

# Benchmarking a Respiratory PCR Panel for FDA Submission

*A complete solution for your research!*

## Overview

Accuracy, speed, and regulatory compliance are essential in PCR-based diagnostics. When a leading diagnostics company sought FDA approval for its new respiratory panel, they turned to Boca Biologics to run a method comparison study against an FDA-approved assay. The goal: establish the Limit of Detection (LOD), assess false positives/negatives, and benchmark assay performance under real-world conditions.

## Outcome & Impact

The study concluded successfully—providing the sponsor with:

- Strong data on LOD and overall assay concordance
- Supportive evidence for FDA submission
- A streamlined experience with minimal disruption despite enrollment and comparator-related delays

This case underscores the value of a lab partner who can adapt quickly, manage complex study logistics, and uphold regulatory-grade precision.

## THE CHALLENGE

The primary challenge was conducting the study within a narrow window during respiratory season—requiring strict timing and rapid sample processing. Additionally, to meet FDA expectations, the study had to:

- Demonstrate assay performance via concordance with a validated comparator
- Maintain consistent sample storage and handling throughout the trial

The investigational assay's LOD and rate of false positives/negatives were key performance indicators, impacted by assay design, target gene selection, and internal QC systems.

## BOCA BIO'S ROLE

Boca Biologics provided end-to-end laboratory support, from protocol alignment to sample management and testing execution. Highlights include:

- CLIA-accredited, CAP-certified laboratory environment
- Simultaneous testing of the investigational and FDA-approved assays on identical respiratory specimens
- Use of a third-party discordant assay to resolve mismatched results
- Biospecimen banking and environmental controls maintained under one roof
- Flexible lab scheduling to accommodate peak infection season

While Boca Bio did not perform the statistical analysis (this was sponsor-led), we delivered high-quality, reproducible data to fuel that interpretation.



## KEY TAKEAWAYS FOR PHARMA & DIAGNOSTICS COMPANIES



**Method comparison studies** are essential—not only for FDA approval but also for LDT deployment and commercial readiness.



**LOD benchmarking** is a critical step in evaluating assay sensitivity and minimizing false results.



**Choosing the right partner**—with infrastructure, expertise, and responsiveness—makes or breaks study success.



**Early planning and comparator selection** improve the likelihood of on-time, high-quality results.

## WHY BOCA BIOLISTICS?



With 15+ years of experience supporting diagnostics and assay validation, Boca Bio combines scientific rigor with operational agility. Our lab focuses on research, not routine testing—ensuring your project is treated with the urgency and attention it deserves.



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