A Transformational Swab Design Innovation Drives New Efficiencies

In the past 100 years, healthcare and research markets have experienced amazing technology transformations: characterizing the structure of DNA, sequencing genomes, developing broad categories of antibiotics, chemotherapies, and vaccines. Thanks to a century's worth of amazing innovation, we are healthier and living longer than our ancestors.

In the same time period – while all these trailblazing changes came to life – the nasopharyngeal swab remained stuck in the past.

4 Reasons Why Yesterday's Swabs Impede Today's Progress

Without meaningful change over the past century, old-style swabs are poorly suited in today's environment.

First, traditional swabs are assembled as one material – the swab head – that is wound or assembled around another material – the swab handle. Multiple manufacturing steps, including adding absorbent flocking coatings or components, add to the overall time it takes to manufacture swabs. On top of this, the manufacturing process is not easily scaled during times of demand. The world acutely experienced this shortcoming early in the COVID-19 pandemic. Essential items, like swabs, that were previously well-stocked and taken for granted suddenly became scarce and widely hunted. This meant that thousands of people could not be tested for the SARS-CoV-2 virus in a timely manner.

Second, once sample is collected onto an old-style swab head, virus particles may remain trapped in the material instead of eluting into solution during processing. If virus is present in low levels and little of it ends up being tested, the result may be incorrect. An infected person that falsely tests negative risks spreading the pathogen throughout their community.

Third, antiquated swabs often require use of viral transport media (VTM). This media was originally necessary when culturing the virus. As cultures are no longer required for today's molecular methods, including PCR and NGS, VTM is an extra, needless expense. On top of this, VTM dilutes the sample and may include PCR inhibitors. In order to remove the inhibitors and concentrate sample to measurable levels, extra steps, like extraction and concentration, are added to the workflow. In addition to adding time and expense, a small amount of sample is inevitably sacrificed during the manipulation.

Fourth, old-style swabs are scratchy and uncomfortable against sensitive nasopharyngeal tissue. Some patients may feel as if the clinician was trying to directly poke at their brain. Others may correlate a swab's flocking to stiff hairbrush bristles. A fear of pain or an uncomfortable experience may dissuade patients from being tested.

The Swab Revolution: Out with the Old and In with the New

Very early in the COVID-19 pandemic, the Rhinostics founders recognized the urgent and unmet need for a completely new type of swab. One that would enhance, rather than impede, workflow efficiencies and progress.

They partnered with researchers at Harvard University and the Wyss Institute to develop a swab that could be quickly and cost-effectively manufactured in high quantities without relying on traditional supply channels.

The founders and research teams also recognized an opportunity to throw out the old 'status quo' and create a design that benefited the people being swabbed and offered clean, high concentration samples compared to antiquated swabs.

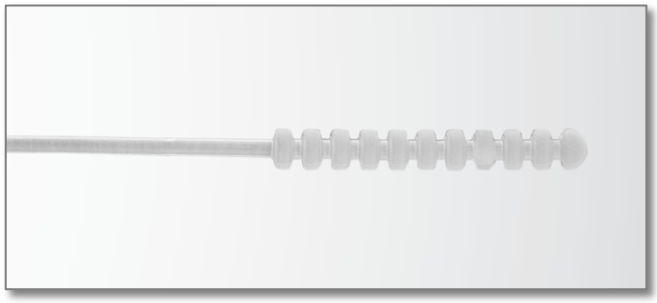
The result of these efforts led to an innovation called the GrooveSwab® Nasopharyngeal Swab. This novel swab can be used to collect sample from the nasopharynx for use in any relevant pathogen test.

Inspiration from an Unlikely Source

Nature is an endlessly deep well of inspiration. When rethinking the traditional swab head design, the research teams were inspired by cats...more specifically, their tongues. A cat's tongue is covered in tiny spines called papillae. These papillae use surface tension forces to effectively wick and trap liquids.

Tiny spikes on a cat's tongue help to trap liquids.

In a swab format, a head designed to mimic the fluid dynamics of the papillae could aid in sample collection and processing. With this idea in mind, the researchers brought novel swab designs to life; each completely different compared to antiquated swab heads. All the prototype designs collected liquid, such as the respiratory mucosa needed for COVID and other respiratory pathogen tests, without requiring an absorbent coating. The optimal design was configured as a stacked ring structure and forms the GrooveSwab head.



The head of the GrooveSwab Nasopharyngeal Swab features a stacked ring structure that helps to capture copious sample while ensuring a comfortable patient experience.

