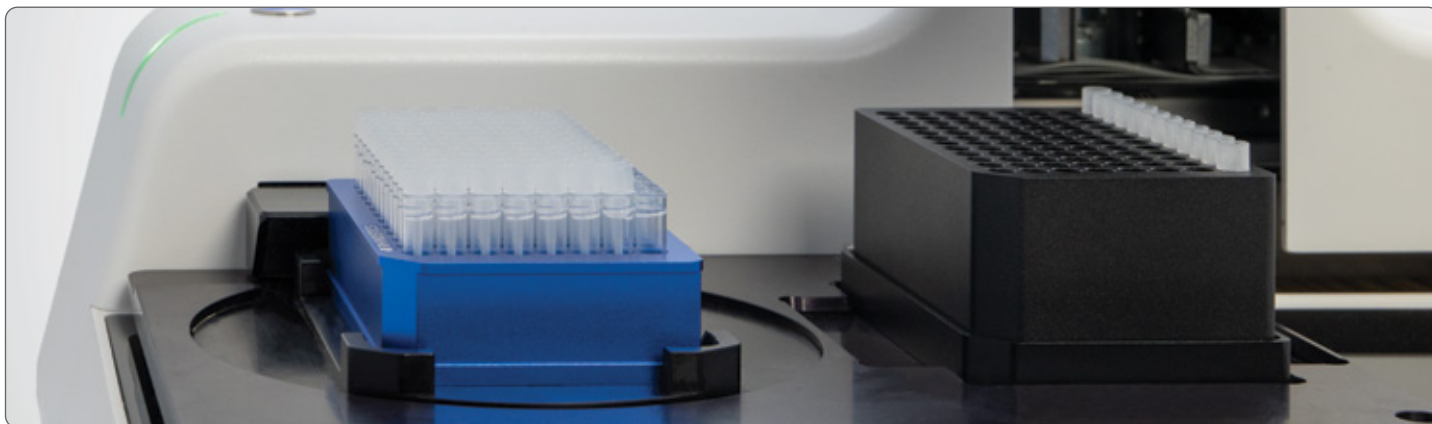


Building Connections To Create a Cost- Effective Swab Sample Self-Collection Future





Summary

Nexus Medical Laboratories specializes in offering improved access to laboratory testing for telehealth providers, partner laboratories, companies, schools, and associations. In their CLIA-certified laboratory, they process self-collected samples using an automated workflow that includes use of the RHINOstic® Automated Swab, LabElite® I.D. Capper, and Microlab® STAR automated workstation. This automated workflow enables ultra-rapid, reliable, and high-quality testing services at an affordable price.

For several years, the founders of Nexus Medical Labs watched the slow but steadily increasing demand for test kits based on self-collected sample collection. They also collected evidence to show a gap in the number of labs that dedicated efforts toward processing these samples.

They had the foresight to understand the significant multi-faceted potential of at-home collection. Patient experiences are enhanced through increased privacy and convenience, decreased hassle, and rapid access to results. Provider discussions are more informed. Aggregator test services are rapid yet affordable. Kit and device manufacturer products can develop and expand into new markets.

Then, the COVID-19 pandemic burst onto the global stage.

Accelerating Purpose-Driven Change

Seemingly overnight, demand skyrocketed for at-home SARS-CoV-2 kits and self-collected samples. Existing processing laboratories were overwhelmed with an influx of COVID-19 samples, which delayed time to results and shifted resources away from other critical testing needs.

The founders were determined to kick their plan into high gear. In record time, they secured funding, sourced space, procured and validated equipment, hired and trained staff, obtained necessary certifications and authorizations, and in early 2022, opened the doors to Nexus in Watertown, MA.

COVID-19 was heavily interwoven with the lab's business goal; and as such an urgent market need, it only made sense to primarily focus on testing self-collected COVID-19 samples. Today, their client base ranges widely; from universities with large-scale community interactions down to entertainment productions with small and often close-proximity interpersonal interactions.

“Speed, consistency, and cost-effectiveness are paramount in telemedicine and other self collection-based industries that we serve, so cutting-edge automation is key to our success,” notes Michele Hope, VP of Lab Operations at Nexus. “On top of that, automation enables instant scaling which helps us to maintain a low cost per test while easily managing spikes in testing demand like those that we’ve seen during variant surges to date.”

