Veranex
Transforming Your MedTech Innovation

CASE STUDY

LEXAGENE MIQLAB™

Point-of-Care Diagnostic Platform

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

The Problem

LexaGene came to Veranex 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 Background

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).

> "VERANEX'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

Solution

LexaGene partnered with Veranex 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, Veranex 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, Veranex 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.

ABOUT VERANEX

Veranex is the only truly comprehensive, global, tech-enabled service provider dedicated to the medical technology industry. Offering expert guidance from concept through to commercialization and across the development continuum, Veranex enables accelerated speed to market, controlled development costs, development risk mitigation, and accelerated market viability assessment.

At every stage, Veranex customers realize efficiencies in cost and time, while our integrated and comprehensive solutions unify the entire development process. With Veranex as your end-to-end partner, you're well-positioned to deliver the safest, most effective devices to improve outcomes to patients everywhere.

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