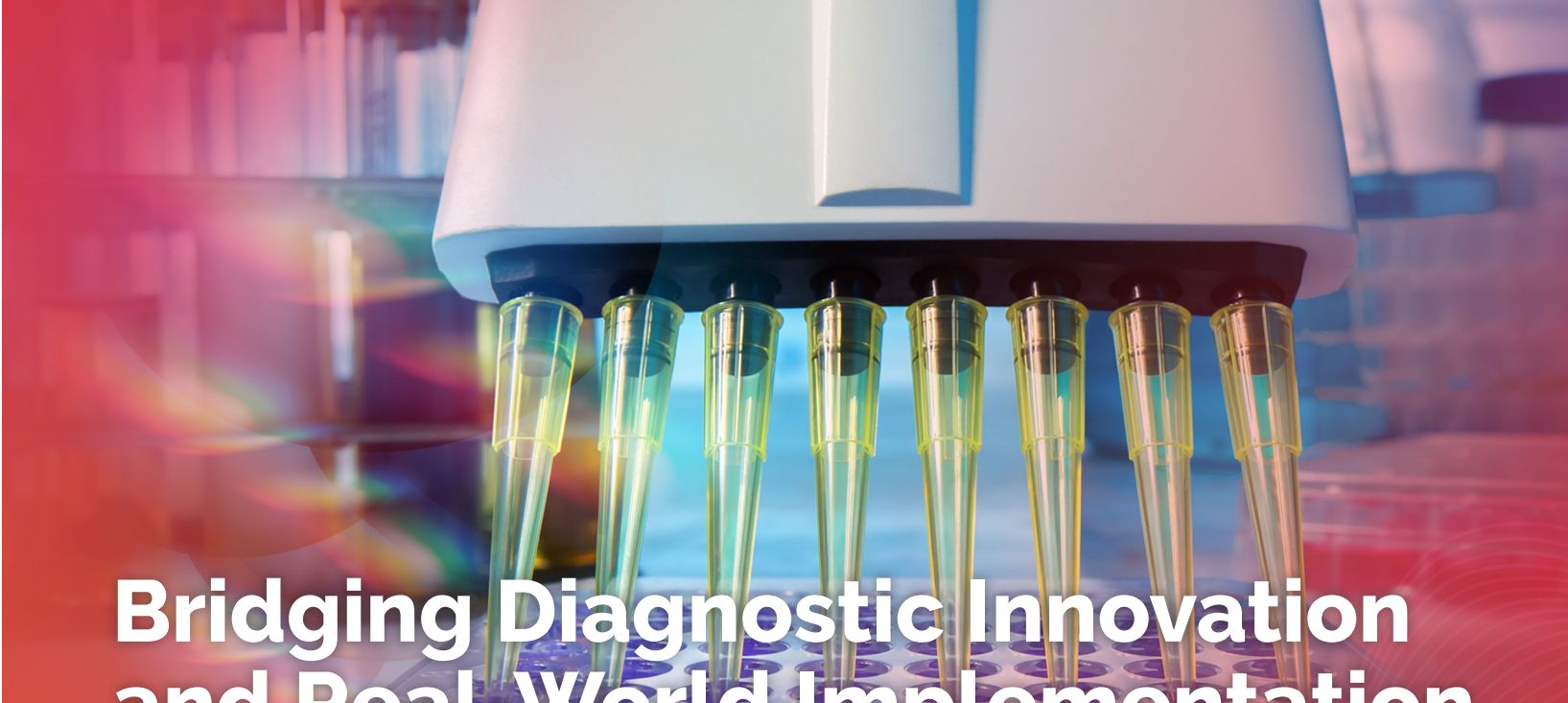

Bridging Diagnostic Innovation and Real-World Implementation

How Versiti Clinical Trial Solutions and Quantigen Biosciences Helped Co-Diagnostics Advance Accessible Molecular Diagnostics Through Translational Science, Validation Strategy, and Collaborative Problem-Solving

From Innovation to Implementation

Expanding access to molecular diagnostics in low- and middle-income countries (LMICs) requires more than analytically robust assays and innovative instrumentation. Diagnostic solutions must also be cost-effective, environmentally resilient, operationally simple, and scalable in settings with limited infrastructure and personnel.

