual fees and assessor fees and undergo a two day surveillance visit by an assessor(s). This surveillance visit is performed to confirm that the laboratory's management system and technical capabilities remain in compliance with the accreditation requirements. Failure to complete the surveillance assessment within the designated time frame may result in adverse accreditation action (see Section XIV).

For subsequent annual reviews occurring after the renewal of accreditation (see Section X) each clinical laboratory must pay annual fees and submit updating information on its organization, facilities, key personnel and results of any proficiency testing. Objective evidence of completion of the internal audit and management review is also required. If the renewal laboratory does not promptly (within the established 30 day deadline) provide complete annual review documentation, if significant changes to the facility or organization have occurred, and/or if proficiency testing results have been consistently poor, a surveillance visit and payment of the associated assessor fees is required. If incomplete annual review documentation is provided, follow-up information will be requested within 30 days. If the follow-up information is not received by the requested timeframe, a notice of pending suspension of accreditation is sent to the laboratory.

X. Reassessment and Renewal of Accreditation

A2LA conducts a full reassessment of all accredited clinical laboratories every two years. Early reassessments may also be conducted when evaluations and submissions from the laboratory or its clients indicate significant technical changes in the capability of the laboratory have occurred.

Each accredited clinical laboratory is sent a renewal questionnaire ten months prior to the expiration date of its accreditation to allow sufficient time to complete the renewal process. A successful reassessment at the laboratory’s site must be completed before accreditation is renewed for another two years.

If deficiencies are noted during the renewal assessment, the laboratory is required to fully resolve all deficiencies, with objective evidence provided within 60 days, before accreditation is renewed for another two years.
The renewal decision process is similar to the initial decision process (see Section VIII, Accreditation Decisions), except as follows:

1) If there are no deficiencies, renewal is automatically processed without an Accreditation Council panel vote.

2) If there are only a few deficiencies of a minor nature at the non-condition level (i.e., the non-compliances do not pose reasonable risk of harm to a patient) and there is sufficient objective evidence that the deficiencies have been resolved, the President may elect to renew accreditation without an Accreditation Council panel vote.

3) If there are major deficiencies (Condition Level non-compliances), the staff advises the laboratory of the required time-frame (60 days) in which to resolve all deficiencies or be subject to further actions leading to follow up assessment, or suspension or withdrawal of accreditation (see Sections XIV. Adverse Accreditation Decisions, XV. Suspension of Accreditation, and XVI. Withdrawal of Accreditation). The number of deficiencies does not necessarily relate to whether or not a condition is found out of compliance, but rather its impact or potential impact on the quality of laboratory services and the results reported. A2LA considers a condition out of compliance for one or more deficiencies if, in its judgment, the deficiency(s) constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care. Several related non condition level deficiencies or repeat deficiencies from previous assessments may also be considered a condition level deficiency. In these cases, a ballot of the Accreditation Council panel is conducted using the same voting procedure as for initial accreditation decisions.

In cases where condition level deficiencies not requiring a follow up assessment are identified in a renewal assessment (see Section IV), the clinical laboratory may be required to undergo a surveillance assessment at the laboratory’s expense in conjunction with the next annual review to verify continued implementation of corrective actions (see Section IX above).

XI. Handling Complaints and Unanticipated Events

Upon receipt of a complaint from any party (e.g. physicians, laboratory personnel, patients or their relatives, members of the general public), A2LA will evaluate, within 3 business days, the information received and determine if the complaint should be considered a condition level complaint or a non-condition level complaint. Condition level complaints are concerns that could impact the health and safety of the general public or individuals served by the public or that may constitute immediate jeopardy (see Section II, Immediate Jeopardy). Non condition level complaints are any concerns that are not substantiated as condition level complaints. A2LA requires clinical laboratories to undergo unannounced (with no advanced notice) “for cause” assessments as a result of any issue substantiated as a condition level complaint. If a condition level complaint is received or A2LA is notified that a significant question exists regarding the competency of a laboratory or the laboratory’s continued compliance with the applicable requirements of ISO 15189, an unannounced “for cause” assessment, with no advanced notice, is conducted.
Non-condition level complaints are further investigated via on-site assessment, by telephone, by electronic communication, by letter or by documentary review (whichever avenue would most efficiently and effectively resolve the complaint). All A2LA complaint investigations via on-site assessment are unannounced.

