Science Supporting the Microwash

Out with the Swab, in with the MicroWash. Why?

MicroWash provides a comfortable, higher quality and more consistent nasal lavage sample for URI testing with lower infection risk to healthcare workers collecting the sample.

Up to 49% Greater Sensitivity

Independent academic studies over the past 20+ years show an 8-49% increased sensitivity for URI virus detection with nasal aspirate/lavage samples, like the MicroWash, compared to nasal swab samples.

microwash
nasal sampling

MicroWash sets a new gold standard in nasal lavage sample collection, superior to traditional nasopharyngeal irrigation.

Nasopharyngeal irrigation was the pre-pandemic standard collection method for respiratory tract infection testing. However, the process and outcomes present issues:

- For traditional nasopharyngeal irrigation, a healthcare professional would irrigate the patient's nose with 10 mL of saline using a syringe.
- They would then attempt to recapture the effluent saline by rapidly pulling back on the syringe plunger, or worse, allow the saline to free fall from the patient's nose into an open basin.
- This method of collection **lacked standardization**, resulting in **inconsistent specimen quality**.
- The procedure was also messy and placed the healthcare professional at risk.

The MicroWash is the world's first self-contained nasopharyngeal irrigation specimen collection device that consistently delivers high-quality specimens.

MicroWash surpasses the nasal swab on virtually all levels, including comfort, quality, stability and accessibility.

Nasal swabs quickly became the standard collection method for upper respiratory tract infection testing during COVID-19, due to being readily available. Yet, they were invasive, painful and prone to collection errors.

The MicroWash device, however, doesn't hurt — in fact, many users say it is refreshing.
Can you say that about the nasal swab?

- On a 10-point Likert analog pain scale, MicroWash was rated **0.3/10** and nasal swabs were rated **8/10**.
- The MicroWash can be utilized in any healthcare venue including emergency departments, outpatient clinics, nursing homes, assisted living communities and hospitals.
- Healthcare personnel can quickly learn to administer the MicroWash.
- The MicroWash device has a shelf life of **10+** years.

MicroWash samples can be PCR tested for a large number of URI pathogens with a very quick turnaround.

The vast majority of antigen tests only screen for 1 pathogen. A small number of antigen test kits screen for 2-3 pathogens at most. Nasal lavage samples from the MicroWash can be PCR tested for **more than a dozen** URI pathogens, including **COVID-19**, **influenza and RSV**.

MicroWash specimen testing can provide a diagnosis in **24 hours**, well within the recommended time window to start disease-specific therapeutics.

Antigen tests are dependent on lateral flow technology and have low sensitivity.

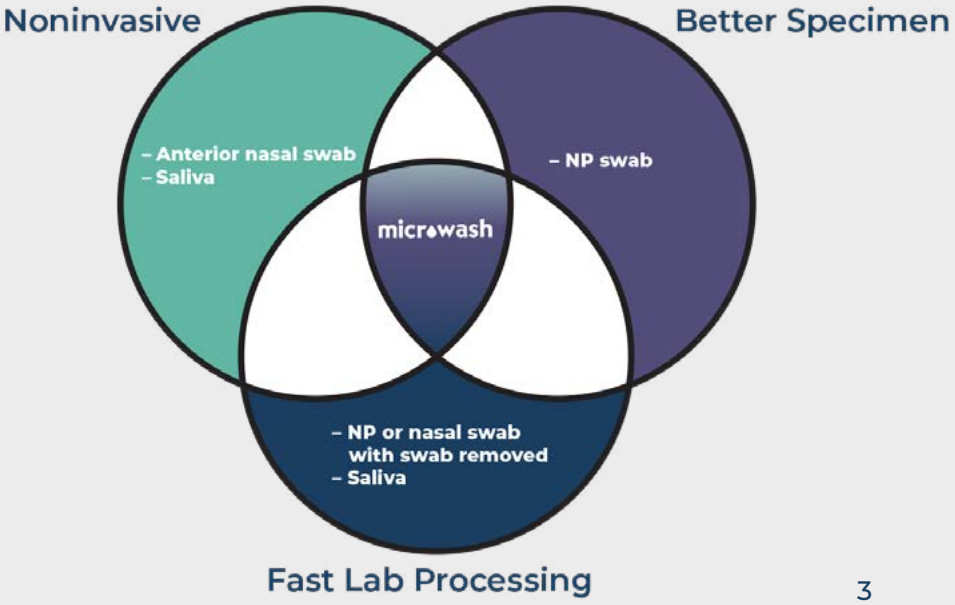
Additionally, antigen tests may not turn positive for 4+ days post symptom onset, putting the patient outside the therapeutic window for successful treatment. Consider the following:

- Several research studies have shown PCR sample testing has sensitivity for multiple pathogens in the high 90% range, while antigen tests are in the 50% to 70% range.
- This multi-pathogen sample testing capability is even more critical with recent data demonstrating an increase in cases of individuals with multi-pathogen infections, resulting in high acuity illness and a more prolonged and complicated clinical course.
- Many patients are either initially infected with or later super infected by more than one pathogen (e.g., Mycoplasma superinfection cases in China in 2023-2024). Multi-pathogen PCR sample testing is clearly needed in these cases.

