

# A 20-year Contribution to *In Vitro* Enteric Diagnostics

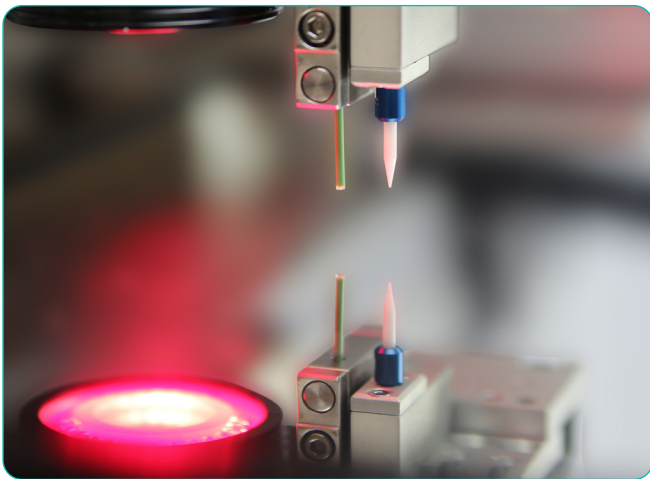
*Lateral flow testing offers rapid detection of many pathogens but can be problematic when analyzing fecal matter, as clogging caused by insoluble material may result in inconsistent sample flow and test failure. QUIK CHEK™ diagnostic tests from TECHLAB, part of SSI Diagnostica Group, employ advanced upflow technology to overcome the unique challenges of fecal sample analysis by lateral flow. It is essential that these assays perform reliably and consistently, and the company relies on BioDot's advanced striping and cutting systems for accuracy and reproducibility during production.*

TECHLAB, part of SSI Diagnostica Group, is an innovator in rapid enteric diagnostics, and is known for its *Clostridioides difficile* (*C. difficile*) diagnostics solutions, as well as offering tests for parasitology, intestinal inflammation, Shiga toxins, *Campylobacter*, and respiratory pathogens. The company grew out of research at the Virginia Tech Anaerobe Laboratory in the 1970s and 1980s, where its founders helped to identify *C. difficile* as a major hospital pathogen, and developed the first commercial diagnostic reagents for its identification. The company was established in 1989 to bring these innovations to market, initially focusing on R&D while its early products were manufactured and distributed by another firm. As demand increased and external manufacturing arrangements shifted, TECHLAB, part of SSI Diagnostica Group, brought production in house and began its transition into a full diagnostics manufacturing company. Since then, the company has gone from strength to strength, undergoing the Medical Device Single Audit Program (MDSAP) process and achieving ISO 13485 certification and FDA registration. Today, its Virginia manufacturing site in Radford is complemented by others in Florida, California, Denmark, and China, giving it a global presence that supports worldwide distribution.

**Steven Harvey, vice president of operations and Virginia site lead**, joined the company in 1995 and oversees global operations and leads the Virginia sites directly. He described the company's route to success

over the past three decades: "I joined the company when it was a small start-up with around 12 employees. At that time, it was mostly an R&D company, with a couple of FDA-approved products being manufactured and distributed by another firm. That company was bought out and, with production set to move to another site, I was asked to help establish a manufacturing business capable of in-house fabrication. Thirty years on, we're now a leading global manufacturing company in the diagnostics arena, employing over 160 people at our Virginia site."

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Steven continued: “QUIK CHEK is a rapid membrane enzyme immunoassay. Its upflow technology uses porous pads and membranes to filter the insoluble materials typically present in fecal samples to avoid clogging. We use BioDot systems to stripe an antibody to a specific target onto a membrane, which requires consistent dispensing of very specific volumes over the length of the material. The Vision QC option then performs in-process inspection to verify that the line has been printed onto the membrane correctly, and meets the necessary width specifications. However, one membrane was difficult to run on a reel-to-reel machine. BioDot helped us to develop a way of working with this material that overcame this challenge. We spent a week at the company’s Irvine facility, then technicians from BioDot’s service department came to Virginia to help us establish the system on site, working with us to achieve our goals.”

Steven explained the benefits of choosing BioDot solutions for the company’s processes: “One of our products uses dots instead of lines. BioDot was one of the few companies that could generate the dots and spacing necessary for the control line area to work, and we have stuck with the company ever since. As well as manufacturing facilities, we also have an R&D arm that is responsible for new product development, looking for novel biomarkers and enhancing existing technologies by employing new test formats to boost sensitivity and specificity. The big advantage here is that BioDot has smaller benchtop units that use the same dispensing technology as the larger reel-to-reel systems, so scaling up from R&D to production is straightforward. This seamless transition simplifies process validation and saves a lot of time. There is also the option to add or replace platform modules – changing the configuration

according to the assay’s performance criteria – which is really beneficial for R&D, allowing researchers to explore different optimization parameters to meet the required specifications.”

“We are also looking at cross-site redundancy, so that we have a backup plan should we need to move manufacturing to another facility, for instance, if materials are harder to obtain in one area than another,” Steven added. “Having the same technology platform across our sites means that we can quickly relocate production should we need to, supporting supply chain continuity. This also simplifies staff training.”

TECHLAB, part of SSI Diagnostica Group, had two BioDot RR4500™ reel-to-reel web handling dispensing systems before the COVID-19 pandemic, and added four RR120™ systems to bolster its existing manufacturing capacity when it joined the National Institute of Health’s RADx™ Tech initiative. In addition to these systems, the company uses several other liquid dispensing automation and manufacturing solutions from BioDot, including an LM8020™ laminator, an AR4000™ dipstick assembly roller, three CM4000™ dipstick cutters, a CM5000™ guillotine cutter and three ZX1000™ reagent dispensers. Typically, these are maintained by its in-house team of equipment technicians. “Installation of the reel-to-reel striping machines for the RADx contract was pretty turnkey; BioDot came to our facility, took them out of the crates and set them up for us. The company also works with our equipment maintenance team, offering guidance that enables our technicians to undertake installation and servicing of our BioDot systems in house, as well as rapidly troubleshoot any issues. We have enjoyed this successful relationship for over 20 years, and look forward to building on it further in the future,” Steven concluded.

To learn more about TECHLAB, part of SSI Diagnostica Group, visit <http://www.ssid.com>

For more information about BioDot’s liquid dispensing automation and manufacturing solutions, see [www.biodot.com/products](http://www.biodot.com/products)