In addition, various unanticipated events may lead to an unannounced, on-site assessment outside of the renewal cycle. Such events could include substantial changes in managerial personnel, continued unsatisfactory PT performance or a significant change in the type of testing performed.

The laboratory is responsible for any assessment fees or expenses resulting from the for cause assessment.

XII. Adding to the Scope of Accreditation

A clinical laboratory may request an expansion to its scope of accreditation at any time. Such a request must be submitted in writing to A2LA headquarters. Each request is handled on a case-by-case basis. Unless the previous assessor can verify the competence of the laboratory to perform the additional tests, another assessment at the laboratory’s site is normally required. If the assessor can recommend a scope addition without an assessment, but this recommendation requires extensive review of supporting documentation requiring more than two hours, A2LA may invoice the laboratory for this review time at the prevailing assessor rate. If the additional tests involve a new specialty/subspecialty, another assessment is likely required. Similarly, if a clinical laboratory relocates, a follow-up assessment is normally warranted.

XIII. Laboratory Reference to A2LA Accredited Status

The requirements pertaining to the use of the “A2LA Accredited” symbol and to any other reference to A2LA accreditation are outlined in the document titled R105 – Requirements When Making Reference to A2LA Accredited Status. The document is available from A2LA Headquarters or on the A2LA website, www.A2LA.org. Failure to comply with these requirements may result in suspension or enforced withdrawal of a laboratory's accreditation.

XIV. Accreditation Status and Adverse Accreditation Decisions

There are various levels of status that may be assigned to clinical laboratories that cannot uphold the requirements for initial or continued accreditation:

**Denial** - If a new applicant is ultimately unable to meet the requirements for accreditation (even after follow-up assessment), initial accreditation is denied. The laboratory may reapply at a later date. A laboratory may appeal to A2LA against a decision to deny accreditation.

**Voluntary Withdrawal** – A new applicant clinical laboratory, not yet accredited, or a renewal laboratory, can decide to terminate further accreditation action and voluntarily withdraw from the accreditation program. The laboratory contact must inform A2LA in writing of this request. A2LA does not publicize the fact that a new laboratory had applied and then withdrawn nor will it advertise that a renewal laboratory has elected to voluntarily
discontinue its accreditation. If A2LA learns that the accredited laboratory is going, or has gone out of business, the laboratory is contacted for further detail and the lab’s accreditation is voluntarily withdrawn. If there are any open deficiencies at the time of voluntary withdrawal that could negatively impact the test results provided to clients, the laboratory would still be required to address the deficiency even though the accreditation had been voluntarily withdrawn. If a laboratory wishes to remove specialty or sub specialty capability from the clinical scope of accreditation, A2LA will revise the scope of accreditation accordingly, update the A2LA website and provide the laboratory with the revised scope.

Inactive Status– A clinical laboratory is designated as inactive when it has specifically requested in writing that its accreditation be allowed to temporarily expire due to unforeseen circumstances that prevent it from adhering to the A2LA Conditions for Accreditation. An inactive laboratory must cease testing on its Scope of Accreditation until the inactive status is lifted. To regain accredited status, the Inactive lab must notify A2LA in writing of this desire, agree to undergo a full reassessment, paying all renewal fees and reassessment costs. A laboratory that has relocated is also designated as inactive until its ability to perform the tests on its scope at the new location has been confirmed (e.g. by a visit to the laboratory’s site).

The Inactive status can be given to a laboratory for no longer than one year, after which time the laboratory is removed from A2LA records and designated as withdrawn.