MicroWash can eliminate swab extraction errors while offering an unmatched shelf life.

MicroWash specimens are swab-free, meaning there is no swab inside the specimen transport tube requiring manual extraction, potentially resulting in PCR testing delays/complications.

MicroWash kits have a longer shelf life compared to nasal swab kits making them a viable option for multiple cold/flu seasons and pandemic stockpiling.



Supporting References and Research

Overview: Swabs Versus Saline Washes

Comparison of Nasopharyngeal Swab v. Nasopharyngeal Saline Wash or Saliva Collection in Testing for Respiratory Viruses >
ClinicalTrials.gov ID: NCT05864118

Summary
Respiratory tract infections (RTIs) are prevalence community diseases and is the third leading cause of death worldwide. Rapid diagnosis of RTIs is essential as it drives decision points such as treatment disposition and containment.

According to recent CDC (The Centers for Disease Control and Prevention) updates, nasopharyngeal swabbing is the preferred method of specimen collection for most RTIs such as SARS-COV-2. This process is invasive and traumatizing for patients as it requires probing (20 seconds) of the posterior nasopharynx with a swab applicator. In some cases, this procedure has resulted in pain and injury.

Because of the invasive nature of the procedure, patients often refuse testing or withdraw during the collection process, resulting in inadequate specimen procurement. The study principle investigators (PI) have developed 2 novel specimen collection devices:

1. Nasopharyngeal wash collection device (NP wash device) and
2. Saliva collection device (the Oral Capsule).

Both devices are designed for ease of use either by a healthcare professional or a patient. The benefits of such collection devices include:

1. Minimizing the invasive nature of the procedure because a swab applicator is not utilized.
2. Minimizing infection risk to healthcare professionals because the study devices can be self-administered when applicable.

Ongoing MicroWash UNMC 1000 Patient Clinical Trial: *Data and Results Pending*

Supporting References and Research

UNMC and UMD Research, Publications and Data

UNMC MicroWash Pilot Study

Pandemic driven innovation: A pilot evaluation of an alternative respiratory pathogen collection device. >

Nguyen TT, Zeger WG, Wadman MC, Schnaubelt AT, Barksdale AN.

Am J Emerg Med Nov. 2022; 61:111-116. doi: 10.1016/j.ajem.2022.08.047. Epub 2022 Aug 30. PMID: 36087464

- Patients dislike and avoid the nasopharyngeal swab sampling procedure due to pain and discomfort.
- A new device (MicroWash) utilizing irrigation debridement rather than direct mucosal surface friction yields a high-quality sample without the pain and discomfort.

UNMC Emerging Pathogens Laboratory URI COVID-19 Antibody Community Study

- Comparison of nasopharyngeal swab sampling and classic nasopharyngeal irrigation technique – Advantage nasopharyngeal irrigation supported by a significant body of literature.
- Comparison of classic nasopharyngeal irrigation and MicroWash – Advantage MicroWash. EPL uses the MicroWash exclusively in their antibody research supported by a pilot study that showed the MicroWash advantage (unpublished data).
- The MicroWash EPL research utilization is summarized in this article:
  - **Pandemic Driven Innovation and Post Pandemic Collaborations – The Emergency Medicine and Emerging Pathogens Laboratory Teams >**

