

CASE STUDY

ATIVA'S POINT-OF-CARE DIAGNOSTIC PLATFORM

Bringing Rapid Diagnostic Testing to Patients in Point-of-Care

Veranex helped a hematology startup transform a central lab test into a CLIA-waived, rapid point-of-care diagnostic platform.

► The Problem

Complete blood count (CBC) tests allow for the evaluation of a patients' overall health and are used in several therapeutic areas, including medication management, blood disorders, infectious disease, and oncology. A crucial diagnostic tool, most CBC platforms or manual tests require cumbersome machinery, and thus are limited to large, central laboratories only, decreasing patient access and increasing costs. Current standard for CBC protocols is to use multiple machines or single machines with extensive external tubing and reagent storage concerns: these require a large time investment by the lab and result in delays.

► The Background

Ativa Medical, a startup company with a revolutionary concept for CBC testing, aspired to create a point-of-care (PoC) instrument that supports rapid results in a CLIA-waived environment. The company had a general product concept but wanted to partner with Veranex to truly transform these preliminary ideas into functional prototype units, and ultimately clinical systems.





► Innovation Opportunity

Veranex is developing a CBC analyzer platform that is both smaller and faster than most CBC tests on the market. While a traditional CBC test can take one or two days, the Ativa Essent can yield results in under 5 minutes. Additionally, the Essent has a much smaller footprint, with no need for external tubing, reagent storage, or a connected PC. The platform's size reduction, coupled with its ease of use, makes it an ideal platform for any provider, including physician's offices and hospitals. After clinical trials, Ativa is planning to pursue a CLIA waiver for the Essent, which would make it one of the first CLIA-waived CBC platforms on the market.

Veranex Skills Used

- System architecture
- Cartridge integration development
- Reagent pack design and development
- Reagent storage and dispense
- Precision fluid handling
- Optics development
- Software and electronics development
- Systems integration and assembly

► Veranex's Involvement

Veranex designed Ativa's Essent platform from a novel concept to a functional preclinical device in an impressive time frame. Veranex also developed a multitest reagent pack similar to a printer's ink cartridge, where it can run up to a hundred tests per consumable, which in turn dramatically decreases the cost per test and increases accessibility for a large breadth of patients.





Value Delivered

Veranex developed Ativa's Essent system from a concept to a Phase 3 preclinical platform. The Ativa Essent device takes up significantly less space than previous CBC platforms, while producing faster results than the industry standard, in a more economic package. This platform brings central laboratory capabilities to the physician's office, decentralizing the CBC market. These innovations make the Essent easily marketable as a rapid point-of-care diagnostic platform.

Veranex and Ativa are currently working to bring the device to clinical trials in the U.S.



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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