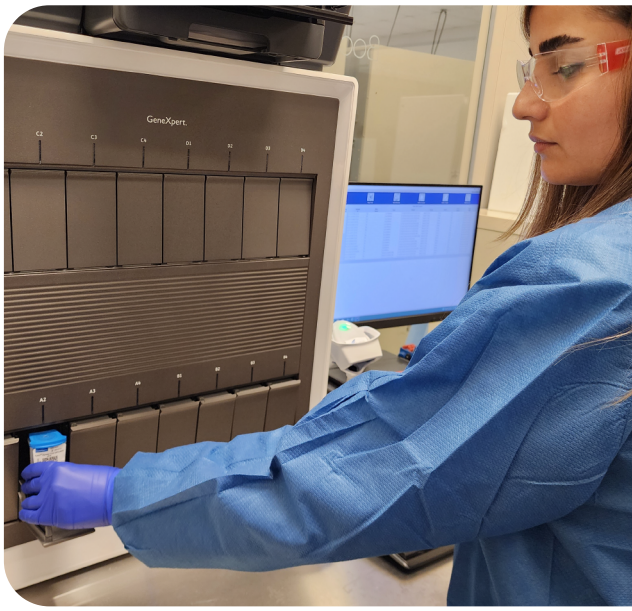
Prospective Study

Point-of-care comparative study supports successful 510(k) clearance with CLIA waiver designation

Study of 300 adults immunized with a competitor's product completed within four months



Challenge

Medical devices submitted to the FDA for 510(k) approval require evidence that the investigational product (IP) is "substantially equivalent" to an existing approved device (i.e., a predicate device). Recruiting subjects and clinically testing both the IP and the predicate device can be time-consuming and costly, especially when using different vendors for IP and predicate management.

Client: Small biotech developing point-of-care diagnostics

Solution

Study enrollment:
2x nasopharyngeal swabs from ≤850 subjects
6 clinical sites

Subjects:
Suspected respiratory infection (influenza A/B, COVID-19)
At least 12 month of age

Completed in 4 months with 700 subjects

Clinical component:
Point-of-care investigational product trained and managed in a CLIA-waived environment and performed on a single swab per subject.

Laboratory component:
To evaluate equivalency, the second swab was shipped frozen for predicate device testing. Raw data and results delivered within two days of sample receipt.

Results

Boca Bio managed both the clinical point-of-care IP device and the predicate device at its laboratory. Recruitment achieved the requested positivity rate with only 700 donors over 4 months, despite the study not being conducted during the peak respiratory season.

Based on the study data, the 510(k) submission was approved with a CLIA waiver, allowing point-of-care sites to use the device without meeting stringent CLIA requirements.

> **"This milestone would not have been possible without your partnership and commitment throughout the clinical program."**
>
> *– VP Product Development*

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Summary

The U.S. Food and Drug Administration (FDA) created the 510(k) process for new medical devices that demonstrate equivalency to currently available technologies (i.e., predicate devices), protecting patients from unsafe and ineffective products while promoting innovation with a streamlined regulatory pathway.

To support a 510(k) submission, an American biotech company specializing in point-of-care diagnostics engaged Boca Bio to conduct a pivotal trial demonstrating that its new point-of-care investigational product (IP) for respiratory infection diagnosis is equivalent to an existing technology. It was estimated that 850 subjects aged 12 months or older with respiratory symptoms would be recruited to meet positivity requirements. The trial involved two critical components: point-of-care testing of the IP at six clinical sites and parallel testing with a predicate device at Boca Bio's lab in Florida (**Figure 1**).

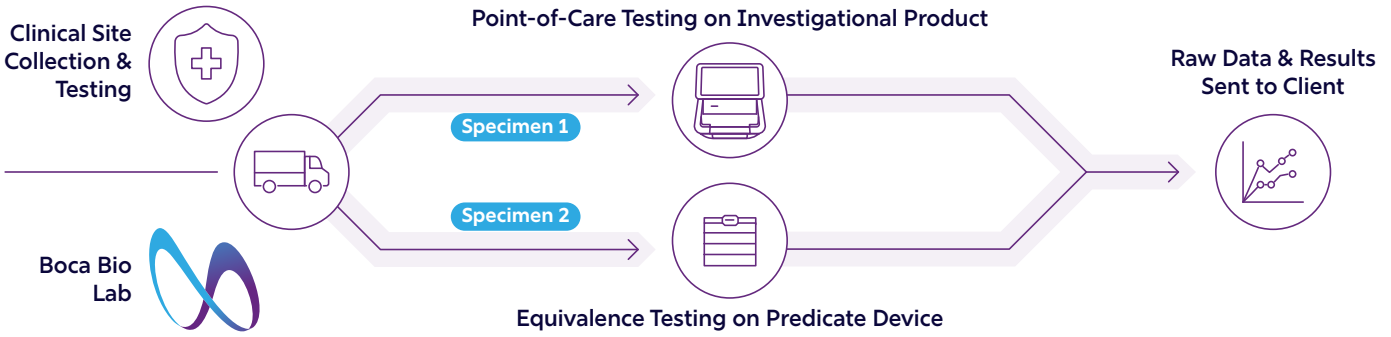

Figure 1. Equivalency study workflow at Boca Biolistics with parallel clinical and laboratory operations. See our analytical method comparison and clinical research service capabilities for more information.

To satisfy the clinical component, the IP devices were sent to each of the six clinical sites, and staff were trained on their workflows, which were managed under a CLIA-waived setting to support the 510(k) submission. Two nasopharyngeal swabs were collected from each donor; one was evaluated with the point-of-care IP device on-site, while the other was sent to the Florida laboratory for equivalence testing.

Equivalence testing was completed within two days of sample receipt, and all raw data with results were delivered to the client. Clinical and laboratory coordination required extensive quality control, as well as inventory and sample traceability.

Overall, only 700 donors were needed to complete the study, which was completed within four months. The reduced time and effort to completion were possible despite the study being conducted during non-peak respiratory disease season.

The client successfully obtained FDA 510(k) clearance and a CLIA waiver, enabling US marketing of a novel point-of-care device for rapid testing of respiratory infections without specialized training or workflows. Boca supported this important breakthrough by providing **clinical samples, venues, and equivalence testing**, delivering them **faster than expected and under budget**.

Ensuring sample traceability

Boca Bio maintains full traceability of all specimens and materials through a robust chain-of-custody system, ensuring accurate tracking from collection to final delivery. Our preservation protocols are designed to sustain sample integrity, utilizing validated temperature controls and specialized packaging solutions.

During handling and shipping, all materials are managed in accordance with regulatory standards and industry best practices, with continuous monitoring to safeguard quality and reliability throughout transit. Specimen quality is our top priority, enabling our clients to achieve the best possible outcomes and advance their research, leading to safer, more effective products for patients.

Do you need clinical and laboratory support in your 510(k) submission? **Contact us**

Reference

FDA Continues to Take Steps to Strengthen the Premarket Notification [510(k)] Program - Program Updates | FDA (no date). Available at: https://www.fda.gov/medical-devices/510k-clearances/fda-continues-take-steps-strengthen-premarket-notification-510k-program-program-updates (Accessed: April 15, 2026).

FDA 510(k) Clearance Explained: How It Works (2025 Guide) (no date). Available at: https://www.complizen.ai/post/what-is-510k-fda-medical-device-overview (Accessed: April 15, 2026).

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