UNMC EPL and Emergency Department COVID-19 Antibody Study

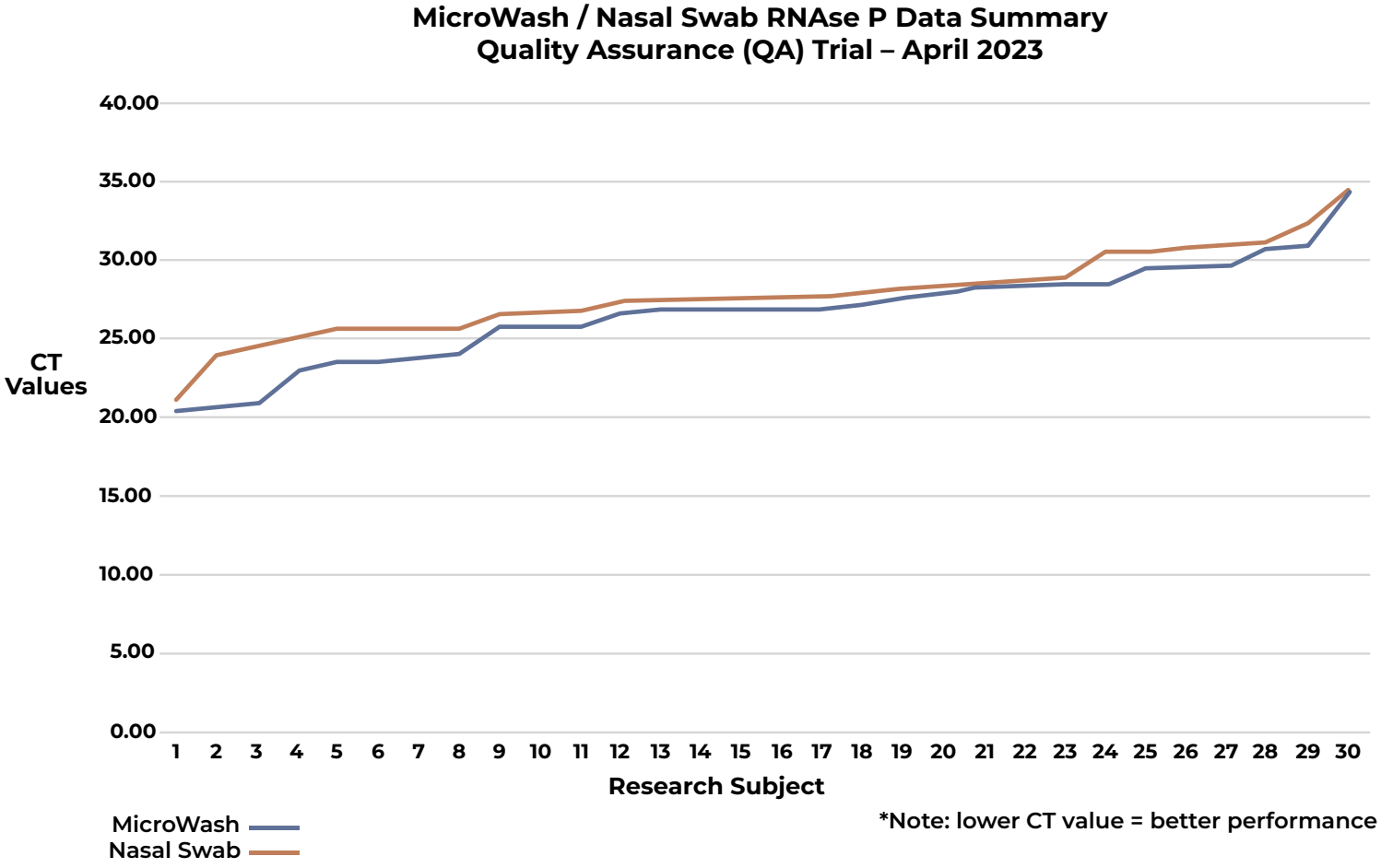
- July 2024 Study to confirm the unpublished, small pilot data from the EPL showing a significant advantage (greater than 10%) of MicroWash samples compared to standard nasal wash samples for COVID-19 antibody detection.
- 30 healthy UNMC healthcare workers will have their COVID-19 antibodies measured in: MicroWash, standard nasal wash, saliva and finger-stick blood.
- Study results to be available in Q1 2025.

Supporting References and Research

UNMC and UMD Research, Publications and Data (Cont.)

UNMC Supplementary MicroWash Sample Quality Study – April 2023

- MicroWash sample in one nostril and nasal swab sample in the other nostril measuring RNAse-P to quantify and compare the cellularity of the samples.
- The MicroWash sample was collected from healthy study participants, and the nasal swab sample was collected by a trained healthcare professional with significant experience in nasal swab sample collection.
- MicroWash samples demonstrated a **4.2% superiority** over the nasal swab specimens. This calculation was based on the difference between the CT means of the two groups.



Supporting References and Research

UNMC and UMD Research, Publications and Data (Cont.)

