

Increase Stick-to-Itiveness Even When Lab Disruptions Loom Large

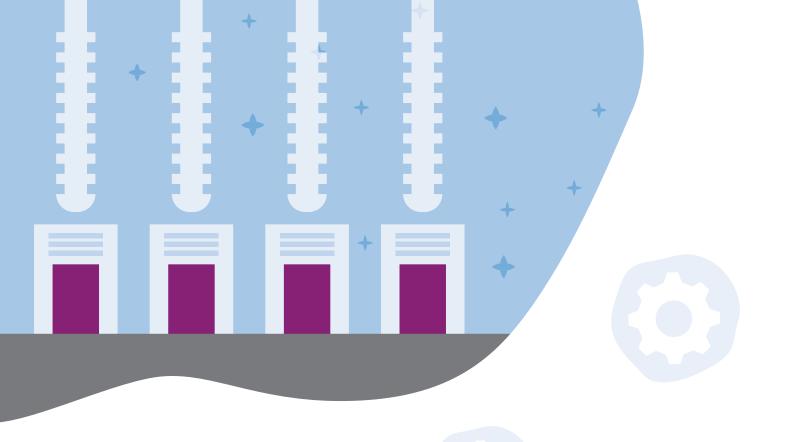


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Introduction

Global or regional disease outbreaks bring about surging demand on sample testing laboratories. This disrupts the lab's normal ebb and flow of activity and stretches lab personnel to their limits.

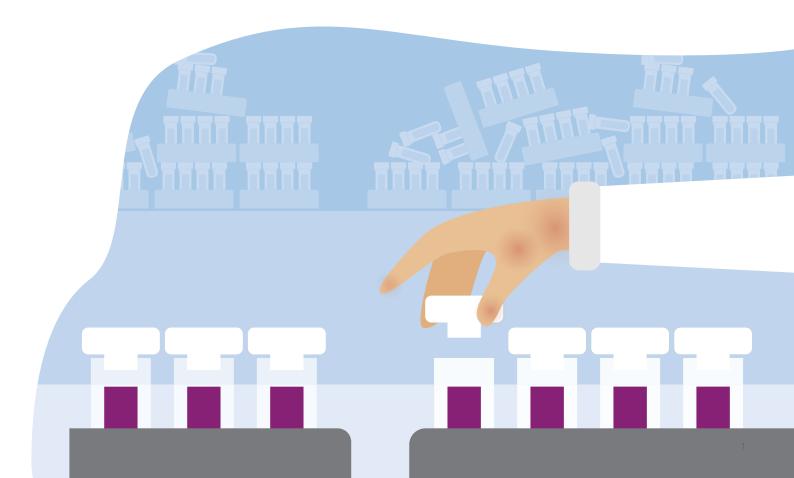
Workflows remained unchanged for decades and included laborious manual decapping and accessioning steps. Swab collection materials were constructed of hydrophilic flocked materials that risk sample contamination, resist elution, and require use of viral transport media (VTM). VTM was originally used to feed virus for culture; a practice that is unnecessary in PCR or protein-based applications, such as those used in COVID-19 tests methods.