Breaking Through Old Bottlenecks

Automation is not a new concept in many laboratories; however, most labs focus on automating sample preparation and analysis steps. In a swab-based workflow, this means that accessioning, decapping, and capping steps are still performed manually. Nexus took a different approach to automation so that they could enhance speed and cost-effectiveness for their clients.

Nexus' molecular SARS-CoV-2 test, which has Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA), relies on an automated workflow. But unlike a typical automated workflow that neglects the time and effort needed in the workflow beginning steps, this assay workflow puts automation quite literally at the forefront.

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The Automated RHINOstic Workflow

The Nexus SARS-CoV-2 test workflow relies on three critical components: the RHINOstic Automated Swab from Rhinostics, Inc., the LabElite I.D. Capper from Hamilton Storage Technologies, and the Microlab STAR automated workstation from Hamilton Company.

Michele already had considerable experience with an automated RHINOstic workflow, including the Hamilton equipment, when working at a different laboratory. She says, "I heard a lot of great feedback about the ease of collection using the RHINOstic as well as the ease of processing using this combination of rugged and reliable products; I agreed with that feedback and felt that this workflow aligned perfectly with our need to rapidly process high throughput sample volumes and scale at a moment's notice."

The patent-pending and U.S. FDA Class I exempt RHINOstic device integrates a unique, polypropylene-based swab with an automation-friendly cap. After the nasal, buccal, or vaginal sample is collected, the swab is placed into a barcoded transport tube and ready for dry transport. The hydrophobic material and lack of viral transport media (VTM) help to reduce reagent costs, leaking/aerosol risks, and assay inhibitors. It also aids in ensuring complete sample elution compared to spun fiber swabs.

Once in the lab, the RHINOstic devices are placed in a RHINOrac™ in a biosafety cabinet

containing a LabElite I.D. Capper. The all-in-one LabElite I.D. Capper combines hands-free capping and decapping of RHINOstic devices. It also features high-speed barcode reading of full tube racks along with automatic information upload to a connected LIMS. The I.D. Capper is equipped with a 12-channel head and conversion kit when used in concert with RHINOstic devices.

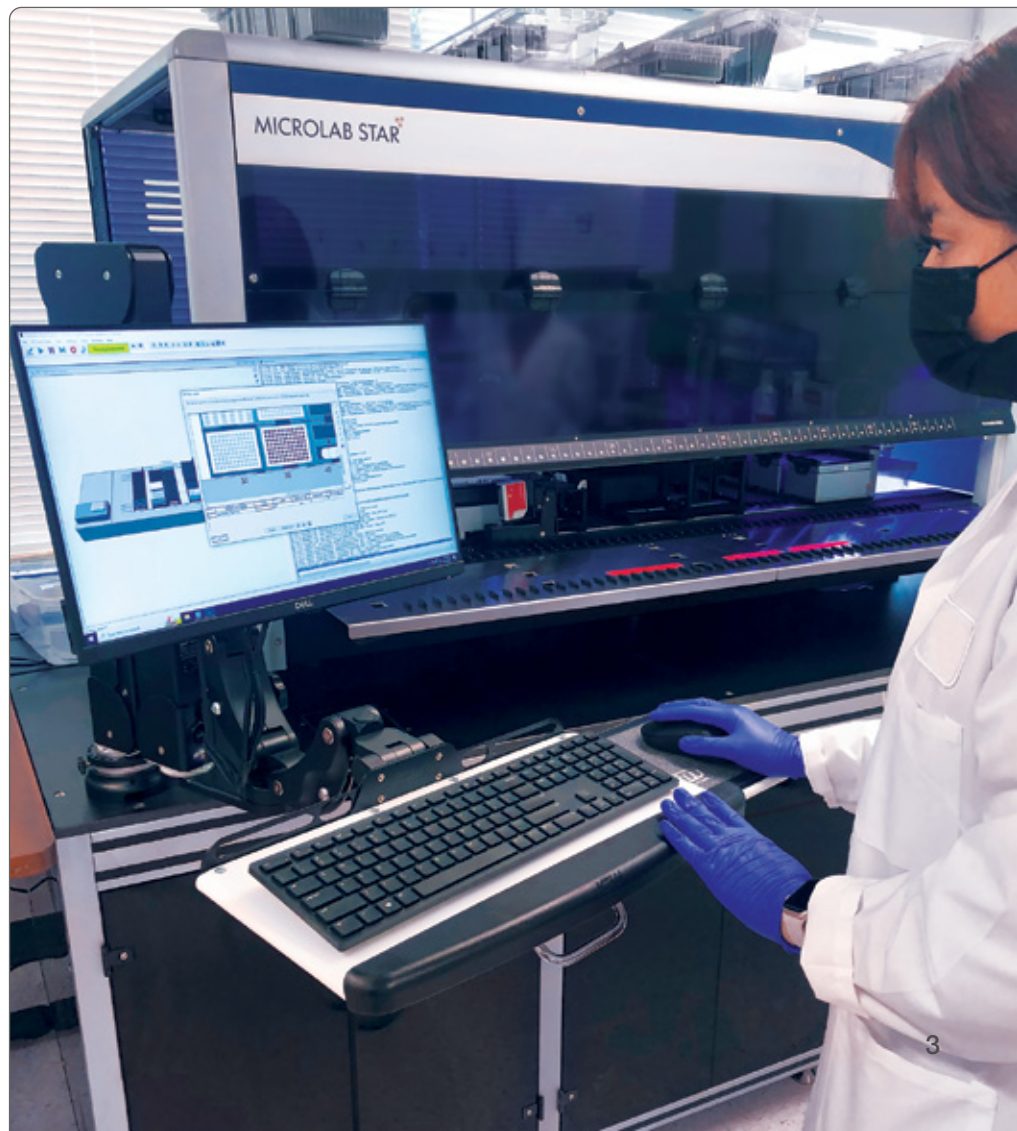
Once the tubes are decapped and the swabs are placed in a RHINOrest™ for safekeeping, a small amount of elution reagent is added to each tube, the swabs are automatically recapped onto the tubes, and particles fully elute from the swab. The RHINOrac containing sample tubes is then placed in an incubator or on a heating block for viral inactivation.

