



# Frequently Asked Questions Related to the A2LA ISO 15189 Clinical Laboratory Accreditation Program

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## ISO and the International Organization for Standardization

### Q. What does “ISO” stand for?

- A. ISO is not an acronym; it is a word chosen by the International Organization for Standardization. “ISO” is taken from the Greek word “isos,” meaning equal. The three official languages of ISO are English, French and Russian; thus the organization’s name would have different acronyms in different languages. For this reason, it adopted the short name ISO (a registered trademark of the organization) which is the same in every country.

### Q. What is the International Organization for Standardization?

- A. The organization today known as ISO began in 1926 as the International Federation of the National Standardizing Associations (ISA) and became known as the International Organization for Standardization in 1947. The International Organization for Standardization is a worldwide federation of national standards bodies from more than 160 countries, one from each country. The national standards bodies make up the ISO membership and they represent ISO within their country.

The organization’s mission is to promote the development of standardization to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological, and economic activity. Its work results in international agreements, which are published as international standards.

A list of ISO membership bodies may be found at [http://www.iso.org/iso/home/about/iso\\_members.htm](http://www.iso.org/iso/home/about/iso_members.htm)

### Q. What are the member categories to ISO and what is A2LA’s status?

- A. There are three membership categories for national standards bodies (see description below).
- Full members (or member bodies) **influence** ISO standards development and strategy by participating and voting in ISO technical and policy meetings. Full members sell and adopt ISO International Standards nationally.
  - Correspondent members **observe** the development of ISO standards and strategy by attending ISO technical and policy meetings as observers. Correspondent members can sell and adopt ISO International Standards nationally.
  - Subscriber members **keep up to date** on ISO’s work but cannot participate in it. They do not sell or adopt ISO International Standards nationally.

The American National Standards Institute (ANSI) is the U.S. member body to ISO. ANSI coordinates the development of voluntary consensus standards in the United States and represents the needs and views of U.S. stakeholders in standardization forums around the globe. ANSI’s membership is comprised of a broad range of businesses and industrial organizations, standards setting and conformity assessment bodies, trade associations, labor unions, professional societies, consumer groups, academia and government organizations for the purpose of enhancing global business competitiveness and improving the quality of life for the world’s citizens. A2LA has been an active member on several ANSI committees for decades and, through this involvement, has been instrumental in the development of ISO standards, including ISO 15189.

### Q. What is a “standard”?

- A. A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. ISO International Standards ensure that products and services are safe, reliable and of good quality. They are strategic tools that reduce costs by minimizing waste and errors and increasing productivity. They help companies to access new markets and facilitate free and fair global trade.

Government and industries around the world have been using international standards for more than half a century to facilitate trade, establish a technical base for regulation and safeguard consumers.

**Q. Are ISO and ILAC synonymous or related in any way?**

- A.** ISO and ILAC are two separate entities (see below for more information about ILAC). ISO focuses on the development of standards worldwide and ILAC focuses on the deployment of those standards worldwide to promote trade and acceptance amongst member organizations. ISO and ILAC have a Memorandum of Understanding (MOU) that addresses matters of conformity assessment policy, standards development and practice as they relate to accreditation. The MOU consolidates practices and provides an ongoing mechanism for technical cooperation between ISO and international accreditors (such as A2LA) in order to contribute to the development and subsequent implementation of ISO standards.

## **ISO 15189**

**Q. What is ISO 15189 and what is its basis?**

- A.** ISO 15189:2012 is a standard that provides the specific requirements for quality and competence that are particular to clinical laboratories. The standard promotes global harmonization of clinical practices. It protects the health and safety of patients and healthcare providers, supports efficient exchange of information and protection of data and improves the overall quality of care. ISO 15189 is used by laboratory customers, regulatory authorities and accreditation bodies to ensure competence.

In 2012, ISO published a revised and updated version of the standard, ISO 15189:2012 (Medical Laboratories – Requirements for Quality and Competence), which contains quality management system requirements as well as technical requirements. It also contains an increased focus on technical competence and now requires mandatory assessment against measurement uncertainty and traceability.

