



# Case Highlight:

## Accelerating Diagnostic Innovation Through Long-Term Partnership

### Introduction

In-Vitro Diagnostic (IVD) organizations are essential to the clinical trials ecosystem, particularly in developing assays that support disease detection, patient stratification, and therapeutic decision-making. To bring these products to market, IVD firms must demonstrate analytical and clinical performance, regulatory compliance, and clinical utility through formal studies.

Versiti's longtime partner, a global leader in molecular diagnostics that specializes in rapid, automated testing solutions spanning from centralized laboratories to point-of-care testing, plays a critical role in addressing public health challenges through scalable, accessible diagnostic tools. For over a decade and a half, they have partnered with Versiti on over 75 studies to support the development and validation of cutting-edge diagnostic assays.

### A Legacy of Collaboration

#### Partnership Initiation

Versiti's relationship with this organization formally kicked off around 2009, with initial engagements focused on infectious disease testing and building of custom specimen collection kits. Over time, as the client's needs evolved and Versiti's capabilities expanded, the relationship deepened into a comprehensive, multi-service collaboration.

#### Expanding the Scope of Services

What began as a focused testing engagement grew into a full-service partnership inclusive of broader contract research organization (CRO) services. Versiti's suite of services expanded through the strategic addition of affiliate organizations with expertise in clinical diagnostics, molecular biology, quality and regulatory consulting, and Institutional Review Board (IRB) Services. Key services provided to the IVD organization over the years have included:

- **Kit Building & Infectious Disease Testing:** The foundation of the early relationship.
- **Sample Management:** Including aliquoting, storage, and logistics.
- **Assay Optimization:** Collaborative work with client scientists to refine DNA extraction and assay performance.
- **Instrument Procurement & Leasing:** Versiti procured and managed diagnostic instruments, reducing the client's capital burden. This enabled:
  - **Centralized Comparator Testing:** Integration of in-house testing that previously required third-party labs, making data management more streamlined and timelines more efficient
  - **Full Study Management:** Conducted testing across multiple laboratories under one Versiti umbrella within a single contract.

## Example: Adaptability through Instrument Procurement.

When the client needed additional instruments for a high-volume study, Versiti procured them directly—eliminating the need for external coordination or capital investment.

In doing so, Versiti manages the **instrument maintenance, reagent sourcing, and operational logistics** tied to these expenditures. This model not only reduced the client's financial risk and capital investment but also accelerated study timelines by eliminating procurement, testing, and data-based delays.

This level of operational flexibility is a hallmark of Versiti's approach—meeting clients where they are and adapting services to fit their evolving needs.

## The Power of Long-Term Partnership

The enduring relationship has delivered tangible and intangible benefits:

### Continuity and Trust

- Longstanding professional relationships enable seamless communication.
- Deep understanding of client workflows and expectations.

### Operational Efficiency

- Single contract model across a diverse range of CRO services simplifies project management
- Reduced administrative overhead and faster execution timelines.

### Scalability and Flexibility

- Ability to quickly scale resources, including instrument procurement for comparator testing in-house.
- Flexible service models and cost-bundling options tailored to client needs.

## Workflow Comparison: Versiti vs. Traditional Multi-Vendor Model

Traditional multi-vendor models can result in fragmented communication, longer study timelines, and logistical inefficiencies. This client valued an increasingly more streamlined approach that enhanced results and accelerated timelines without sacrificing quality. The following comparison illustrates how Versiti's integrated model outperforms traditional multi-vendor approaches:

Stage	Traditional Multi-Vendor Approach	Versiti Integrated Model
<b>Contracting</b>	Multiple contracts to negotiate, review, and manage.	One master contract covering all services.
<b>Kit Building &amp; Sample Logistics</b>	Kits built by one vendor, shipped to another for testing. Risk of delays and miscommunication.	Versiti builds kits and manages logistics internally, ensuring seamless handoffs.
<b>Testing &amp; Comparator Analysis</b>	Samples sent to external labs for comparator testing. Adds time and complexity.	In-house testing and comparator analysis through laboratories in Wisconsin, Indiana, and Texas.
<b>Instrument Access</b>	Client must purchase or rent instruments independently, or work with multiple vendors.	Versiti is able to procure, lease, and maintain instruments as part of service.
<b>Data Integration &amp; Reporting</b>	Data from multiple sources must be consolidated.	Unified data management and reporting from a single vendor.
<b>Study Completion</b>	Client reconciles invoices, timelines, and deliverables across vendors.	Versiti delivers a complete, coordinated package with fewer administrative burdens.

## Conclusion

Versiti's long-term collaboration with this global diagnostics leader highlights the value of an integrated, science-driven approach to IVD development. Unlike traditional CROs that can require coordination across multiple vendors, Versiti consolidates services: testing, kit building, sample logistics, comparator analysis, instrument support, and more, under a single contract and operational framework.

This model reduces administrative overhead, shortens timelines, and improves data continuity across studies. It also allows for greater flexibility—whether that means scaling instrument capacity quickly or adapting workflows to meet evolving regulatory or scientific requirements.

By combining technical expertise with operational efficiency, Versiti functions not just as a service provider, but as a strategic partner; one that understands the complexity of diagnostic development and is equipped to support it from early feasibility through clinical validation.



For more information about our services, contact: [Clinicaltrials@versiti.org](mailto:Clinicaltrials@versiti.org)

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