INNOVATION MATTERS

The stacked ring structure is also featured in the RHINOstic® Automated Nasal Swab from Rhinostics.

One Material. Many Reasons.

When considering construction materials, polypropylene was a straightforward choice for three major reasons.

The first reason relates to manufacturing. This versatile plastic is hydrophobic, chemically and biologically resistant, and sterilizable. It is also well suited for injection molding and retains its shape even after bending or flexing. It's no wonder that polypropylene is already widely used in life science consumables and medical devices.

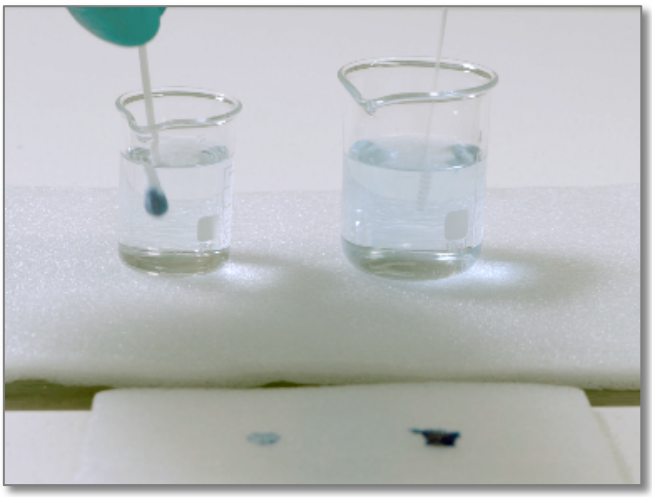
INNOVATION MATTERS

The RHINOstic Automated Nasal Swab and Standard Nasal Swab from Rhinostics are also made from polypropylene.

By using a single, injection molded material that is widely available, the GrooveSwab could be manufactured quickly and at a low cost compared to the multi-step, two material manufacturing process of old-style swabs. The GrooveSwab manufacturing process could also be rapidly and easily scaled in response to market demands.

The second reason centered around patient comfort. Polypropylene, especially in the stacked ring structure of the GrooveSwab, feels soft against delicate nasopharyngeal tissue compared to the friction of a flocked swab's bristles or a wound swab's tough synthetic fibers. Which would you rather have rotated around against the sensitive tissue in your nasopharynx?

The third reason focused on performance. The hydrophobic nature of polypropylene means that sample particles could be quickly and fully eluted into liquid during processing, contrary to old flocked or spun fiber swabs that retain and trap sample. With a solid design, there's also no risk of flocked particles shedding into solution and contaminating the sample.

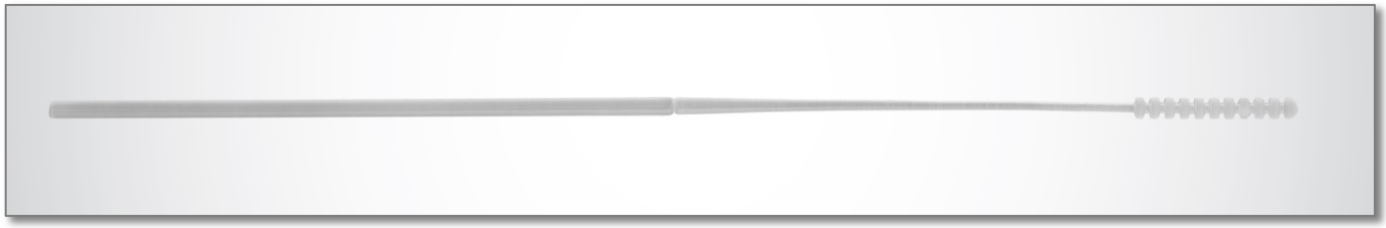


Better elution leads to better results. An antiquated swab (left) retains sample in the spun fiber head while the GrooveSwab (right) fully elutes sample into solution.

INNOVATION MATTERS

When evaluating swabs using control or contrived samples, many labs consider wettability, however, fluid retention is not an indicator of fluid or viral particle release. It is more logical to apply a specific volume of known concentration sample onto the swab, then proceed with the test.

Ask for our 'General Guidelines Pertaining to Rhinostics Swab Evaluation and Testing Protocols'.



The novel GrooveSwab Nasopharyngeal Swab from Rhinostics may be used for a variety of pathogen tests that require sample to be collected from sensitive nasopharynx tissue.

Viruses are very stable on the polypropylene swab, even when stored or transported without viral transport media (VTM). In a recent study comparing foam swabs to polypropylene swabs, results indicate that samples stored under dry conditions outperformed those stored in saline (Figure 1).