**Q. What is a “quality management system”?**

- A.** A quality management system (QMS), as required by ISO 15189:2012, is a compilation of organizational documents that establishes the policies and procedures needed to direct and control an organization with regard to quality. It relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement. A QMS captures the requirements of an organization and structurally provides a roadmap that explains **who, what, when, where** and **how** sustainable and repeatable outcomes will be achieved.

**Q. What makes up a quality management system?**

- A.** A quality management system consists of policies, procedures, SOPs and records, all of which provide proof of goals, assign responsibility, describe how those responsibilities are to be performed and provide evidence of past accounts or occurrences of compliance.

**Q. How widespread is ISO 15189? Is this accreditation program widely accepted?**

- A.** ISO 15189 is an internationally-recognized standard, with over 40 ILAC-recognized accreditation bodies offering ISO 15189 accreditation programs. In some countries it is the standard by which laboratories are reimbursed. Although ISO 15189 is not mandatory in the U.S., an increasing number of clinical labs have recognized the benefit of being accredited by an internationally-recognized accreditation body (such as A2LA) along with their CLIA accreditation.

**Q. How is ISO 15189 accreditation different from ISO 9001:2008 certification?**

- A.** ISO 9001 is a registration of a quality management system and serves as the basis for many of the other ISO standards because of its intentional generalness.

ISO 15189 incorporates the essential elements of ISO 9001 and adds technical competency factors relevant to clinical laboratories. Its primary application is to improve the management and technical structure of clinical laboratories. ISO 15189 accreditation (as opposed to ISO 9001 registration) includes both an assessment of the QMS and an evaluation of the technical competency of the laboratory.

**Q. What sorts of requirements are contained within ISO 15189?**

- A.** The standard is divided into five sections:
1. Scope
  2. Normative references
  3. Terms and conditions
  4. Management requirements
  5. Technical requirements

Sections 4 and 5 of the document make up the bulk of the standard and are the sections used to assess clinical laboratories. They contain all of the requirements for a clinical laboratory's quality management system, as well as the technical requirements used as the basis for confirming a clinical laboratory's competence to perform specific clinical tests.

## **ILAC and Its Significance**

**Q. What is ILAC?**

- A.** ILAC (the International Laboratory Accreditation Cooperation) is an international cooperation of accreditation bodies (or accreditors) formed more than 30 years ago to help remove technical barriers to trade. When first started in 1977, the aim was to develop international cooperation for facilitating trade by promoting the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of mutual recognition agreements (MRAs) among accreditors that would fulfil this aim. The ILAC Arrangement (first signed in November 2000) provides significant technical underpinning to international trade. The key to the Arrangement is the global network of accredited laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The Arrangement's accreditation body signatories have, in turn, been rigorously peer-reviewed and shown to meet ILAC's criteria for competence.

**Q. Is an accreditor's participation within ILAC mandatory?**

- A.** Participation within ILAC is not mandatory for all accreditors. Indeed, not every accreditor would be found to meet the stringent requirements for signatory status within the ILAC MRA and so they make the "business decision" not to seek this important recognition.

**Q. What is an ILAC "peer evaluation" and what are the benefits of undergoing one?**

- A.** A peer evaluation is the means by which an accreditation body (or accreditor) is found competent and acceptable for consideration as an ILAC MRA signatory. All ILAC MRA signatories have been rigorously evaluated by their fellow signatories to ensure their compliance with ISO/IEC 17011 ("General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies") and to ensure that they are implementing ISO standards within the accreditation programs they offer in a manner that is consistent world-wide. Ask yourself: "Who has accredited my accreditor?" Signatory status within an international MRA, such as ILAC, is the only answer you should accept. Otherwise, what assurance do you have that your

accreditor is competently operating a program for assessment of and accreditation to ISO standards?

## **The A2LA ISO 15189 Clinical Program**

**Q. Who is A2LA?**

**A.** A2LA is the largest, multi-discipline accreditation body in the U.S., having accredited over 3500 labs to various ISO standards over its 35-year history. A2LA is also a non-profit, membership organization based in Frederick, Maryland and its accreditations to ISO standards are recognized and accepted not only domestically within the U.S., but also world-wide.

**Q. Why did A2LA launch a clinical program?**

**A.** A2LA launched a clinical program in an effort to continue fulfilling its vision of “being the premier provider of accreditations accepted everywhere and by everyone”.