Versiti Clinical Trial Solutions (VCTS), through its Quantigen Biosciences laboratory, partnered with Co-Diagnostics to support the development and implementation of PCR-based infectious disease technologies for Mycobacterium tuberculosis (MTB) and HPV detection. The collaboration combined Co-Diagnostics' expertise in device design and manufacturing with VCTS' capabilities in molecular assay evaluation, workflow optimization, difficult-sample processing, and analytical validation.

The result was a highly collaborative scientific partnership focused on overcoming the technical and operational barriers that can limit the adoption of life-saving diagnostics in underserved communities around the world.

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A Partnership Built for Translation

Co-Diagnostics was introduced to Quantigen Biosciences through a representative of the Bill & Melinda Gates Foundation, which had previously awarded grants supporting the development of MTB and HPV testing on Co-Diagnostics' Pro platform. Recognizing the technical complexity of the work, the Foundation recommended Quantigen as a development and validation partner based on its expertise in molecular diagnostics and translational assay development.

Following an on-site visit and initial technical discussions, the relationship quickly evolved beyond a traditional client-vendor engagement. VCTS worked closely with Co-Diagnostics to evaluate assay performance, develop analytical validation strategies, optimize workflows, execute validation studies, and proactively identify implementation challenges before they became obstacles to scale.

Support included:

- Limit of Detection (LoD) and Limit of Blank (LoB) studies
- Stability, precision, microbial interference, and interfering substance studies
- Multi-site validation support
- Laboratory-specific collection protocols
- Proficiency panels and field-verification materials
- Validation planning aligned with WHO prequalification guidance and country-specific regulatory requirements

This collaborative approach enabled Co-Diagnostics to generate the data required to support future regulatory submissions across multiple regions while strengthening readiness for real-world deployment.

Solving Complex Workflow Challenges

One of the collaboration's most significant technical challenges involved enabling consistent recovery of high-quality DNA from sputum samples. Drawing upon prior experience with this highly challenging matrix, VCTS recommended incorporating two additives into the sample-preparation workflow: TCEP, a reducing agent that helps liquefy viscous sputum, and EGTA, a chelating agent that reduces calcium-mediated inhibition of DNA polymerase activity.

Co-Diagnostics ultimately integrated both additives into a single lyophilized bead within the sample lysis consumable, creating a simplified workflow capable of supporting both sputum and tongue-swab specimens.

The teams also addressed elevated assay failure rates associated with residual PCR inhibitors. **Based on VCTS recommendations, the sample dilution buffer volume was increased from 1.2 mL to 2.0 mL, reducing assay failure rates from approximately 8% to just 0.5%.**

Together, these improvements enhanced workflow robustness and increased confidence in the platform's ability to perform reliably in decentralized and resource-constrained settings.

> "What made this collaboration stand out was the relationship behind the work. The VCTS | Quantigen Biosciences team combines deep technical expertise with a level of trust and collaboration that makes solving difficult problems much easier."
>
> — Joseph Featherstone, Co-Diagnostics

Outcomes and Broader Impact

Through the collaboration, Co-Diagnostics advanced several key elements of diagnostic development and implementation readiness, including:

- More robust sample-preparation workflows
- Significant reduction in assay failure rates
- Enhanced analytical validation strategies
- WHO-aligned and country-specific validation planning
- Greater readiness for multi-site and international deployment
- Increased confidence in workflow scalability for LMIC environments

This collaboration demonstrates the value of integrating translational laboratory science, validation strategy, and implementation-focused problem-solving early in the development process. As molecular diagnostics continue to move toward decentralized and point-of-care models, partnerships that bridge scientific innovation with real-world operational requirements will play an increasingly important role in expanding global access to advanced testing.

The Role of Versiti Clinical Trial Solutions

Versiti Clinical Trial Solutions supports biotechnology, diagnostic, and clinical research organizations through integrated scientific, laboratory, and translational-development services. Through Quantigen Biosciences, VCTS combines molecular diagnostics expertise, analytical validation capabilities, operational infrastructure, and collaborative scientific leadership to help organizations move from innovation to implementation.

By aligning scientific rigor with practical deployment requirements, VCTS helps partners accelerate development readiness, navigate validation challenges, and expand access to advanced diagnostics worldwide.

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Versiti Clinical Trial Solutions
clinicaltrials@versiti.org

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