In addition to helping to reduce reagent and shipping costs, this enables up to 30X sample concentration compared to swabs that are stored and transported with VTM. A more concentrated sample along with no potential PCR inhibitors (because VTM was not used) means that even low viral loads may be detected in the assay. It also means that extraction/concentration steps may be bypassed to save time as well as reagent and consumable costs.

Mean ΔCt (Control 4°C – Test Condition 40°C):

	Time	Storage	S gene	N gene	ORF1ab	MS2
Puritan Foam	24 + 2 hr	DRY	-0.1	-0.2	-0.2	0.0
Nares Bristle			-0.3	-0.1	-0.4	-0.2
Nares Disc			-0.1	0.0	-0.1	-0.3
Nares Oval			-0.2	0.0	-0.3	0.0
Puritan Foam		SALINE	2.0	1.3	1.6	0.1
Nares Bristle			1.0	0.9	0.8	-0.1
Nares Disc			1.3	1.4	1.0	-0.1
Nares Oval			1.6	1.4	1.4	0.1

Figure 1. Mean delta C_t values for three SARS-CoV-2 genes (S, N, ORF1ab) analyzed from samples taken using a variety of different swabs, including polypropylene swabs (Nares Bristle, Nares Disc, Nares Oval). Results indicate $C_t \leq 0.5$ for dry storage conditions as opposed to $C_t \leq 2.0$ for saline storage conditions (data from internal study).

Swab Efficiency in Action

In practice, the combination of design and material proved that the GrooveSwab Nasopharyngeal Swab was a modern, highly effective alternative to antiquated nasopharyngeal swabs.

To prove this point, the research teams conducted studies at the University as well as with collaborators at SUNY Downstate Health Services University and TGen North. The studies included clinical volunteers, remnant clinical samples, and contrived samples.

Clinical volunteers who evaluated the GrooveSwab gave it higher marks for comfort compared to traditional nasopharyngeal swabs (Figure 2A). Even clinicians rated the GrooveSwab on par with, or better than, traditional nasopharyngeal swabs in context of ease of use (Figure 2B).

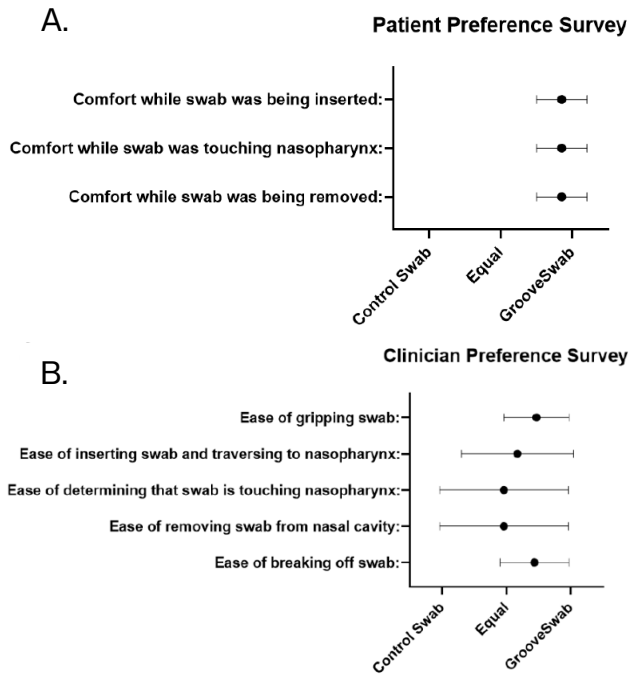


Figure 2. Survey results of (A) patient and (B) clinician preferences across various metrics for GrooveSwabs vs. control swabs. Data and caption derived from "Low cost, injection molded, nasopharyngeal swabs for addressing global diagnostic supply shortages", Martinez, M.R., et al. 2021, MedRxIv preprint doi: https://doi.org/10.1101/2021.07.19.21260235.

When several swabs were compared by RT-qPCR quantitation of a housekeeping protein (GAPDH) as well as the SARS-CoV-2 N gene, including low and high titers, the GrooveSwab's specially designed, polypropylene head performed as well as, or better than, many commercially available swabs (Figure 3).

INNOVATION MATTERS

Dry swab samples eluted into 100 µL of reagent are 30x more concentrated than swab samples diluted in 3 mL of VTM. Labs can bypass concentration steps to save time. And, by fully eluting sample into solution (instead of retaining sample in flocked or spun fibers), labs can be assured of excellent elution profiles!

