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CASE STUDY


# LexaGene MiQLab™

## Instrumentation, Reagents and Consumables

## Point of care diagnostic platform

*Delivering rapid, automated COVID-19 pathogen detection at point of need.*

### Background

LexaGene came to Ximedica to leverage their rapid molecular testing, currently focused on veterinary diagnostics, to create a point-of-need solution for accurate pathogen detection in human clinical diagnostics, specifically in support of the COVID-19 pandemic.

### The Problem

Redesigning a full automated PCR-based diagnostic system for commercial readiness to respond quickly to COVID-19 IVD needs and testing in multiple markets, including veterinary diagnostics can be time consuming and a financial burden. Older units were cumbersome and required several iterations to build a complete, efficient unit that delivered accurate test results in a single unit (or expeditiously).

> **"XIMEDICA'S TEAM IMMEDIATELY IMPRESSED ME WITH THEIR PROFESSIONALISM, RESPONSIVENESS TO CHANGES IN REQUIREMENTS, SUCH AS SHORTENING THE TIMELINE TO DELIVERY, AND THEIR ATTENTION TO DETAIL IN DESIGNING A TRULY ELEGANT SYSTEM."**

**Jack Regan**
CEO, LexaGene

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## Solution

LexaGene partnered with Ximedica to help improve the design functionality of its diagnostic system helping the company to become commercially competitive in the human IVD space for COVID-19 testing. To make this move, Ximedica deployed an expert team with extensive experience in human-centered industrial design, diagnostic instrument design, reagent management, and understanding of molecular diagnostic workflows to help ready the new MiQLab™ system for commercialization.

## Results

Adapting a diagnostic analyzer to support commercial readiness and human IVD use posed challenges for both teams. With a focus on human-centered design and usability, Ximedica was able to deliver a new instrument design to ready MiQLab™ for manufacturing, FDA submission, and ultimately commercialization in record time—less than 6 months—during the COVID-19 pandemic. LexaGene is currently pursuing FDA Emergency Use Authorization for SARS-CoV-2 (COVID-19) testing.

ISO 13485:2016 Certified (Notified Body: NSAI): Certificate # MD19.4422
Design process and photos depicting LexaGene MiQLab™ system.
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