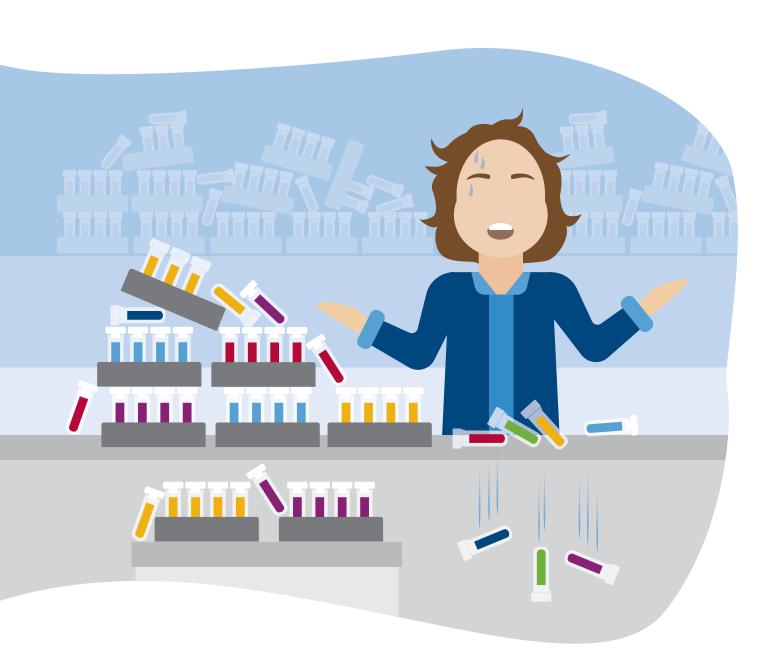
The COVID-19 pandemic effectively demonstrated the consequence of a swab shortage, swab material limitations, and testing bottlenecks that delayed diagnosis at the worst possible time. Laboratories were pushed to the edge of their limits and beyond to keep up with the increasing and variable COVID-19 testing volumes.

So, how can labs persevere through these disruptions and deliver consistent, timely results? Fortunately, new and unique innovations completely rethink nasal swab design and workflow processing to aid clinicians, commercial diagnostic labs, and university or public health testing labs.

The patent-pending RHINOstic nasal and buccal swab collection device integrates a unique, polypropylene-based swab with an automatable cap. In addition to the all-in-one configuration, comfortable sample collection, and simplified dry transport, the RHINOstic is amenable to automation via the LabElite DeCapper equipped with a 12-channel head and conversion kit. This elegant and impactful system innovation improves sample decapping and accessioning to bypass disruptions due to traditional swab shortages. It also helps to improve sample processing workflows to minimize disruptions throughout the lab.

In this piece we'll discuss how—with the combination of RHINOstics with the LabElite Decapper in an automated workflow—busy testing labs can stick to a plan that maximizes productivity while minimizing disruptions, even during trying times. Labs can manage the ebbs and flows of COVID-19 and respiratory testing volumes with the same equipment and personnel.





Time is So Precious

When it comes to determining the presence of pathogens or antibodies in a sample, every minute counts. In this setting, the goal isn't just to reach an arbitrary number regarding minutes per sample or samples per day. Patient health and wellbeing are at stake. Delays in patient sample testing could make the difference between a brief office visit and an extended hospital stay or worse.

The clock starts ticking the moment the sample is collected. How much time are healthcare professionals spending on calming patients, swabbing patient noses, and even changing their protective gear after being sneezed upon as the swab irritates sensitive tissues?

Once delivered to the testing lab, technicians exert precious time to manually accession the samples with a handheld barcode reader. In a worst case scenario, they must decipher cryptic handwriting on a collection tube.

Pity goes to those who draw the short straw on the to-do list for they must manually decap a full rack of tubes. Manual decapping 96 samples can take a long time. It can also trigger repetitive motion injuries and time out of the lab during recovery.

Automation Provides Time to Work Smarter, Not Harder

The RHINOstic consists of a polypropylene swab that is integrated into a cap, and a transport tube labeled on the bottom with a unique two-dimensional (2D) barcode. The swab allows for rapid and easy sample collection from the front of the nose. In addition to minimizing patient discomfort, it can facilitate self-swabbing to reduce the amount of time that healthcare professionals spend on collecting samples and can be performed in remote locations. This time savings is especially useful at large or drive-thru collection facilities.

The RHINOstic offers dry collection, where VTM is not required, with 72 hours ambient temperature stability. This is a significant advantage, preventing spills of VTM during self-collection, shipping or decapping in the laboratory. In addition, the cost and logistics of sourcing VTM can create headaches and unnecessary burdens. COVID-19 testing is based on PCR and antigen testing, not viral culture.