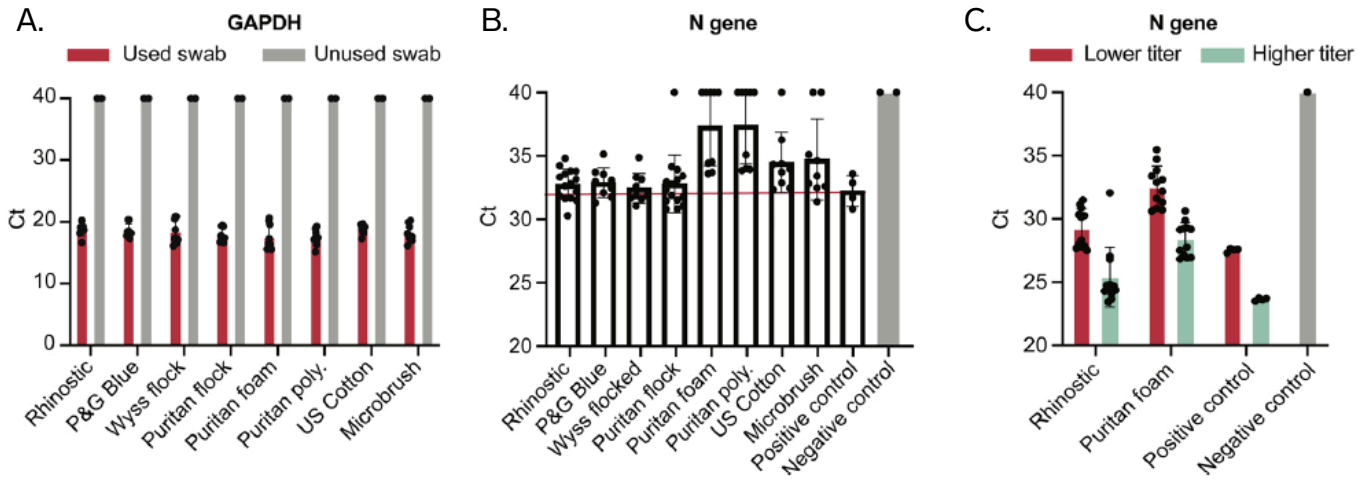


Figure 3. (A) RT-qPCR quantitation of human GAPDH mRNA from used swabs containing nasal matrix (pink) or matched unused swabs (grey). (B) RT-qPCR quantitation of the SARS-CoV-2 N gene from packaged synthetic virus applied to clean, unused swabs. The grey bar is the negative control, PBS input into RT-qPCR. The pink line is a guideline for complete recovery based on the positive control. (C) RT-qPCR quantitation of SARS-CoV-2 N gene from swabs in the presence of nasal matrix spiked with a lower (~140 copies/µL, pink bars) or higher (~1600 copies/µL, green bars) titer remnant clinical sample. The grey bar is the negative control, PBS, and the positive controls are the lower or higher titer remnant clinical samples directly input to RT-qPCR. All RT-qPCR data in all show technical replicates of at least 3 biological experiments. Data and caption derived from "Accessioning and automation compatible anterior nares swab design", Pettit, M.E., et al. 2021, J Virol Methods doi: https://doi.org/10.1016/j.jviromet.2021.114153.

Achieving Triumph Amid a Crisis

Time often seemed relative during the pandemic, especially when hyper focusing on disrupting a long-held status quo in favor of a modern approach that benefits the entire world.

When the Rhinostics co-founders and research teams took a moment to catch their breath from their grueling pace, they realized that only two months had passed from GrooveSwab's design to clinical trials at academic collaborators and teaching hospitals. This breakneck speed was unheard of under normal circumstances, but the teams were compelled to achieve their vision.

By rethinking this modern swab, they were able to bypass traditional supply chain disruptions, improve comfort and ease of use, and enhance processing performance while reducing costs and time to results.

Through courageous innovation, the small GrooveSwab is now destined to make a positive and lasting impact on resear

ch and medical communities as well as those that they serve. Nasopharyngeal swab sampling and processing is finally on par with today's technology transformations, and patients can be assured of a comfortable sampling experience.

NASOPHARYNGEAL SWAB INNOVATION MATTERS

Isn't it time to replace your old nasopharyngeal swab? Learn more, order a sample, or request a quote. Contact your local Rhinostics representative, visit www.rhinostics.com, or email sales@rhinostics.com.