

# CASE STUDY



**ADL HEALTH**  
ACCOUNTABILITY · ADAPTABILITY · ACCURACY

## Achieving CMS and International Recognition



American Association for Laboratory Accreditation

# ADL Health

## clinical accreditation journey

Case Study

Starting a full-scale clinical testing laboratory amid a global pandemic was a significant undertaking for the team at ADL Health; but, despite the challenge, the organization successfully opened its doors in 2020.

Headquartered in San Antonio, TX, ADL Health is a molecular diagnostics group that develops and commercializes genetic products and services for reproductive health, precision medicine, and infectious diseases. Their scope of accreditation includes microbiological and chemical testing, including virology, mycology, bacteriology, parasitology, toxicology, and routine chemistry.

The laboratory opened with a CLIA certification, which according to The Centers for Medicare and Medicaid Services (CMS), “regulates all laboratory testing...performed on humans throughout the U.S.” With their CLIA certification, they began helping to meet the sky-high demand for quick and accurate rRT-PCR testing for COVID-19.

Many of these COVID-19 tests were done to meet travel testing requirements, and with patients traveling internationally, ADL Health needed to obtain international recognition as well as federal recognition. ISO 15189 is the global standard for quality and competence in medical laboratories, so ADL Health began working towards an ISO 15189 accreditation to add to their CLIA certification.

### **A2LA Platinum Choice Accreditation Program**

To maintain both a CLIA certification and ISO 15189 accreditation, ADL Health pursued the A2LA Platinum Choice Accreditation Program, which combines the requirements of both standards into one assessment.

“We knew we needed to be assessed to both standards, so this was a great fit for us,” said Tamara Kirby, ADL Health Lab Manager. Due to the pandemic, the laboratory’s first assessment took place remotely, with the A2LA assessor reviewing their quality management system and technical expertise via video conferencing.

“Being remote didn’t prevent our assessor from being professional and thorough,” said Tamara. “They assessed all our processes and did not admonish us for any of our shortcomings.”





After their initial assessment, ADL Health's assessments have taken place on site at their San Antonio headquarters. Their laboratory was the first to earn ISO 15189:2022 accreditation from A2LA. ISO 15189:2022 is the latest version of the standard, and ADL Health was quick to apply the updated standard to their quality management system and test methods.

"Every assessment we've had with A2LA has been done with a culture of quality and improvement," said Dr. Michael Pikulski, ADL Health Chief Scientific Officer. "Having the assessor identify nonconformities helps us to become a more quality laboratory. It's a growth opportunity and a positive experience."



The Advanced Diagnostic Laboratory (ADL) Health building, located in San Antonio, Texas.

## The Benefits of Choosing 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 the Platinum Choice Accreditation Program for your clinical laboratory? Scan the QR code to visit our [Clinical Accreditation Program](#) page at [A2LA.org](https://www.a2la.org). Fill out the "[Accreditation Estimate Request Form](#)" at the top to get started.

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