Case Study

Clinical Laboratory Accreditation

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





Labcorp

clinical laboratory accreditation

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 Atlantic Division Regional Laboratory (ADRL). This laboratory serves populations globally for low volume, specialized testing and is Labcorp's largest laboratory. Labcorp's corporate entity, The National Office of Quality, oversees quality programs, systems, and processes for its diagnostic labs, including the CET and ADRL.

The Journey to Accreditation

The quality team at CET and ADRL decided to seek ISO 15189:2012 accreditation to better serve their global customers. LabCorp's customers and their regulators often require the use of an accredited reference laboratory, and ISO 15189 accreditation successfully fulfills this 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), as well as other global organizations, made A2LA a clear choice for the laboatory.

After the initial application, the team at CET and ADRL 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 takes place.

In a pre-assessment, an A2LA assessor visits the lab as they would in a regular assessment and typically spends a day reviewing quality systems with laboratory staff. At the end of the day, the assessor provides a deficiencies report to the CAB, which then has the option to address the deficiencies before the official 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 ISO 15189 accreditation. The CET and ADRL have been accredited with A2LA since 2019.



The Benefits of Accreditation

The CET and ADRL's A2LA certification can be found displayed in the lab, driving a culture of quality, and serving as a source of pride for the people who work there.

The ISO 15189:2012 accreditation fulfilled the requirements of their customers to use an accredited reference laboratory and inspired even more confidence in the results of their laboratory's developed, esoteric testing.

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