MicroWash Versus Nasal Swab – Summary of All Clinical Studies to Date

- Sample Processing Control (ie, SPC, measure of sample cellularity/quality) data was analyzed for 33 clinical study participants with URI symptoms.
- Paired data MicroWash and nasal swab samples in the same study participant.
- Study participants from clinical trials at UNMC and Nelson Laboratories (Bozeman, MT).
- MicroWash samples demonstrated a **2.6% superiority** over the nasal swab specimens in their SPC CT values. This calculation was based on the difference between the CT means of the two groups.
- Although the P value was not statistically significant (see summary table below) at 0.19, the data still showed a noticeable trend in favor of the MicroWash samples.

t-Test: Paired Two Sample for Means		
	MW SPC	*NS SPC*
Mean	27.84	28.56
Variance	0.30	8.64
Observations	33	33
Pearson Correlation	-0.13	
Hypothesized Mean Difference	0	
df	32	
t Stat	-1.35	
P(T<=t) one-tail	0.09	
t Critical one-tail	1.69	
P(T<=t) two-tail	0.19	
t Critical two-tail	2.04	

Supporting References and Research

Independent Academic Research, Publications and Data

COVID-19 PCR Testing Superior to Antigen Testing

1. COVID-19 Rapid Antigen Tests With Self-Collected vs Health Care Worker–Collected Nasal and Throat Swab Specimens A Randomized Clinical Trial >

Tobias Todsen, MD, PhD, Kathrine K. Jakobsen MD, Mathias Peter Grønlund MD, et al.
JAMA Netw Open. 2023;6(12):e2344295.

Summary

Of 2941 participants enrolled, 2674 (90.9%) had complete test results and were included in the final analysis (1535 [57.4%] women; median age, 40 years [IQR, 28-55 years]); 1074 (40.2%) had COVID-19 symptoms, and 827 (30.9%) were positive for SARS-CoV-2 by RT-PCR.

Health care worker–collected throat specimens had higher mean sensitivity than HCW-collected nasal specimens for rapid antigen testing (69.4% [95% CI, 65.1%-73.6%] vs 60.0% [95% CI, 55.4%-64.5%]). However, a subgroup analysis of symptomatic participants found that self-collected nasal specimens were more sensitive than self-collected throat specimens for rapid antigen testing (mean sensitivity, 71.5% [95% CI, 65.3%-77.6%] vs 58.0% [95% CI, 51.2%-64.7%]; P < .001).

Combining nasal and throat specimens increased sensitivity for HCW- and self-collected specimens by 21.4 and 15.5 percentage points, respectively, compared with a single nasal specimen (both P < .001).
Key Conclusion: Significant PCR sensitivity advantage compared to antigen testing.

2. CDC – Nucleic Acid Amplification Tests (NAATs) superior to antigen tests >

Summary

The “gold standard” for clinical diagnostic detection of SARS-CoV-2 remains laboratory-based (moderate- and high-complexity) NAATs. In situations where test sensitivity is of paramount importance, NAAT tests are preferred.

Antigen tests do not have the same limits of detection as most NAATs, which have a higher sensitivity. Compared to NAATs, antigen tests are more likely to return a false negative, especially when testing before symptom onset when the level of antigens in a specimen is lower.
Key Conclusion: CDC recognizes that NAATs (e.g., PCR) are superior to antigen testing.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

COVID-19 PCR Testing Superior to Antigen Testing (Cont.)

3. The performance of rapid antigen tests against SARS-CoV-2 variants >

Jacqueline Prestedge and Deborah A. Williamson

The Lancet. Volume 23, ISSUE 8, P883-884, August 2023.

Summary

The study found that, when compared with RT-PCR, the overall sensitivity of LFDs was 63·2% (95% CI 61·7–64·6; 2609 LFD-positive samples of 4131 RT-PCR positive samples) and was higher in symptomatic participants (68·7% [66·9–70·4]; 1859 of 2706) versus asymptomatic participants (52·8% [50·1–55·4]; 724 “of 1372), and in unselected community-based settings (71·6% [69·8–73·4]; 1705 of 2381) versus pre-deployment testing (52·8% [49·8–55·8]; 593 of 1123). The findings by Eyre and colleagues are consistent with other clinical studies of LFD performance.

Key Conclusion: Significant PCR sensitivity advantage compared to antigen testing. LFDs (lateral flow devices) are a type of antigen test.

4. Sensitivity of rapid antigen tests for COVID-19 during the Omicron variant outbreak among players and staff members of the Japan Professional Football League and clubs: a retrospective observational study >

Michio Murakami, Hitoshi Sato, Tomoko Irie, Masashi Kamo, Wataru Naito, Tetsuo Yasutaka, and Seiya Imoto

BMJ Open. 2023; 13(1): e067591. Published online 20 Jan 2023

Summary

Of the 656 cases, 65 were positive for both the rapid antigen and PCR tests, 38 were negative for the antigen tests and positive for the PCR test, 1 was positive for the rapid antigen test and negative for the PCR test and 552 were negative for both (table 2). The sensitivity of the rapid antigen test compared with the PCR test was 0.63 (95% CI: 0.53 to 0.73) and the specificity was 0.998 (95% CI: 0.995 to 1.000).