**Q. Is A2LA an ILAC Arrangement Signatory? What is the significance of this?**

**A.** Yes, A2LA was one of the original 28 signatories to the ILAC MRA in November 2000 in Washington D.C. Our Scope of Recognition within ILAC includes the accreditation of medical testing laboratories to ISO 15189. This means that your A2LA ISO 15189 accreditation is accepted by our partners in over 70 countries around the world as being equivalent to the accreditations issued within their own countries. ISO 15189 accreditation by an organization that is not an ILAC MRA signatory can make no such statements and there is no basis for its recognition or acceptance in other countries, or even within the United States, by other accreditors.

**Q. What is the difference between A2LA and other accreditors that offer an ISO 15189 program?**

**A. Our International Recognition:**

A2LA is the largest, multi-discipline accreditor in the United States. We are a full signatory to the ILAC Mutual Recognition Arrangement (MRA), which is crucial for several different reasons:

- As an ILAC MRA signatory, A2LA undergoes periodic and rigorous peer evaluations by fellow MRA signatories to ensure that it remains in compliance with ISO/IEC 17011, “General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies”. This is the ISO standard that sets out the rules and requirements for the operation of an accreditor. Without a system of peer evaluation and mutual recognition, there is no guarantee that an accreditor is operating to the highest possible standard and there is no guarantee that an accreditor is assessing and accrediting laboratories in a competent manner.
- Included in A2LA’s Scope of Recognition through ILAC is the accreditation of clinical laboratories to ISO 15189. This provides an independent attestation of A2LA’s competence to offer these accreditations and A2LA is the only accreditation body in the U.S. that is internationally-recognized for ISO 15189 accreditation.
- A2LA’s ILAC recognition for the accreditation of clinical testing laboratories to ISO 15189 means that your laboratory’s ISO 15189 accreditation through A2LA will be accepted internationally, breaking down restrictive barriers to trade and offering greater opportunities than accreditation through an organization that is not recognized beyond its own customer base.

**Our Experience and Access to Expertise:**

A2LA has gained tremendous experience in accrediting laboratories to ISO standards over the past 35 years. A2LA launched its ISO 15189 clinical accreditation program in November 2000. We have been instrumental in the revision of the standard and we currently accredit against the 2012 version. We are not new to this business and we are certainly not new to the use of ISO standards. ISO standards can be challenging to interpret and implement and so you should partner with an accreditor that knows them and has been working with them for 35 years. Our experience also spans all possible levels of expertise needed by a full service clinical laboratory, not just a single area such as pathology.

An A2LA clinical assessment is no “coffee cup audit”. Only so much can be expected of a volunteer assessor corps because they are, after all, volunteers. A2LA’s assessors, on the other hand, are paid, contracted clinical experts and they are required to undergo intensive training (including a week-long orientation course and written exam) and periodic oversight to ensure they are conducting our clinical assessments in accordance with A2LA’s procedures and strict expectations for thoroughness and professionalism. Once A2LA accreditation is achieved, you and your customers can be assured that you have demonstrated competence at the highest level, as confirmed by one of the recognized world leaders in accreditation.

A2LA has an established Medical Testing Advisory Committee (MedTAC), which is active in the development of accreditation and assessment guidelines for clinical testing laboratories in accordance with ISO 15189. The MedTAC is composed of experts in the clinical field and also affords your laboratory a chance to be heard and to be instrumental in the furtherance of the A2LA clinical laboratory accreditation program.

#### Our Services:

Because we are a multi-discipline accreditor, A2LA can serve as a “one stop shop” for all of an organization’s accreditation needs. We understand and accommodate the fact that many organizations do not offer just one type of testing or one type of service. A2LA can accredit for any type of testing in addition to services offered by proficiency testing providers, reference material producers, product certifiers and more. All of this can be done by one accreditor, A2LA, during one on-site visit, saving you time and money.

Do not mistake our multi-discipline nature as being a “watered down” approach to determining competence in each area for which we offer accreditation. Each of our accreditation programs is given the same attention to detail, is held to the same expectations for thoroughness and top-level expertise, and is operated with the same customer service which sets us apart from our competitors.

