

HOW A GLOBAL TOP-3 DIAGNOSTICS LEADER SCALED SAMPLE ACCESS WITH BOCA BIO



BocaBio

Driving Science Forward for Patients Worldwide

THE CHALLENGE

The project sponsor, a global top-three diagnostics provider developing in-vitro diagnostic tests for diseases such as HIV and hepatitis, approached Boca Bio about biospecimen procurement for the development of new products.

The sponsor's tests are critical tools for diagnosing patients with complex chronic conditions. Accurate diagnosis is necessary for developing treatment plans that give patients better quality of life and a longer life expectancy. Diagnostic screening for complex diseases isn't a one-size-fits-all proposition. Diseases such as HIV require different types of testing to measure factors like antigens, antibodies, or viral load. Each testing variant must comply with strict regulatory requirements to gain approval.

The sponsor had two teams, the Molecular division and Core Diagnostics, developing new diagnostic assays that would address the needs of clinicians treating patients with a wide range of disease states. Full approval required extensive documentation of product accuracy using real patient samples.

THE GROWING NEED FOR HIGH-QUALITY, HARD-TO-FIND BIOSPECIMENS

Obtaining high-quality biospecimens with accurate reactivities or rare disease states was essential for validating new assays. As the demand for biospecimens increased to keep up with regulatory approvals, the sponsor sought a partner to assist in acquiring suitable samples to complete their studies and submission.

To be successful, the sponsor required consistent access to HIV-positive samples with specific viral titers, genotyping, and HIV 1/2 differentiation. Before partnering with Boca Bio, the sponsor either sourced samples in-house or relied on other biospecimen providers. However, they found both approaches to be time-consuming and inefficient.

The samples they received often lacked consistency, quality, and reproducibility. When vendors delivered unreliable samples, the sponsor faced a number of challenges:

- Rising project costs from wasted time and unusable samples
- Delayed submissions as teams waited for consistent specimens
- Risk of lower approval rates due to inconsistent or poor-quality data
- Misplaced focus on troubleshooting assays instead of working with reliable samples
- Added strain on R&D teams, pulling resources away from innovation

With sample procurement challenges mounting, the sponsor reached out to Boca Bio for assistance with their comprehensive sample needs. Working with the project leads, the Boca Bio team developed a plan to locate and deliver even the most specifically defined sample types quickly and reliably.



THE SOLUTION

Boca Bio's unique capacity and expertise in biospecimens, clinical research services, central laboratory, and biostorage all proved critical for helping the sponsor accomplish their project goals on time.

The Boca Bio research team worked with the sponsor to identify their exact biospecimen qualifications for successful project completion and approval. They pinpointed four key priorities:



- ✓ Access to rare and complex disease populations
- ✓ Reliable data and consistency
- ✓ Repeatable results across samples
- ✓ Ability to deliver quickly and at scale



RAPID ACCESS TO HARD-TO-FIND SAMPLES

Boca Bio worked with the project sponsor to identify the specific specimen needs. While other suppliers struggled to locate the rare, high-quality biospecimens required for the project, Boca Bio could tap a million-specimen inventory and global collection network. To source samples that met the sponsor's requirements, Boca Bio identified candidate samples in their repository, and conducted batch screening in their CAP/CLIA lab to identify qualifying samples. Within days, Boca was able to provide a catalog of thousands of suitable samples for the sponsor's study.

HIGH-QUALITY TESTING, VALIDATED ACROSS ASSAYS

Boca Bio runs its own central lab, equipped with 10 molecular analyzers and 4 immunoassay analyzers. This setup makes it possible to deliver fast, flexible, and multi-assay testing.

As the sponsor prepared for regulatory submission, Boca Bio stepped in as the clinical testing site for the method comparison study. The lab is CLIA-certified and CAP-accredited, offering more than 200 tests and the flexibility to bring new assays and modalities online when needed. With this infrastructure in place, the sponsor got the results required to move forward with FDA-facing studies. Boca Bio's testing capabilities made it possible to meet regulatory standards on time and with confidence.

RELIABLE DATA MANAGEMENT AND TRACEABILITY

Boca Bio managed more than 18,000 samples for this project using its LIMS, Matrix Gemini, giving the sponsor access to over two decades of data in one place. Robust record-keeping and sample tracking made it easy to retrieve exactly what was needed at every stage of the study. Matrix Gemini offers a secure, customizable web portal that gave the sponsor real-time access to their data. The sponsor also relied on Boca Bio's comprehensive LIMS to automate workflows, standardize processes, manage inventory, and integrate with lab instruments. Detailed reports and audit trails ensured data quality and kept everything aligned with regulatory requirements. In addition to the technology, Boca Bio provided white-glove support. Every sample was stored securely and handled with care, giving the sponsor confidence in its integrity. This combination of reliable systems, state-of-the-art facilities, and attentive service made regulatory reviews smoother, reduced the risk of errors, and gave the sponsor peace of mind from start to finish.