Key Conclusion: Significant PCR sensitivity advantage compared to antigen testing.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

COVID-19 Antigen Test Reliability Delayed Compared to PCR

The New Normal: Delayed Peak Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Viral Loads Relative to Symptom Onset and Implications for Coronavirus Disease 2019 (COVID-19) Testing Programs >

JK Frediani, R Parsons, KB McClendon, et al.

Clinical Infectious Diseases, ciad582, published 28 Sept. 2023

Summary

This delayed peak relative to the onset of symptoms has been observed in other studies conducted later in the pandemic [22–24], but the implications of this finding for testing practice—in particular, home antigen testing practice — have not been sufficiently highlighted.

Key Conclusion: Antigen tests not reliable until 4+ days post symptom onset. PCR is more sensitive than antigen testing at any time post symptom onset.

Naso-oropharyngeal Swabs Deliver Highest Viral Load at Beginning of Infection

The swab site of the upper airways influences the diagnostic sensitivity for the omicron variant of SARS-CoV-2. >

Atzler F, Dahms F, Paul G, Perisic S

J Med Virol 2024 Jan;96(1):e29390. doi: 10.1002/jmv.29390. PMID: 38235822

Summary

- Viral load differs significantly depending on swab collection site in the upper airways.
- For maximum clinical sensitivity, a combined naso-oropharyngeal swab should be considered. In case a single point and single sample measurement is the norm, a nasopharyngeal swab can deliver the highest viral load at the presumed beginning of the infection.

MicroWash Tie-In: MicroWash samples the nasopharynx in its entirety in one sample, reflecting the approach of the combined naso-oropharyngeal swab technique.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Nasopharyngeal Samples Preferred to Anterior or Mid-Turbinate Swabs

Relative sensitivity of anterior nares and nasopharyngeal swabs for initial detection of SARS-CoV-2 in ambulatory patients: Rapid review and meta-analysis. >

Zhou Y, O'Leary TJ.

PLoS One 2021 Jul 20;16(7):e0254559. doi: 10.1371/journal.pone.0254559. eCollection 2021. PMID: 34283845

Summary

- Anterior nares swabs are less sensitive (82% - 88%) than nasopharyngeal swabs (98%).
- Mid-turbinate and anterior nares swabs seem to perform similarly.

MicroWash Tie-In: MicroWash sample quality reflects that of nasopharyngeal swabs, surpassing the quality of anterior nares and mid-turbinate swab.

Nasal Aspirate/Nasal Wash Versus Flocked Nasal Swab

1. Comparison of nasopharyngeal flocked swabs and aspirates for rapid diagnosis of respiratory viruses in children. >

Chan KH, Peiris JS, Lim W, Nicholls JM, Chiu SS.

J Clin Virol 2008 May;42(1):65-9. doi: 10.1016/j.jcv.2007.12.003. Epub 1 Feb. 2008. PMID: 18242124

Summary

- Nasopharyngeal aspirate (NPA) was more sensitive than flocked nasal swab (fNS) for detecting RSV by both RT-PCR (100% vs. 92.3%).
- NPA remains the optimal specimen for diagnosis of respiratory infections by RT-PCR.
- However, collection of NPFS is easier to perform in an outpatient setting, was more acceptable to parents and less likely to generate aerosols than NPA engendering potentially less infection control hazard.

MicroWash Tie-In: MicroWash is engineered to mitigate the shortcomings of nasal aspirates, including ease of use and reduction in risk of aerosolization.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Nasal Aspirate/Nasal Wash Versus Flocked Nasal Swab (Cont.)

2. Detection of multiple respiratory pathogens during primary respiratory infection: nasal swab versus nasopharyngeal aspirate using real-time polymerase chain reaction. >

Meerhoff TJ, Houben ML, Coenjaerts FE, Kimpen JL, Hofland RW, Schellevis F, Bont LJ

Eur J Clin Microbiol Infect Dis 2010 Apr;29(4):365-71. doi: 10.1007/s10096-009-0865-7. Epub 29 Jan. 2010. PMID: 20111881

Summary

- Sensitivity of the nasal swab was lower than the nasopharyngeal aspirate, in particular, for respiratory syncytial virus (51% vs. 100%) and rhinovirus (75% vs. 97%).
- It is concluded that, for community-based studies and surveillance purposes, the nasal swab can be used, though the sensitivity is lower than the aspirate, in particular, for the detection of mild cases of respiratory syncytial virus (RSV) infection.

MicroWash Tie-In: MicroWash yields a nasopharyngeal aspirate quality sample, while providing an easy, standardized sampling technique.