**Q. I have heard that A2LA and ILAC are “product-focused”, meaning that their emphasis is on and their only expertise is in the accreditation of product testing laboratories. Is this true?**

**A.** No, this is not true. The ILAC MRA includes and A2LA accredits all types of testing laboratories, not just product testing laboratories. This includes, for example, environmental testing, biological testing, forensic examination, pharmaceutical testing and clinical testing. A2LA has established accreditation programs in each of these areas, all of which are included in our Scope of Recognition under the ILAC MRA.

**Q. Does the ILAC peer evaluation of A2LA include an examination of A2LA’s ability to accredit clinical laboratories, specifically?**

**A.** Absolutely. A peer evaluation team is selected to cover all areas for which an accreditor is seeking recognition under the ILAC MRA. Therefore, each team selected to evaluate A2LA includes at least one member with internationally-recognized expertise in the clinical field. This individual then systematically examines all aspects of the A2LA clinical laboratory accreditation program, including observation of one or more actual A2LA on-site assessments of a clinical laboratory to ISO 15189.

**Q. Is A2LA as competent to accredit clinical testing laboratories as they are to accredit other types of labs?**

**A.** Absolutely. Rest assured that no accreditor is accepted into the ILAC MRA and recognized to accredit clinical labs to ISO 15189 unless they have been rigorously evaluated and found competent to do so. The fact that A2LA's Scope of Recognition under the ILAC MRA includes accreditation of clinical laboratories to ISO 15189 provides you with an independent attestation of our competence in this area.

**Q. What aspects are there to an A2LA ISO 15189 assessment?**

**A.** An A2LA clinical laboratory assessment is a three-tiered approach. First, it includes a thorough examination of the clinical laboratory's compliance with the requirements of ISO 15189. Second, it includes an in-depth review of the clinical laboratory's own policies and procedures and their adherence with them. Finally, for each applicant to the A2LA clinical program, a Scope of Accreditation is drafted. This document outlines all of the specialties and sub-specialties (along with the specific tests performed within each) for which the clinical laboratory is seeking accreditation. A2LA assessors then perform a technical assessment against the Scope to ensure that the clinical laboratory is technically competent to perform every test listed.

**Q. How does A2LA ensure accurate evaluation of both QMS and technical issues in its ISO 15189 assessments?**

**A.** A2LA assigns assessors with the education and expertise to complement a laboratory's desired Scope of Accreditation. All of our clinical assessors have extensive experience in assessing CLIA laboratories and have been found to meet A2LA's stringent requirements for being contracted members of our assessor corps. A lead assessor is assigned as are additional assessors depending on the extensiveness of the laboratory's desired Scope of Accreditation. The time spent on-site by our assessors is not only commensurate with the desired Scope and but also takes into account the time necessary for a thorough review of the laboratory's management system. All of our assessors, while undeniably technical experts, also undergo extensive training on the assessment of all QMS elements. A2LA approaches this training as an ongoing investment to ensure the high caliber of our assessor corps. All assessors are observed and evaluated performing actual assessments and this evaluation process occurs at regular intervals throughout the term of their contract with A2LA, ensuring a continual level of consistency and expertise.

**Q. What are the steps in the A2LA accreditation process and how long does the process typically take from start to finish?**

**A.** To begin the process, the laboratory completes and returns the application for accreditation, including all supporting documentation specified within the application form. A2LA staff reviews the submitted application to ensure that it is complete and then proposes an assessor (team) based upon the laboratory's desired Scope of Accreditation. The laboratory is informed of the proposed assessor (team) and is provided with bios to ensure that there is no actual or potential conflict of interest in having the assessor (team) visit the laboratory. Once the assessor (team) has been agreed to, the application package is provided to the assessor (team).

The (lead) assessor contacts the applicant to discuss the scheduling of the on-site assessment and, at that time, requests additional management system documentation to aid in the assessor's document review, which is done in advance of the assessment. (Laboratory's do have the option of undergoing a pre-assessment, during which the assessor will point out any areas that are not currently in compliance with ISO 15189 and the A2LA accreditation requirements prior to the full assessment.) A full on-site assessment is performed which includes, among other things, an entry briefing, review of management system documentation and records, examination of sample handling processes, interviews of technicians, observation of tests being performed, review of technical records and reporting processes. A written assessment report, including a report of any areas of non-conformance, is provided to the laboratory at the closing meeting of the assessment.