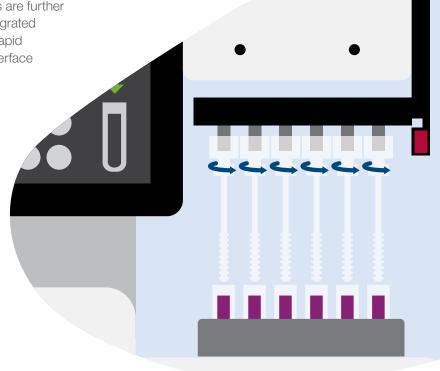
The capped swab is easy screwed into the collection tube for secure transport to the processing lab.

In the processing lab, RHINOstic tubes containing samples are placed onto the LabElite DeCapper. This automated tube decapping device enables labs to get more done in less time, and with less human intervention, compared to manual methods. These benefits are further enhanced when the LabElite DeCapper is integrated within a larger automated workflow system. Rapid navigation through the simple touchscreen interface saves time, even for novice users.

A 2D barcode reader embedded in the LabElite DeCapper automatically reads each tube's bottom barcode for immediate and hands-free accessioning compared to time-consuming manual scanning of side barcodes.

During accessioning, up to 96 RHINOstic tubes may be automatically decapped on the LabElite DeCapper in less than two minutes while elution buffer is added, either with a multi-channel pipette or any Hamilton automated liquid handler. The samples can then be heat inactivated in an aluminum sample block or with a chemical inactivation agent before assay set up with the LabElite Decapper and Hamilton automated liquid handler. This is substantially less time than the time it takes to decap the tubes manually, and the automated method also allows users to attend to other tasks while the tubes are decapped.

Accessioning and decapping RHINOstics on one unit reduces workflow steps, while the increased throughput enables more tests to be completed at once compared to manual methods to reduce or prevent backlogs. On top of this, as human intervention is minimal, the need for time-consuming retesting due to human error is greatly reduced.







Sample Integrity is Vital

The cold hard truth for any laboratory is that data is worthless if the sample is compromised. This isn't just a lab problem; it creates issues all the way back to the patient. If a new sample must be collected, the patient is inconvenienced, potential treatment windows are shortened, labor hours are increased, and additional costly reagents and consumables are used. If a new sample cannot be collected, such as those used in time-based population studies, the research itself may be weakened.

Samples collected using traditional flocked or spun-thread swabs are typically preserved in VTM. If damaged or incorrectly sealed, sample contents may leak on to other samples during transport, causing a dangerous contamination situation.

When decapping sample tubes manually, VTM may splash out of the container or create small aerosols and contaminate samples in close proximity. Cleaning and decontamination protocols to contain the spill are time-consuming and costly.

Varying VTM composition and shedding particles from flocked swabs may interfere with sensitive assay chemistries and skew results. Skewed results may be further exaggerated if the samples must be concentrated prior to assaying.

Automation Establishes a Safe Zone to Protect **Valuables**

Samples collected via the RHINOstic may be dry shipped. This is really important. RHINOstic samples do not require VTM.

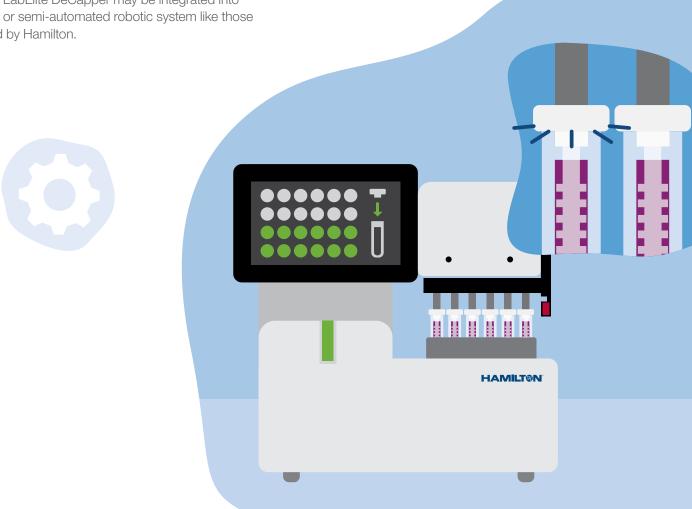
Without VTM, RHINOstic avoids skewed or variable results due to interference from VTM components. The lack of VTM also bypasses contamination risks caused by leaking cross-threads in the cap or splashing during manual decapping.

