Ultra-High Throughput (UHTP) Assay Development: Utilizing the Nexar™ PCR Platform for COVID Testing

Introduction

In December 2019, an outbreak of an atypical, pneumonia-like illness was reported in Wuhan, China. Within months, the illness was identified as COVID-19, a novel coronavirus, and was declared a global pandemic by the World Health Organization (WHO). By April 2020, the United States became the epicenter of the crisis, surpassing other countries with more than 500,000 confirmed cases and 18,600 deaths.

Amid the rapid spread of the disease and severe shortages of diagnostic testing resources, Quantigen, a division of Versiti Clinical Trial Services (VCTS), partnered with the Gates Foundation to develop a transformative, end-to-end COVID testing solution. This case study highlights how Quantigen's innovative approach addressed critical diagnostic challenges during the pandemic.

Addressing Key Diagnostic Challenges

Existing COVID-19 diagnostic methods faced multiple limitations:

- Invasive sample collection methods: Nasopharyngeal swabs caused patient discomfort and were impractical for at-home use.
- Supply chain bottlenecks: Shortages of viral transport media (VTM), swabs and other consumables severely restricted testing capacity.
- Turnaround time (TAT): Logistical delays extended TAT, impeding timely diagnosis.
- Limited throughput: Available testing methodologies were not scalable for population-level testing needs.
- Virus stability concerns: Initially, virus stability was believed to require VTM; however, Quantigen confirmed the stability of CoV RNA on dry swabs, even at room temperature.

Quantigen developed a novel solution that addressed these challenges and established a foundation for ultra-high-throughput testing.

The Testing Solution

Working with the Gates Foundation, Quantigen defined the following objectives for their COVID-19 diagnostic solution:

- Convenient and comfortable sample collection: Transitioning to anterior nares sampling enabled patient-friendly, at-home sample collection.
- Cost-effective collection kits: The new collection kit eliminated the need for VTM, was low-cost (under $5 per unit) and was scalable for mass production.
- UHTP workflow compatibility: The system supported tens of thousands of tests daily using automation.
- FDA Emergency Use Authorization (EUA): The solution met rigorous clinical and regulatory standards, achieving EUA approval in less than six months.

Development Process

Quantigen leveraged its expertise and extensive network of collaborators to deliver a robust testing solution within five months. Key milestones included:

- **Designing a novel collection device:** The SteriPack XpressCollect device supported both in-clinic and at-home collections, paired with app-based accessioning for streamlined workflows.
- **Establishing sample stability:** Quantigen confirmed the stability of COVID-19 RNA on dry swabs, even under warm conditions, validating the practicality of the collection method.
- **Validating direct lysis:** A direct lysis protocol eliminated traditional sample preparation steps, optimizing speed and simplicity.
- **Ensuring assay accuracy:** The Quantigen team rigorously validated the assay against existing methods, demonstrating exceptional accuracy.
- **Repurposing the Nexar™ UHTP PCR system:** Traditionally used for agricultural genomics, the Nexar system was adapted for diagnostic testing in collaboration with Corteva Agriscience, Northwell Health and LGC Biosearch Technologies. The system enabled up to 100,000 reactions per 24-hour period.
- **Securing EUA approval:** On April 27, 2022, the FDA approved the assay for emergency use.

Conclusion

Quantigen's innovative approach to COVID-19 diagnostics demonstrates how agility and collaboration can transform public health outcomes during a crisis. By repurposing the Nexar™ UHTP PCR platform, Quantigen delivered a scalable, cost-effective and reliable testing solution. Beyond its immediate impact on pandemic management, the platform highlights the potential for future applications in routine infectious disease surveillance and pandemic preparedness.

Key Milestones:

- Designing a novel collection device
- Establishing sample stability
- Validating direct lysis
- Ensuring assay accuracy
- Repurposing the Nexar™ UHTP PCR system
- Securing EUA approval

Quantigen continues to set the standard for biomarker assay development, ensuring readiness for emerging global health challenges.

For more information about our services, contact: **Clinicaltrials@versiti.org**

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