XV. Revocation or Suspension of Accreditation

Suspension of all or revocation of a part of a clinical laboratory's scope of accreditation may be a decision made by either the President or Accreditation Council panel. The accreditation applicable to a specific laboratory may be revoked or suspended upon adequate evidence of:

- non-compliance with the requirements of a nature not requiring an immediate enforced withdrawal (e.g. identification of immediate jeopardy, illegal activity or condition level deficiencies during an assessment);

- failure to provide full corrective action responses resulting from deficiencies cited during a surveillance, renewal or follow up assessments within the specified timeframe;

- improper use of the “A2LA Accredited” symbol (e.g., misleading prints or advertisements are not solved by suitable retractions and appropriate remedial measures by the clinical laboratory); and

- other departures from the requirements of the A2LA accreditation program (e.g., failure to pay the required fees, submit annual review information within 60 calendar days after it is due, or complete a surveillance assessment within the designated time frame or non-compliance with R902 – Conditions for Accreditation for Clinical Testing Laboratories Meeting ISO 15189 Requirements).
If the proposed revocation or suspension involves a noncompliance not requiring immediate adverse action (e.g. immediate jeopardy) A2LA will give the clinical laboratory written notice of the proposed revocation or suspension and give the laboratory 30 days to provide a corrective action response.

When an accredited clinical laboratory’s accreditation is revoked or suspended, A2LA shall confirm the official adverse action in a certified letter (or equivalent means) to the Laboratory Director, stating:

- the noncompliance(s) that has been identified
- the rationale for imposing suspension or revocation;
- the conditions under which the suspension or revocation will be lifted;
- that the suspension or revocation will be publicized on the A2LA website;
- that the revocation or suspension is for a temporary period to be determined by the time needed to take corrective action but not exceeding 60 days, after which time an enforced withdrawal action is taken (the exception to this being revocation/suspension due to unsuccessful PT performance, for which the laboratory’s accreditation is revoked/suspended for a minimum of 6 months);
- that the laboratory must immediately cease testing for all specialties, subspecialties or analytes that have been removed from the scope of accreditation due to revocation or suspension.
- that, within thirty (30) days of receipt of the notice, the laboratory may submit in person, or in writing, information in opposition to the revocation or suspension, including any additional information that raises a genuine dispute over material facts;
- that a further review will be conducted to consider such information and a further written notification will be sent to the laboratory by certified mail, return receipt requested, indicating whether the revocation or suspension has been lifted, modified, left in force or converted to an enforced withdrawal of accreditation.

Failure to meet with the criteria for acceptable proficiency test results can result in automatic revocation of accreditation for the specialty under question (not the entire scope). These specialties are identified in the specific requirements in 42CFR493, Subpart H or in the R903 – General Requirements: Proficiency Testing for Clinical Testing Laboratories Meeting the ISO 15189 Requirements.

XVI. Enforced Withdrawal of Accreditation

A2LA shall forcibly withdraw all or part of accreditation for any of the following causes:

- under the relevant provisions for revocation/suspension of accreditation;
- if surveillance or reassessment indicates that deficiencies are at the immediate jeopardy or condition level as judged by the Accreditation Council panel;
- when complaints are received relating to one or more of the clinical laboratory's test reports and investigation reveals condition level deficiencies in the management system and/or competence in conducting the specific tests;
- if the accreditation requirements are changed and the clinical laboratory either will not or cannot ensure conformance to the new requirements;
• on any other grounds specifically provided for under these program requirements or formally agreed between A2LA and the laboratory;
• if PT referral is confirmed (see Section VII);
• when such action is necessary to protect the reputation of A2LA; and
• at the formal request of the laboratory (voluntary withdrawal in Section XIV).

This enforced withdrawal may be immediate (i.e., without any prior sanctions, such as suspension) upon evidence of egregious violations of the requirements for accreditation, such as PT referral, fraud or other illegal activity, etc.

When it is proposed to enforce withdraw accreditation, A2LA shall issue a written notice by certified mail stating:
• that withdrawal is being considered;
• the reasons for the proposed withdrawal sufficient to put the clinical laboratory on notice of the cause;
• that the laboratory must immediately cease testing for all specialties, subspecialties or analytes that have been removed from the scope of accreditation due to withdrawal of accreditation for that testing;
• that, within thirty (30) days of receipt of the notice, the clinical laboratory may submit in person, or in writing, information in opposition to the enforced withdrawal, including any additional information that raises a genuine dispute over material facts; and
• the effect of proposed withdrawal, including removing the clinical laboratory's name from the A2LA on-line directory and publicizing the action on the A2LA website.

A laboratory may appeal to A2LA against a decision to enforce withdrawal of accreditation.