3. Flocked nasal swab versus nasopharyngeal aspirate for detection of respiratory tract viruses in immunocompromised adults: a matched comparative study. >

Ohrmalm L, Wong M, Rotzén-Östlund M, Norbeck O, Broliden K, Tolfvenstam T

BMC Infect Dis 26 Nov. 2010;10:340. doi: 10.1186/1471-2334-10-340. PMID: 21110854

Summary

- Most studies comparing collection of samples by nasal swabs and nasopharyngeal aspirates involve immunocompetent children with URI symptoms. This study compares the two collection techniques in adults with febrile neutropenia.
- Nasopharyngeal aspirate significantly superior to nasal swabs in collecting epithelial cells.
- Overall sensitivity of nasal swabs for any virus and for rhinovirus was 65% and 78%, respectively.
- 'We found the overall sensitivity of 65% to be too low to replace nasopharyngeal aspirate.'

MicroWash Tie-In: MicroWash provides the high-quality samples of a nasopharyngeal aspirate needed to diagnose infection early in immunocompromised patients.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Nasal Aspirate/Nasal Wash Versus Flocked Nasal Swab (Cont.)

4. Comparison between nasopharyngeal swab and nasal wash, using culture and PCR, in the detection of potential respiratory pathogens. >

Gritzfeld JF, Roberts P, Roche L, El Batrawy S, Gordon SB.

BMC Res Notes 13 April 2011; 4:122. doi: 10.1186/1756-0500-4-122. PMID: 21489228

Summary

- Nasal washing was more comfortable for volunteers than swabbing (n = 24).
- In detection by culture, the nasal wash was significantly more likely to detect pathogens than the nasopharyngeal swab ($p < 0.00001$).

MicroWash Tie-In: MicroWash provides the high-quality samples of a nasopharyngeal aspirate needed to identify carrier states for consequential pathogens.

2002 Study Illustrates Significant NP Aspiration (NPA) Sample Sensitivity Advantage Compared to Nasal Swab (NS) Sample For RSV

Comparison of nasopharyngeal aspirate and nasal swab specimens for detection of respiratory syncytial virus in different settings in a developing country >

Stensballe LG, Trautner S, Kofoed P-E, Nante E, Hedegaard K, Jensen IP, Aaby P

Trop Med Int Health. 2002 Apr;7(4):317-21. doi: 10.1046/j.1365-3156.2002.00867.x.

Summary

- Using NS samples was associated with a 27-31% reduction in sensitivity compared with NPA specimens.

MicroWash Tie-In: There is a strong body of literature supporting a significant specimen quality and sensitivity advantage of nasal aspiration/nasal lavage (like the MicroWash) compared to nasal swab specimens.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Clinical Applications in Long-term Care Facilities + Early Detection to Reduce Healthcare Resource Utilization

Rapid Detection of Influenza Outbreaks in Long-Term Care Facilities Reduces Emergency Room Visits and Hospitalization: A Randomized Trial. >

Temte JL, Checovich MM, Barlow S, Shult PA, Reisdorf E, Haupt TE, Hamrick I, Mundt MP.

J Am Med Dir Assoc 24 Dec. 2023 (12):1904-1909. doi: 10.1016/j.jamda.2023.05.035. Epub 2023 Jul 5.

PMID: 37421970

Summary

- The use of low-threshold criteria to trigger nursing staff-initiated testing for influenza with RIDT resulted in increased prophylactic use of oseltamivir.
- This study demonstrated significant reductions in all-cause ED visits (22% less), hospitalizations (21% less), and hospital length of stay (36% less).

MicroWash Tie-In: MicroWash allows for easy, painless sampling on a large scale, for monitoring purposes and to guide rapid therapeutic intervention in populations at high risk from viral infection.

Saline Nasal Wash Sample At Least Equivalent, If Not Superior, to VTM Sample for PCR Testing

There is a significant body of literature showing saline nasal wash samples, like the MicroWash, are equivalent and in some cases superior in quality to standard viral transport media (used for nasal swab samples) for PCR testing, even with a delay in testing of 7 or more days.

1. Validation of saline, PBS and a locally produced VTM at varying storage conditions to detect the SARS-CoV-2 virus by qRT-PCR >

Caroline Ngetsa, Victor Osoti, Dorcas Okanda, Faith Marura, Krupali Shah, Henry Karanja, Daisy Mugo, John Gitonga, Martin Mutunga, Clement Lewa, Benedict Orindi, Philip Bejon, Lynette Isabella Ochola-Oyier

PLoS One. 2023 Feb 13;18(2):e0280685. doi: 10.1371/journal.pone.0280685. eCollection 2023

Summary

Overall, this study demonstrated that normal saline, PBS and the locally manufactured VTM canbe used for COVID-19 sample collection and testing, thus expanding the range of SARS-CoV-2 viral collection media.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Saline Nasal Wash Sample At Least Equivalent, If Not Superior, to VTM Sample for PCR Testing (Cont.)