The LabElite DeCapper further protects sample integrity. Optimized torque levels remove the RHINOstic cap without splashing or creating aerosols, and also prevent overtightening and cross-threading when the RHINOstic cap is replaced.

To further prevent human-derived contamination errors, LabElite DeCapper may be integrated into a fully- or semi-automated robotic system like those offered by Hamilton.

The RHINOstic swab's sturdy polypropylene construction does not shed particles that could potentially interfere with assay chemistries. Without additional sample cleanup steps to remove interfering particles, the pathogen particles may be eluted faster, which goes back to the benefit of time savings.

Finally, without VTM, low-titer samples do not require a pre-assay concentration step to achieve results within the assay detection threshold. Instead, the sample may be resuspended directly into assay buffer so that users can be assured of consistent results. This is ideal for applications involving PCR, next generation sequencing (NGS), ELISA methods, and more.







Lab Members are Vulnerable

People are the most valuable resource in a lab. Critical thinking, planning, adapting, and decision-making are the strongest skills that people bring to a lab, and they simply cannot be duplicated by any machine. On the other hand, people are also fragile, and vulnerable to accidents or harm. This can interfere with their ability to adequately function in a lab environment. Even a seemingly mild interference can snowball to impact the lab.

For example, let's consider a repetitive motion injury caused by manual tube decapping. At the onset, this seems like a mild interference that impacts a sole individual. That individual could don a supportive brace in response to the injury, but while continuing to manually decap tubes, the injury is not healed and instead, may slowly worsen.

Options range from decapping more slowly, which reduces lab throughput, or reallocating that task to another team member, putting that person at risk of the same injury. When a team member requires sick leave to treat and rehabilitate the injury, other team members must compensate for lost lab throughput and productivity.

A more acute risk is accidental contact with hazardous or potentially infectious samples through splashes and aerosol generation. In addition to the threat of a life-threatening disease to the exposed, significant time and effort are spent on cleaning and decontamination measures, which again, reduce productivity and trigger backlogs.

Automation Erects a Not-So-Invisible Protective Shield

An automated workflow that incorporates the RHINOstic and LabElite Decapper consistently protects users from multiple angles.

As we covered previously, the RHINOstic does not require VTM. So, in addition to protecting samples from cross-contamination due to splashing and aerosol creation during decapping, it also protects people from the same harm.

LabElite DeCapper offers hands-free processing. This means that users are not exposed to the tube contents and do not have to perform repetitive motions.

They simply place a rack of RHINOstics on the device's deck, enter instructions via the touchscreen, and walk away while the LabElite DeCapper automatically uncaps the tubes. Once decapping is complete, users remove the rack of RHINOstics from the deck and transfer them for downstream processing.

For even further hands-free convenience and user protection, the LabElite DeCapper may be integrated into a larger automated system.





Increased Productivity Requires Change

Just because the "same old routine" is familiar doesn't mean that it's optimal. There are always areas for improvement and unexpected disruption can bring these areas to light in a pronounced way.

Starting at the COVID-19 pandemic onset, traditional swabs were scarce, which hampered vital testing efforts. Samples that were submitted to approved testing labs sat in a queue as the labs were deluged with samples.

Especially for labs incorporating manual methods, the time to results spanned days. This is vital time that patients either self-quarantined, often taking time off of work to do so, or continued on their normal routines, spreading the virus to others if they were indeed infected.

When it comes to public safety and wellbeing, familiarity should not be held in higher regard compared to productivity.