XVII. Appeals Procedure

A laboratory may appeal any adverse accreditation decision but the sanction will not be lifted until the appeal process is complete. In addition, the laboratory must cease testing entirely or for any specific specialty/sub-specialty/analyte revoked (depending upon the type of sanction enforced) while the appeal is pending. (NOTE: Any requirement for an on-site visit to the laboratory (whether it be a routine assessment or a follow-up assessment or an unannounced “for cause” assessment) is not considered an action that is subject to appeal.)

There are two possible levels that an appeal can reach before being resolved:
1) Accreditation Council (nine-member appeals panel);
2) Board of Directors.

The A2LA staff shall advise the clinical laboratory in writing of its right to challenge an adverse accreditation decision by the President or initial Accreditation Council panel (see Section VIII). The appeals policy, including a clinical laboratory’s right to a hearing, are contained in the A2LA Bylaws.
An appeal shall be lodged by the clinical laboratory no later than thirty (30) days after notification of the decision by forwarding a certified letter to A2LA for timely consideration by the nine-member appeals panel of the Accreditation Council.

Any decision from an appeals vote which would deny or enforce withdrawal of a clinical laboratory's full accreditation or which would revoke a part of the accreditation must be agreed upon by a two-thirds vote of those voting from the nine-member appeals panel of the Accreditation Council. Votes must be received from all members with specific technical background necessary to review the clinical laboratory’s scope of accreditation. The decision of the Accreditation Council's appeals group is communicated in writing to the appellant.

If the decision is not favorable to the appellant, the appellant may lodge a further appeal within thirty (30) days of notification by forwarding a certified letter to A2LA for timely consideration by the Board of Directors. This letter shall include appropriate substantiation for the appeal. This letter and appropriate background documentation will be promptly transmitted to the members of the Board of Directors appeals group, the composition of which to be determined by the Board Chairman taking into account any conflict-of-interest considerations and the nature of the appeal.

The decision of the Board of Directors shall be final and is communicated in writing to the appellant.

XVIII. Reinstatement Policy

Once a previously revoked, suspended or forcibly withdrawn laboratory seeks reinstatement, it may be necessary to assess the lab prior to reinstatement of the accreditation in order to establish assurance that the prior deficient practices which resulted in the adverse action have been corrected satisfactorily. Once a clinical laboratory subjected to an adverse action fulfills all of the requirements for accreditation, including financial obligations, the Director of that laboratory may request reinstatement of accredited status in writing. A2LA staff will review the corrective action responses provided by the laboratory or the assessment results and request that a reinstatement ballot be provided by the Accreditation Counsel (AC). As with all other AC ballots, the laboratory will be afforded the opportunity to reject any AC member who might present a potential conflict of interest.

A three-member panel of subject matter experts from within the AC will review the suspension/revocation/enforced withdrawal documentation and the laboratory’s response to those citations. The panel will then vote for or against reinstatement. If reinstatement is granted, the A2LA web site posting of the laboratory’s revocation, suspension or enforced withdrawal will be removed, and the laboratory’s accredited scope of testing will be returned to A2LA’s web site directory of accredited laboratories as of the date of reinstatement. Reinstatement is not “back-dated”. The clinical laboratory may resume testing for the specialty, sub specialty or analytes that had been revoked, suspended or withdrawn from the scope of accreditation.
XIX. Confidentiality Policy

All information provided by clinical laboratories in connection with a request for an application package, an application for accreditation, an assessment or proficiency test is confidential. Such information is examined by a small group of A2LA staff, assessors, and Accreditation Council and external bodies as needed for recognition of the program. All are made aware of its confidentiality. A2LA agrees to hold all disclosed confidential or proprietary information or trade secrets in trust and confidence. The information shall be used only for accreditation purposes, and shall not be used for any other purpose. It shall not be disclosed to any third party without written consent of the applicant laboratory, as required by law or judicial or administrative process or regulation (such as through a properly issued and served subpoena).

Documents necessary to convey information about accredited laboratories and their scopes of accreditation are not confidential.