2. Stability of SARS-CoV-2 in Phosphate-Buffered Saline for Molecular Detection >

Garrett A. Perchetti, Meei-Li Huang, Vikas Peddu, Keith R. Jerome, Alexander L. Greninger

Journal of Clinical Microbiology; Vol 58 No 8; 13 July 2020

Summary

It has been demonstrated that nasopharyngeal specimens containing SARS-CoV-2 can be stored in phosphate-buffered saline (PBS) as a substitute for viral transport medium (VTM) for up to 7 days.

3. Evaluation of Saline, Phosphate-Buffered Saline, and Minimum Essential Medium as Potential Alternatives to Viral Transport Media for SARS-CoV-2 Testing >

Kyle G. Rodino, Mark J. Espy, Seanne P. Buckwalter, Robert C. Walchak, Jeffery J. Germer, Emily Fernholz, Aimee Boerger, Audrey N. Schuetz, Joseph D. Yao, Matthew J. Binnicker

Journal of Clinical Microbiology June 2020 Volume 58 Issue 6 e00590-20

Summary

These data support the use of MEM, PBS, or 0.9% saline as alternatives to VTM for SARS-CoV-2 testing.

4. Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Is Comparable in Clinical Samples Preserved in Saline or Viral Transport Medium >

Jared Radbel, Sugeet Jagpal, Jason Roy, Andrew Brooks, Jay Tischfield Michael Sheldon, Christian Bixby, Dana Witt, Maria L. Gennaro, Daniel B. Horton, Emily S. Barrett, Jeffrey L. Carson, Reynold A. Panettieri Jr., Martin J. Blaser

The Journal of Molecular Diagnostics Volume 22, Issue 7, July 2020, Pages 871-875

Summary

The current study establishes PBS as a clinically useful transport medium with the potential to increase viral detection capacity, thus improving clinical care and surveillance efforts.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Saline Nasal Wash Sample At Least Equivalent, If Not Superior, to VTM Sample for PCR Testing (Cont.)

5. Evaluation of Saline as Potential Alternative to Viral Transport Media for COVID-19 Samples Stored at Different Temperatures >

P Sinha, DK Jain, S Gupta, Monika Gupta, Megha Gupta, A Agarwal, R Sharma, N Vyas

Journal of Clinical and Diagnostic Research. 2021 Apr, Vol-15(4): DC19-DC22

Summary

Looking into the cost and logistics issues especially during pandemics, saline is a good and cheaper alternative to VTM and with its use, testing capacity can be expanded.

Optimizing Automated PCR Testing Workflow

Swab-Free Transport as an Optimized Preanalytical Workflow for SARS-CoV-2 Amplification >

Greene DN, Matthys T, Lockwood CM.

J Appl Lab Med 29 April 2021;6(3):606-613. doi: 10.1093/jalm/jfaa197. PMID: 33119112.

Summary

SARS-CoV-2 was detected in all proof of principle samples with CT values indicative of dilution.
The rare exception was for a few samples where the dilution pushed the viral load below the LOD.
Paired samples were 100% concordant for SARS-CoV-2 and RNaseP detection.

Discarding the swab after inoculating the transport buffer is an appropriate preanalytical modification. Adopting this approach can save up to 1 minute per sample. For labs processing more than 500 samples per day, this equates to 1 full-time equivalent shift per day.

MicroWash Tie-In: MicroWash is a swab-free system with all the advantages outlined in this article.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Swab Removal from Specimen Tube and Sample Quality

Impact of swab removal in the detection of SARS-CoV-2 weakly positive specimens >

Zorzoli A, Bennett-Slater S, MacLean A, McAllister G, Gunson R, Templeton K.

Access Microbiol 12 Dec. 2023;5(12):000718.v3. doi: 10.1099/acmi.0.000718.v3. eCollection 2023. PMID: 38188247

Summary

- Most automated PCR testing requires the removal of the swab from the specimen tube prior to analysis as the retained swab may cause processing errors [1-2].
- The process of removing the swab from the specimen tube is time intensive and places lab technicians at risk for infection.
- Removal of the swab from the specimen tube may impact results for weakly positive specimens [2], resulting in false negative results.
- Swab-free specimens can save labs up to 1 minute/sample. For labs processing more than 500 samples/day, this equates to one full-time equivalent shift/day [1].

MicroWash Tie-In: Microwash eliminates the swab in the specimen tube problem, increasing lab efficiency, reducing risk to lab technicians, all while providing a high-quality specimen.

