



The American Association for Laboratory Accreditation

**R652- CONDITIONS FOR ACCREDITATION
FOR MEDICAL TESTING LABORATORIES
MEETING ISO 15189 REQUIREMENTS**

Document Issued:
November 6, 2009

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

In order to apply, the applicant laboratory's Medical Director and/or Authorized Representative 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 Medical Director and/or Authorized Representative are responsible for ensuring that all of the relevant conditions for accreditation are met as of the date this document is signed. During the on-site assessment, the assessor will examine records and documentation to verify compliance with these Conditions for Accreditation as of the date they are signed and will determine that the Medical Director and laboratory management team are knowledgeable about the accreditation requirements and that those requirements are upheld.

The Conditions for Accreditation include:

- 1) Afford accommodation and cooperation 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 (including arrangements for witnessing accredited activities when requested and practicable) for the purposes of assessment, surveillance, reassessment and resolution of complaints and fulfillment of Mutual Recognition Arrangement (MRA) and/or specifier requirements;
- 2) Comply at all times with the criteria, requirements, and conditions for accreditation; including participation in proficiency testing as required by national, regional or local regulations. Please see *R653-General Requirements: Proficiency Testing for Medical Testing Laboratories Meeting the ISO 15189 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) Retain and have readily available, all quality and technical records supporting reported results (as defined in ISO 15189:2007, Clause 4.13) throughout the period between A2LA on-site assessments 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);
- 5) Maintain impartiality and integrity;
- 6) 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;

MASTER CODE:

ASSESSMENT NO:

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- 7) Pay such fees as shall be determined by A2LA;
- 8) 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;
- 9) Upon suspension, withdrawal or expiration of its accreditation (however determined) discontinue its use of all advertising matter that contains reference thereto and return any certificates and scopes of accreditation to A2LA;
- 10) Not use its accreditation to imply product approval by A2LA;
- 11) Endeavor to ensure that no report, nor any part thereof, is used in a misleading manner;
- 12) In making reference to its accreditation status in communication media such as advertising, brochures or other documents, comply with the requirements of A2LA;
- 13) Inform A2LA headquarters 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; organization or management (e.g., managerial staff); plans, policies or procedures, where appropriate; premises; 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;
- 14) Carry out any adjustments to its procedures in response to due notice (by A2LA newsletter, RSS feed, email and/or hardcopy) 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.

As the organization's LABORATORY DIRECTOR, 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.

Signature of Medical Director	Title
Printed Name	Date

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Signature of Authorized Representative	Title
Printed Name	Date

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