In response to a question about whether or not a particular clinical laboratory has applied for accreditation, A2LA simply responds by saying that the clinical laboratory is not accredited. Staff neither confirms nor denies whether a laboratory has ever applied for accreditation. If the clinical laboratory itself is saying that it has applied for accreditation, it is the clinical laboratory's responsibility to release the information regarding its applicant status. If the caller says that the laboratory claims it applied, staff shall take the name, address and phone number of the laboratory to check to see if the laboratory is misleading the client but staff still will not verify the laboratory's application. Should an applicant clinical laboratory require that staff verify for a potential client that it has applied to A2LA, staff shall indicate that it has applied only if the applicant makes such a request to A2LA in writing or designates on the application for accreditation that A2LA is authorized to release information regarding the applicant’s status.

If an inquiry is made about a clinical laboratory whose accreditation has expired but is in the renewal process, staff can indicate that the laboratory is not now accredited but is in the process of renewal, if that is the case. If the renewal laboratory's accreditation has expired with no indication (return of renewal forms or payment) of pursuit of renewal, staff indicates simply that the clinical laboratory is not accredited.

XX. Conflict of Interest Policy

Since its inception, A2LA has had a policy that actual or apparent conflicts of interest must be avoided as mandated by normal business ethics. Consistent with the principles set forth in ISO/IEC 17011, Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, A2LA believes that it is vital that its accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for A2LA. Accordingly, any person directly involved in actions relating to the A2LA accreditation process shall avoid direct participation in A2LA actions that may involve an actual or apparent conflict of interest.
The Chairman of the Board and the President shall, as promptly as possible, take all possible means to prevent or overcome any such actions that may conceivably be in violation of this policy.

Also, A2LA has established a Whistleblower Policy to encourage A2LA employees, directors and committee members to report, in good faith, what he or she believes to be a material violation of the law, Code, practice or policy of A2LA, or of a questionable accounting or auditing matter by A2LA, and to protect those who report such matters from retaliation. By the same token, the employees of A2LA applicant and accredited clinical laboratories are asked to submit any concerns regarding patient testing, employee safety, or ethical or legal violations to A2LA. The identity of the concerned employee will be held in strictest confidence. Such concerns can be reported anonymously using the email address: A&Echair@a2la.org.
PART C

P904 – ISO 15189 PROGRAM POLICY FOR RECORD AND MATERIAL RETENTION

A2LA has established the minimum requirements for the retention of clinical laboratory records and materials. These requirements are equal to or more stringent than the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

Some states and or countries promulgate regulations requiring retention of records and/or materials for longer periods than are specified in this policy. It is recommended that each laboratory carefully review state or national laws when developing their individual record retention policies.

A2LA accredited clinical laboratories must also have a written plan describing the process for sample retention should the laboratory go out of business. This plan will require that retained items be maintained secure until the posted retention period is reached.

Please note: It may be appropriate for laboratories to retain records and/or materials for longer periods of time when required for patient or operational purposes.

<table>
<thead>
<tr>
<th>General Laboratory</th>
<th>Period of Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accession log</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Instrument records including maintenance records, printouts, calibration and verification records</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Quality control records including performance data, instrument printouts, and corrective action.</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Test system performance specifications</td>
<td>The period of time the laboratory uses the test system but no less than 2 years</td>
</tr>
<tr>
<td>Proficiency Testing results including corrective actions</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Management Review documentation</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Reports of internal audits</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Corrective Action Reports</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
<tr>
<td>Preventative Action Reports</td>
<td>2 years or between full assessments whichever is longer</td>
</tr>
</tbody>
</table>
### Period of Retention

<table>
<thead>
<tr>
<th>Quality Assurance Records and QA meeting minutes (Except as notated elsewhere in this guideline)</th>
<th>2 years or between full assessments whichever is longer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records of employee signatures, initials, and identification codes</td>
<td>10 years</td>
</tr>
</tbody>
</table>

**Surgical Pathology (including bone marrows)**

| Wet tissue | 2 weeks after final report |
| Paraffin blocks | 10 years |
| Slides | 10 years |
| Reports | 10 years |

**Cytology (GYN)**

| Slides (negative-unsatisfactory) | 5 years |
| Slides (suspicious-positive) | 5 years |
| Quality Assurance studies | 5 years |
| Report | 10 years |

**Cytology (non-GYN)**

| Fine needle aspiration slides | 10 years |
| Body Fluid slides | 10 years |
| Reports | 10 years |
| Quality Assurance studies | 10 years |

**Note:** Cytology slides may be loaned to proficiency testing (PT) programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of the slides by the PT program and maintains the acknowledgment to document the loan of these slides. Documentation of slides loaned or referred for purposes other than PT testing must be maintained and all slides must be retrievable upon request.