Clinical Applications in Chronic Disease States + Sampling for Microbiome Monitoring

1. Nasal lavage microbiome, but not nasal swab microbiome, correlates with sinonasal inflammation in children with cystic fibrosis >

Chung J, Boutin S, Frey DL, Joachim C, Mall MA, Sommerburg O. J Cyst

Fibros 9 Jan. 2024:S1569-1993(23)01735-6. doi: 10.1016/j.jcf.2023.12.011. Online ahead of print. PMID: 38199892

Summary

- Nasal wash results better reflect the microbiome of the nose and paranasal sinuses than nasal swabs.
- The microbiome of the upper airways may influence inflammation in patients with cystic fibrosis to assist in predicting disease course and guide treatment options.

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Clinical Applications in Chronic Disease States + Sampling for Microbiome Monitoring (Cont.)

2. Nasal Bacterial Microbiome Differs Between Healthy Controls and Those with Asthma and Allergic Rhinitis >

Chen M, He S, Miles P, Li C, Ge Y, Yu X, Wang L, Huang W, Kong X, Ma S, Li Y, Jiang Q, Zhang W, Cao C *Front Cell Infect Microbiol* 3 March 2022; 12:841995. doi: 10.3389/fcimb.2022.841995. eCollection 2022. PMID: 35310838

Summary

- Microbiome is also important in more common diseases, such as asthma.
- 'This study showed the upper airway microbiome is associated with airway inflammation disorders and the level of asthma control.'

MicroWash Tie-In: MicroWash provides an easy, painless way to provide the data needed to optimize care for patients with chronic respiratory disease and may enable the home monitoring program of the future.

Growing Importance of Co-Infection and Super-Infection in URI Cases

During the COVID-19 pandemic, a body of evidence documented pulmonary co-infections and super-infections in hospitalized patients, primarily in the ICU. Multiple viral and bacterial pathogens were identified in these cases. In many situations, these secondary infections resulted in more prolonged hospitalizations, ICU stays and even death.

This situation highlights the need for multi-pathogen testing, with the MicroWash being the ideal sample collection system, in the management of URI cases in the post-pandemic environment.

1. Machine learning links unresolving secondary pneumonia to mortality in patients with severe pneumonia, including COVID-19. >

Gao CA, Markov NS, Stoeger T, Pawlowski A, Kang M, Nannapaneni P, Grant RA, Pickens C, Walter JM, Kruser JM, Rasmussen L, Schneider D, Starren J, Donnelly HK, Donayre A, Luo Y, Budinger GRS, Wunderink RG, Misharin AV, Singer BD NU SCRIPT Study Investigators

J Clin Invest. 15 June 2023;133(12):e170682. doi: 10.1172/JCI170682.PMID: 37104035

Supporting References and Research

Independent Academic Research, Publications and Data (Cont.)

Growing Importance of Co-Infection and Super-Infection in URI Cases (Cont.)

2. Co-Infections and Superinfections in COVID-19 Critically Ill Patients Are Associated with CT Imaging Abnormalities and the Worst Outcomes >

Nicolò Brandi, Federica Ciccarese, Caterina Balacchi, Maria Rita Rimondi, Cecilia Modolon, Camilla Sportoletti, Chiara Capozzi, Matteo Renzulli, Alexandro Paccapelo, Andrea Castelli, Rita Golfieri. *Diagnostics (Basel)*. 3 July 2022; 12(7): 1617. doi: 10.3390/diagnostics12071617

3. Bacterial coinfections contribute to severe COVID-19 in winter. >

Hui Fan, Li Zhou, Jingjun Lv, Shimin Yang, Guozhong Chen, Xinjin Liu, Chunyan Han, Xue Tan, Shengnan Qian, Zegang Wu, Shan Yu, Ming Guo, Chengliang Zhu, Yu Chen & Ke Lan
Cell Research volume 33, pages 562–564 (2023)

Nasal Swab Testing Hesitancy

Universal Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) Testing Uptake in the Labor and Delivery Unit Implications for Health Equity >

Kernberg A, Kelly J, Nazeer S, Russell S, Tuuli M, Stout MJ, Raghuraman N, Carter EB
Obstetrics & Gynecology 136(6):p 1103-1108 December 2020. | DOI: 10.1097/AOG.0000000000004127

Summary

- All consecutive patients presenting for delivery without coronavirus disease 2019 (COVID-19) symptoms were offered testing over four 1-week phases.
- Of 270 patients 223 (83%) accepted testing and 47 (17%) declined.
- The most commonly cited reason for declining testing was concern regarding testing discomfort.

Have Questions?

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