GLOBAL REACH AND SPECIALIZED COLLECTIONS

Boca Bio works with more than 120 collection sites approved by IRB/EC in over 60 countries. This global network gave the sponsor access to samples from a wide range of populations, including rare disease states, without the headache of setting up their own international collection efforts. Over the past two decades, Boca Bio has built a repository of more than one million specimens across many disease areas, and it continues to grow every year. This global reach shortened timelines, cut costs, and expanded the range of specimens available to the sponsor.

END-TO-END SAMPLE SUPPORT AND PROJECT EXECUTION

The Boca Bio team worked with the sponsor's project leads to manage the full scope of the study. Over the course of the project, Boca Bio delivered:

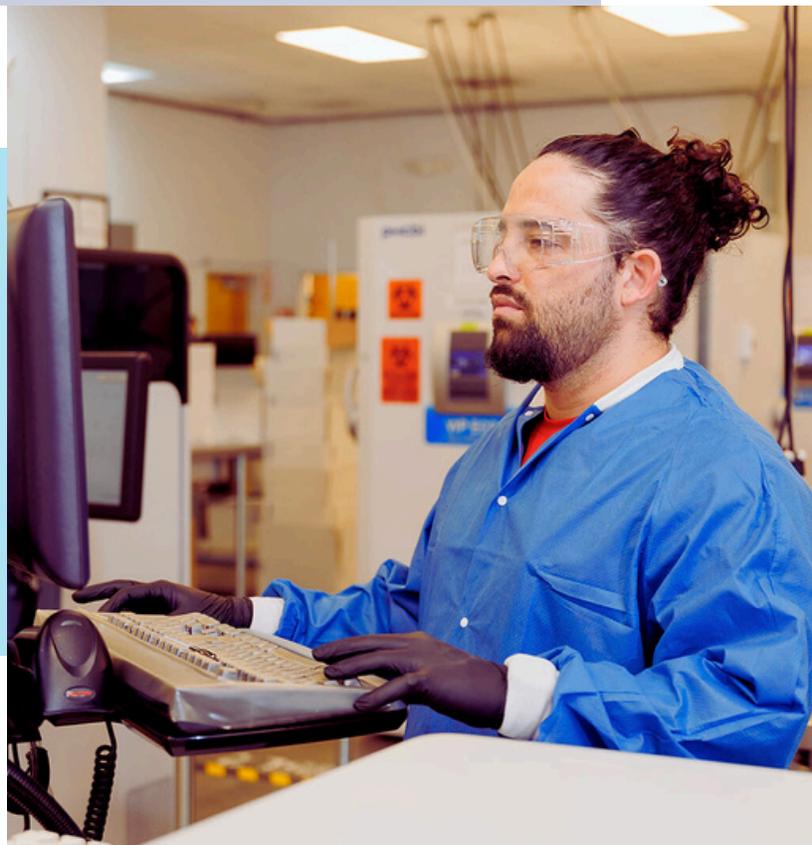
**SAMPLE
SOURCING**

**SAMPLE
TESTING**

**SPECIMEN
STORAGE**

**DATA
DELIVERY**

**RAPID RESPONSES
TO SPONSOR
REQUESTS**



Boca's vertically integrated business model made things easier for the sponsor's research team. They didn't have to worry about when or how specimens would arrive, which kept the project moving on time. Research, documentation, and data delivery all stayed on track, so the sponsor could move ahead with their regulatory filing as planned.

THE RESULTS

Maintaining momentum

Smooth, scalable sample procurement and testing drove time-sensitive studies forward without delays due to sourcing bottlenecks. As a result, the sponsor was able to stay on track with critical timelines, avoiding costly rescheduling or missed submission windows.

Increased focus on science and strategy

Boca Bio coordinated all aspects of sample procurement, testing, and biostorage, adapting to the sponsor's evolving needs along the way. This flexibility and comprehensiveness of Boca Bio's capabilities meant the sponsor's team leads and staff were free to focus on advancing programs instead of chasing down hard-to-find specimens.

Speed and confidence in meeting regulatory expectations

With researchers and project leads dedicated to the scientific aspects of the project, the sponsor proceeded confidently to the final stages of regulatory approval. Flexible access to qualified samples and test results meant the sponsor could respond quickly to regulator queries with clear, validated data. Robust documentation and demonstrable data integrity reduced the risk of pushback or additional regulatory requests during the approval process.

Reduced costly do-overs and delays

During post-regulatory compliance audits, Boca Bio provided the sponsor with complete, traceable data records. The sponsor was able to reply promptly and completely in audits, avoiding costly do-overs or delays. Audits became smoother and less stressful thanks to Boca Bio's structured, compliant systems and historical data access.



THANK YOU

Empowering Innovation, Together

At Boca Biolistics, we're proud to support the world's leading diagnostic innovators in advancing science and improving patient care.

From sourcing hard-to-find biospecimens to providing full-service lab and data support, we're here to help you accelerate discovery—every step of the way.



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