**Non-Forensic Autopsy**

| Wet tissue | 3 months after final report |
| Paraffin blocks | 10 years |
| Slides | 10 years |
| Reports | 10 years |

**Forensic Autopsy**

| Wet stock tissue | 1 year |
| Paraffin blocks | Indefinitely |
| Reports | Indefinitely |
| Slides | Indefinitely |
| Gross photographs/negatives | Indefinitely |
| Accession log | Indefinitely |
| Body fluids and tissues for toxicology | 1 year |
| Representative tissue suitable for DNA Analysis | Indefinitely |
### Period of Retention

<table>
<thead>
<tr>
<th><strong>Clinical Pathology</strong></th>
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<tbody>
<tr>
<td>Patient test records</td>
<td>2 years</td>
</tr>
<tr>
<td>Urine</td>
<td>24 hours</td>
</tr>
<tr>
<td>Serum/CSF/Body fluids (except urine)</td>
<td>48 hours</td>
</tr>
<tr>
<td>Peripheral blood smears/body fluid smears</td>
<td>7 days</td>
</tr>
<tr>
<td>Permanently stained slides – microbiology (i.e. gram stains).</td>
<td>7 days</td>
</tr>
<tr>
<td>Reports</td>
<td>10 years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Cytogenetics</strong></th>
<th></th>
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<tbody>
<tr>
<td>Permanently stained slides</td>
<td>3 years</td>
</tr>
<tr>
<td>Fluorochrome stained slides</td>
<td>3 years or longer at the discretion of the laboratory director</td>
</tr>
<tr>
<td>Wet specimen/tissue</td>
<td>Until adequate metaphase cells are obtained</td>
</tr>
<tr>
<td>Fixed cell pellet</td>
<td>2 weeks after final report</td>
</tr>
<tr>
<td>Final reports</td>
<td>20 years</td>
</tr>
<tr>
<td>Diagnostic images (digitized, prints or negatives)</td>
<td>20 years</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th><strong>Flow Cytometry</strong></th>
<th></th>
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<tbody>
<tr>
<td>Gated dot plots and histograms</td>
<td>10 years</td>
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<table>
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<tr>
<th><strong>Blood Bank</strong></th>
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<tbody>
<tr>
<td>Donor and recipient records</td>
<td>10 years</td>
</tr>
<tr>
<td>Patient records</td>
<td>10 years</td>
</tr>
<tr>
<td>Quality control records</td>
<td>5 years</td>
</tr>
<tr>
<td>Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipient’s protection (e.g., those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Specimens from and potential and confirmed recipients</td>
<td>7 days post-transfusion</td>
</tr>
<tr>
<td>Blood donors units</td>
<td>7 days post-transfusion</td>
</tr>
</tbody>
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### REVISION HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>November 2009</td>
<td>Document issued; superseding the previous R305 document.</td>
</tr>
<tr>
<td>March 2010</td>
<td>Report retention times established for cytology and clinical pathology.</td>
</tr>
<tr>
<td>May 16, 2012</td>
<td>- Changed number of days for Surveillance assessment in section IX and updated header;</td>
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<tr>
<td></td>
<td>- Clarified For Cause assessments as announced or unannounced</td>
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<td></td>
<td>- Page 4 and 14: added ISO/IEC 17043 accredited PT providers as acceptable source for PT.</td>
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<tr>
<td>8/12/14</td>
<td>• Revised document throughout to address accreditation of waived testing.</td>
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<td>• Part B, Section 1 revised to include submission of PT plan (along with results) and to include LIMs as an example of the type of equipment to be outlined.</td>
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<tr>
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<td>• Part B, Section 1 revised to give examples of what are considered a laboratory’s “own methods”.</td>
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