Automation Disrupts Status Quo Bias

Yes, this means countering disruption (large and unexpected) with disruption (small and proactive). In this case, replacing rate-limiting and time-consuming manual testing methods with those incorporating RHINOstics and the LabElite DeCapper in an automated system.

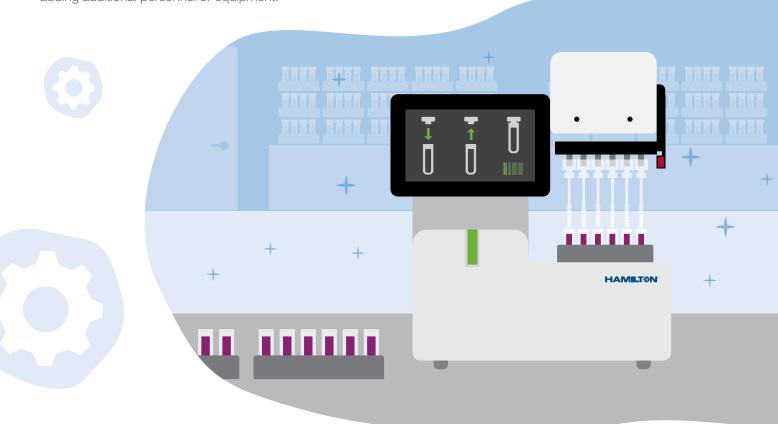
The RHINOstic all-in-one tube configuration does not use materials in the traditional swab supply chain, so it is not subject to shortages when demand unexpectedly surges.

Transitioning to automated decapping, using the LabElite DeCapper, drives speed and efficiency and also enables seamless scalability during high demand. For example, one prestigious university integrated the automated system into their testing workflow*. Here, eight lab personnel can process 10,000 samples on a normal day and can easily scale up to 40,000 samples per day without adding additional personnel or equipment.

On the other hand, a lab incorporating manual methods can also process 10,000 samples on a normal day, however, they need ten times as many people – between 70-80 – to accomplish this feat. Further scaling is not possible without adding even more personnel. That's a lot of labor hours. Time that highly skilled people are spending on low-value tasks.

Beyond increased throughput, the automated system offers consistency from user to user, run to run, and day to day. And, it may be integrated within a larger automated workflow to further reduce active labor hours and processing consistency.

Speed, throughput, and consistency are vital to support quality lab testing results and timely treatment strategies for clinicians and their patients. They also help to ensure that labs grow their revenues while remaining profitable.







Budgets are Stretched Thin

Budget discussions are anything but a walk in the park, especially when it comes to new lab purchases. But when the conversation shifts from raw equipment and consumable costs to labor time in context of costs, the perspective could change markedly.

Labor is a major cost expenditure for testing labs; representing up to 60% of the overall budget. As margins become thinner due to reimbursement decreases, one significant strategy is to decrease labor costs from the equation.

For example, a handheld decapper is less expensive than an automated decapper. However, manual decapping limits throughput compared to an automated model. Additionally, a manual decapper requires more labor time. Is this the best allocation of that user's time, knowing that labor comprises the majority of a lab's operating budget? Or, would the lab be better served if the user devoted their attention to high-value activities such as data interpretation and report generation?