The laboratory then responds to any non-conformities cited by providing A2LA with a detailed corrective action response. A2LA staff reviews the corrective action response to ensure completeness and corresponds with the laboratory directly if any additional information is required. Once the laboratory's response is complete, all information related to the assessment is forwarded to a panel of the A2LA Accreditation Council for a vote. Accreditation is granted upon receipt of affirmative votes from the Accreditation Council and once any concerns raised by the Council have been addressed.

On average, new applicants complete the accreditation process within 5 months, from start to finish. Keep in mind that this is greatly dependent upon the laboratory's readiness, preparation and responsiveness.

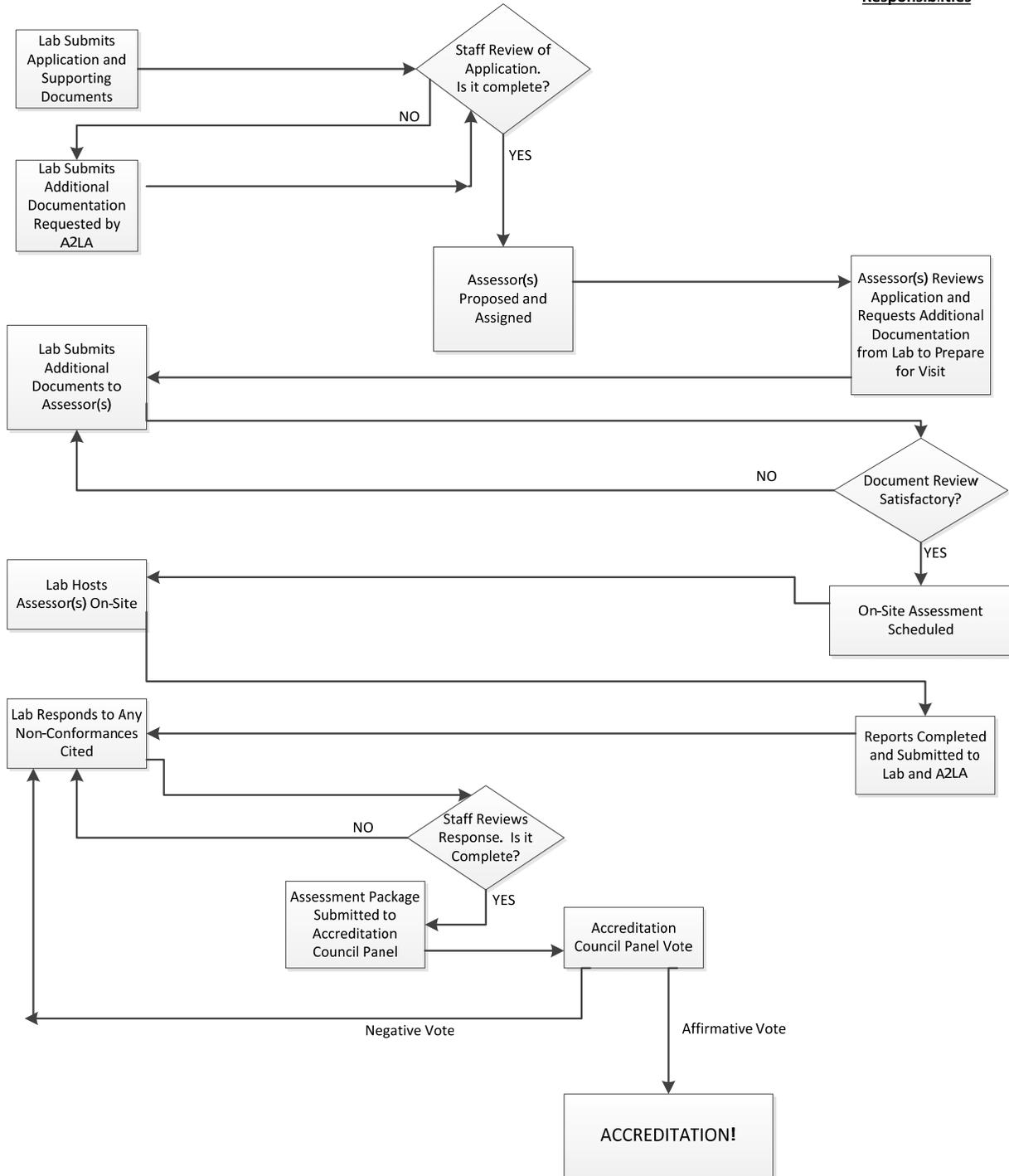
Please refer to the diagram below for an overview of this process:

## The A2LA ISO 15189 Accreditation Process

### Applicant Responsibilities

### A2LA Responsibilities

### A2LA Assessor Responsibilities



**Q. Can A2LA help me to better understand the requirements of ISO 15189 and how to implement them in my laboratory?**

**A.** A2LA is a 501(c)(3) non-profit educational institution. As such we offer a variety of public training courses with the purpose of helping organizations prepare for, achieve and maintain accreditation to ISO standards. One course currently offered by A2LA is “ISO 15189 and Clinical Laboratory Accreditation”, which assists attendees in understanding the benefit of the newly revised ISO 15189 standard and assists them in implementing “best in class” laboratory functions as well as pre-examination, examination and post-examination processes that address the principles of quality clinical laboratory services essential to patient care.

In addition, A2LA offers training courses on specific principles contained within all of the ISO standards used by A2LA as the basis for our accreditation programs. Principles include “root cause”, “corrective action”, “measurement uncertainty”, “internal audits” and “proficiency testing”.

More information may be found on our website (<http://www.a2la.org/training/index.cfm>) or by contacting our Training Manager, Julie Collins, at [jcollins@A2LA.org](mailto:jcollins@A2LA.org).

**Q. Do all A2LA clinical laboratory assessments include a pathologist on the assessor team?**

**A.** Assessor teams are selected based upon a laboratory’s desired Scope of Accreditation. If a laboratory requests the specialty of pathology on their Scope, then a pathologist must be assigned as part of the assessment team. If pathology is not part of the desired Scope, then A2LA does not waste resources or your money in assigning an assessor with expertise in an area that is not relevant to your Scope of Accreditation.

**Q. How should I go about choosing an ISO 15189 accreditor?**

**A.** Similar to how you expect your customers to select a laboratory based upon their qualifications and credentials, so should you when choosing an ISO 15189 accreditor. Anyone can self-declare competence in offering ISO 15189 accreditations, but you need to ask yourself: “*What are their credentials and who has accredited them?*” When it comes to A2LA, the answer is easy. A2LA’s 35 years of experience in accrediting specifically to ISO standards and our signatory status within the ILAC MRA for the accreditation of clinical laboratories to ISO 15189 speak for themselves. Our technical expertise is second-to-none as is our experience with management systems and ISO standards. We not only accredit laboratories to these standards, but we are expert enough in their development and implementation to train others in how to utilize them to better their laboratory’s performance. A2LA is also the only accreditor in the United States that is recognized internationally, by virtue of our signatory status within the ILAC MRA, for the accreditation of clinical laboratories to ISO 15189.

**Q. I am already ISO 15189 accredited by another accreditor. Can I transfer this accreditation to A2LA?**

**A.** Although accreditation to ISO 15189 by an accreditor that is not a signatory to the ILAC MRA cannot be accepted as equivalent to A2LA accreditation, we strive to make the transfer process as little of a burden financially and otherwise as possible. Often, review of the on-site assessment report from another accreditor can be used as a starting-point in the A2LA assessment process, which may save you time and on-site assessor expenses. Every situation is different and so we encourage you to contact us directly ([info@A2LA.org](mailto:info@A2LA.org) or 301 644 3248) and we will be happy to walk you through the transfer process.

**Q. Is A2LA accreditation affordable?**

**A.** A2LA is one of the most transparent organizations in the business when it comes to our fee structure. There are no hidden fees; no “document fees” or other extraneous costs. When you contact A2LA for an estimate on

the cost of our accreditation, you can be confident that you are receiving a complete picture and that you will not be hit with additional fees as you progress through the program. Because the cost is determined by your desired Scope of Accreditation, we invite you to contact A2LA today (301 644 3248) to learn exactly how affordable our accreditation programs are.

For more information about A2LA, please visit our general website ([www.A2LA.org](http://www.A2LA.org)) or our Clinical Laboratory Accreditation Programs pages, specifically, ([www.A2LA.org/clinical](http://www.A2LA.org/clinical)) or call us directly at 301 644 3248 to discuss how A2LA can meet your needs.