After viral inactivation, the rack containing sample tubes is moved to the Microlab STAR that is integrated with a LabElite I.D. Capper where the tubes are decapped again. Sample aliquots are transferred to a 384-well assay

plate along with master mix prior to off-deck PCR analysis using an Applied Biosystems QuantStudio™ 7 Flex Real-Time PCR System from Thermo Fisher Scientific. The Microlab STAR combines patented Compressed O-Ring Expansion (CO-RE®) technology for a precise lock-and-key fit, with unrivaled liquid level detection capabilities across a wide volume range. In addition to highly precise and accurate liquid handling, the STAR's high-capacity deck may be equipped with a wide range of peripheral devices to further enhance walkaway convenience.

The Nexus lab currently houses three Microlab STAR liquid handlers to reach a capacity of up to 20,000 samples per day and to enable redundancy in the event that one of the liquid handlers is offline for planned or unplanned maintenance. "We all agree that the STAR is a workhorse, and we also truly appreciate the responsiveness and helpfulness of our local Hamilton support team in helping us to get up and running quickly," adds Michele.

Benefits Beyond the Lab
 RHINOstic benefits aren't limited to laboratories. In fact, many patients appreciate the comfortable yet sophisticated experience of collecting samples using the RHINOstic.



Expanding into a Successful Tomorrow

Self-collection kits are racing forward as convenient tools that also expand access to necessary healthcare. To process the growing influx of samples, Nexus is poised at the leading edge of technology. Now that the EUA-approved automated SARS-CoV-2 assay is in place, Nexus can expand their goals to move into different testing areas and partner with companies looking to develop and commercialize additional self-collection based tests and devices.

Michele notes that the lab is applying learnings from their COVID workflow to other automated RHINOstic-based assay workflows including those for sexually transmitted infections (STIs), and other respiratory pathogens, including a multiplexed assay for SARS-CoV-2, influenza, and respiratory syncytial virus (RSV) to counter any infection surge as students return to school in the fall. "A significant reason why we can offer testing at a lower cost point compared to many manually processed commercial assays is our ability to scale our automated workflow without impacting labor allocations," she remarks. On top of cost, rapid turnaround times mean that their clients can quickly make informed decisions that impact their business and people.

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The disposable RHINOstic Automated Swab is registered as a Class I exempt medical device with the U.S. FDA and may be used for clinical collection upon CLIA validation.



For additional information on Rhinostics products including technical specifications: Visit www.rhinostics.com

For additional information on Hamilton products including technical specifications: Visit www.hamiltoncompany.com/automated-liquid-handling/platforms

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