

Case Study

Clinical Laboratory Accreditation

Labcorp's Center for Esoteric Testing (CET) and the Atlantic Division Regional Laboratory (ADRL)



Labcorp

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Since its inception in 1995, Labcorp has grown to be one of the largest clinical lab providers in the world. Its flagship location in Burlington, NC is now Labcorp's Center for Esoteric Testing (CET) and the Atlantic Division Regional Laboratory (ADRL). CET serves populations globally for low volume, specialized testing. The facility that houses CET and ADRL is Labcorp's largest in the world.

"I'm one of the quality leads for the CET and ADRL," said Brandon Allen, Associate Director of Quality at the National Office of Quality. The National Office of Quality is Labcorp's corporate entity, which oversees quality programs, systems, and processes for its diagnostic labs. Brandon works on-site at the laboratory full time, overseeing the quality of testing, operations, staff, and more.

The Journey to Accreditation

The quality team at CET and ADRL originally decided to seek ISO 15189:2012 accreditation to better serve their global customers. They have been accredited with A2LA since 2019.

"Our decision to seek accreditation was customer driven," said Brandon. "Our customers' accreditors and regulators often require the use of an accredited reference laboratory, so becoming accredited to ISO 15189 would fulfill that requirement."

Labcorp's global client base was also the driving force behind their decision to partner with A2LA. The accreditation body's strong reputation among customers and its global recognition by the International Laboratory Accreditation Cooperation (ILAC) and other global organizations made A2LA a clear choice for the lab.

After the initial application, Brandon and his team started the journey to accreditation with a pre-assessment. Pre-assessments are for conformity assessment bodies (CABs) becoming accredited for the first time and that want an additional opportunity to find and resolve deficiencies before an official assessment. In a pre-assessment, an A2LA assessor visits the lab as they would in a normal assessment and typically spends a day reviewing quality systems.

The assessor provides a deficiencies report to the CAB, which then has the option to address the deficiencies before the official assessment.



“It gave us a really good idea of where we were in the process and where we needed to be to become accredited,” said Brandon. “After that, we implemented corrective actions based on the findings, so we’d be ready to host the official on-site assessment.”

The pre-assessment primed the CET and ADRL for the assessment, and as a result, the assessor found only a few deficiencies during the audit. After taking corrective actions on those deficiencies, the lab passed the assessment and earned its accreditation.

The Benefits of Accreditation

The CET and ADRL’s A2LA certification can be found displayed in the lab, as it serves as a source of pride to the people who work there. The accreditation fulfilled the requirements of their customers to use an accredited reference laboratory and inspired even more confidence in the results of their laboratory developed, esoteric testing.

“This accreditation has helped drive a culture of quality in our lab,” said Brandon. “Having A2LA hold us to the standard and require us to continuously improve based on ISO 15189 has really helped to push that culture. It’s really been a partnership and you can tell that the program really wants you to succeed.”

ISO 15189 accreditation bolsters doctors’ and patients’ confidence in the quality of test results, allowing them the certainty they need to make important medical decisions.

Choose A2LA

Established in 1978, A2LA maintains a 97% retention rate among its customers, largely in part due to its knowledgeable customer service representatives and expert accreditation services staff. A team of customer care representatives is available during extended business hours to address any issues, and the leadership team consistently strives for improvement within the accreditation industry.



Start The Accreditation Process

Want to learn more about laboratory accreditation for your clinical laboratory? Scan the QR code to visit our [Clinical Accreditation Program](#) page at [A2LA.org](#). Fill out the “Accreditation Estimate Request Form” at the top to get started.

Benefits of ISO 15189 Accreditation

- Enables a robust quality system that considers all aspects of the laboratory, including support staff
- Improves efficiency, saving your organization time, money, and valuable resources
- Identifies potential issues through internal audits, risk reviews, and management reviews
- Establishes a robust complaint process
- Solves issues through cause analysis, corrective action response, and effectiveness reviews

A Better World Through Accreditation

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