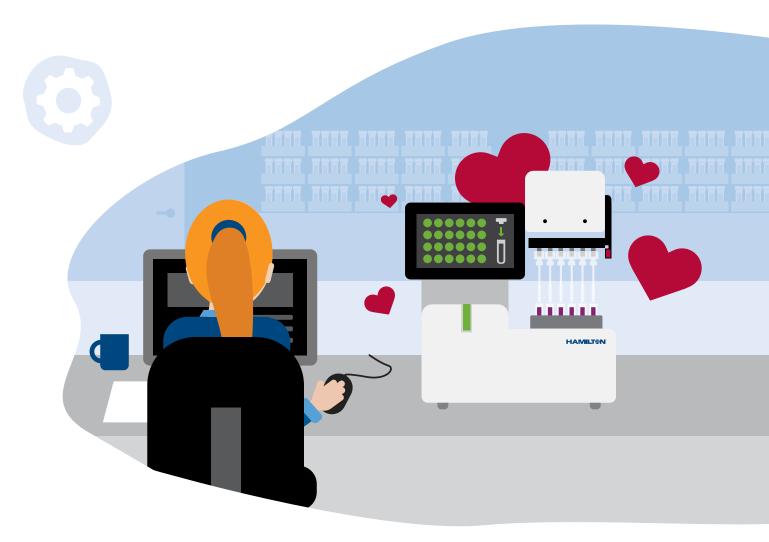
An automated system, consisting of RHINOstics and the LabElite DeCapper, helps to stretch budget dollars further in several ways.

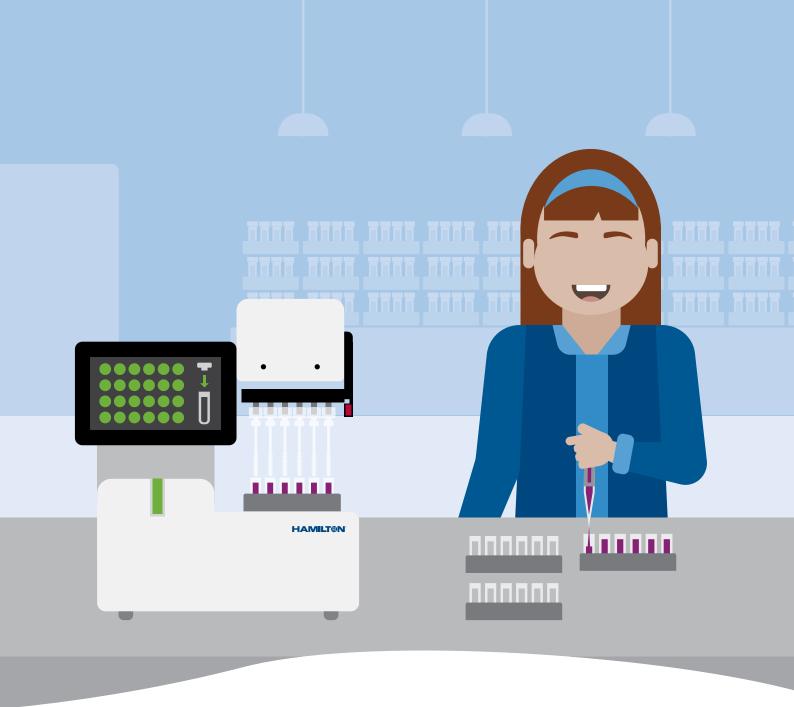
Samples collected via the RHINOstic may be shipped without use of VTM. This recurring media expense can then be removed from the purchase list.

The lack of VTM also eliminates the risk of interferents from media components and bypasses the need to concentrate diluted samples. On top of that, the unique RHINOstic swab polypropylene construction eliminates the risk of interferents that are found in flocked swabs. By eliminating these risks, extraction steps in the workflow can be reduced or eliminated to save time and materials.

The LabElite DeCapper automatically caps and decaps RHINOstics consistently and without fail. This frees users to attend to other high-value tasks so that efficiency and productivity across the lab is increased. This benefit can be further boosted when integrated with an automated liquid handler.

As sample processing using the LabElite DeCapper is easily scaled, the lab does not have to account for additional labor and equipment costs during times of high demand.





Stick with a New Way to Combat Lab Disruption

Disruption, such as the COVID-19 pandemic, is often avoidable. Embracing change through innovation can mitigate barriers created by unexpected disruption. With a fresh perspective on laboratory testing workflows that includes RHINOstics and the LabElite DeCapper in an automated system, labs can achieve speed, throughput, and consistency while maintaining quality, even during times of overwhelming demand.







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