AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology®

COMMENTARY

Approach to Assessment of New Swabs and Viral Transport Media for SARS-CoV-2 Testing

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ABSTRACT In light of the present pandemic of novel coronavirus disease 2019 (COVID-19) and the unprecedented high demand for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing worldwide, there are shortages of established specimen collection devices for respiratory viral testing for diagnostic microbiology laboratories. This creates the need to validate unverified collection devices from manufacturers that may not be a registered supplier for medical devices. As clinical laboratories do not routinely perform quality control of established collection devices, there is a need to have a systematic, robust approach to the assessment of substitute unregistered collection swabs and viral transport media (VTM). A discussion of the aspects requiring consideration when determining the suitability and implementation of new collection devices is presented. These specific assessment criteria include an inspection of device integrity, determination of swab and VTM sterility and *in vitro* performance, VTM stability, and examination of the clinical performance of the device. This method was used in a front-line medical microbiology laboratory on swabs and VTM from an unregistered manufacturer, with suboptimal results that precluded implementation. As the pandemic continues, it will be important for diagnostic laboratories to adopt a flexible and streamlined approach to maintaining adequate supply chains for testing reagents and materials.

KEYWORDS SARS-CoV-2, COVID-19, collection device, swab, viral transport media

The proper collection, storage, and transport of specimens are crucial for the accurate diagnosis of viral infections by nucleic acid amplification testing (NAAT) methods like real-time reverse transcriptase PCR (RT-PCR). Flocked nylon swabs (FLOQSwab; Copan Diagnostics) are often regarded as the gold standard for the collection of nasopharyngeal specimens for the detection of respiratory viruses due to their superior performance compared to other swab types (1). Many different transport media that adequately preserve virus viability and viral nucleic acid recovery can be employed, including viral transport media (VTM) or saline (2). Among these, VTM is widely used for the transport of specimens for downstream respiratory testing (3).

Since the World Health Organization (WHO) declared a pandemic of novel coronavirus disease 2019 (COVID-19) in March 2020, testing for the causative virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has become the cornerstone of pandemic management. Consequently, COVID-19 testing has increased exponentially worldwide. SARS-CoV-2 detection is typically swab based, collected from the nasopharynx (NP), oropharynx (OP), or nose (N) (4). As a result, there is an ongoing depletion of the global supply chain for established specimen collection devices for respiratory viral testing. To address the current collection device shortage, diagnostic microbiology laboratories can either choose to employ preexisting commercial swabs originally not intended for respiratory viral testing or turn to respiratory testing swabs that are not currently registered for use by the respective overseeing governing body. Some

Citation Locher K, Velapatino B, Caza M, Li L, Porter C, Charles M. 2021. Approach to assessment of new swabs and viral transport media for SARS-CoV-2 testing. J Clin Microbiol 59:e01562-20. https://doi.org/10.1128/JCM.01562-20.

Editor Colleen Suzanne Kraft, Emory University

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Accepted manuscript posted online 2 November 2020

Published 20 April 2021

TABLE 1 Methodological assessment of new swab types and viral transport media for SARS-CoV-2 and other respiratory viral testing

Phase	Description	Protocol outline	Acceptance criterion(a)
1	Visual inspection	VTM: leakage, vol, discoloration, turbidity, or visible contamination	No significant leakage or visibly compromised VTM tubes
		Swabs: size, flexibility, breakage	No breakage outside designated breakpoints, flexibility and size comparable with reference swab
2	Evaluation of swabs	Sterility	No bacterial or fungal growth; no contamination detectable by PCR
		In vitro performance	Results comparable with reference swab (C_T difference of <2)
3	Evaluation of UTM	Sterility	No bacterial or fungal growth; no contamination detectable by PCR
		Recovery of viral nucleic acids	Results comparable with reference swab (categorical agreement)
		Stability at different storage conditions	Results comparable with reference swab at different time points (C_T difference of <2)
4	Clinical performance	Performance on patients or volunteers	Results between reference swab and test swab in categorical agreement; tolerable comfort reported by patients

studies have also explored using phosphate-buffered saline (PBS) or saline in lieu of VTM, with good results (5, 6). This protocol focuses on products that include commercially produced VTM but would also be applicable to PBS or saline. Swabs and specimen collection kits containing swabs are regulated as medical devices, and manufacturers are required to comply with regulatory requirements to be able to import or sell these kits (7). Per the Clinical and Laboratory Standards Institute (CLSI) guidelines on the quality control of microbiological transport systems (8), it is a regulatory requirement for the manufacturer to ensure that collection devices meet quality standards. Recent national purchasing of collection devices in Canada yielded swabs that were visibly contaminated (9, 10), stressing the importance of thorough quality assessment of this preanalytical device. The quality and performance of any collection swab and VTM from unregistered manufacturers has to be ensured before the device can be clinically used for specimen collection from patients.

Our frontline clinical microbiology laboratory was required to evaluate new collection devices that were not listed as a registered medical device, often with limited sampling size available. We describe a detailed protocol for the extensive quality and performance evaluation of such new collection devices for the detection of SARS-CoV-2 and other respiratory viruses. In preparation for increased demand for testing as the pandemic moves into the upcoming influenza season, influenza A, influenza B, and respiratory syncytial virus (RSV) were also included in this protocol. The method outlined below can be completed with a small number of paired swabs and VTM.

This assessment comprises four phases (Table 1): overall inspection of the collection kit, evaluation of the swabs, evaluation of the VTM, and, if the device is deemed suitable, a clinical performance assessment. A viral specimen collection device previously validated by the laboratory should be used as the reference standard for the assessment of the new collection devices. In our case, this is Copan's universal transport medium (UTM) and FLOQSwab (Copan Diagnostics, Brescia, Italy).

PHASE 1: VISUAL INSPECTION OF COLLECTION KIT

Each collection kit that is received is visually inspected for the overall integrity of the swabs and VTM tubes. The VTM tubes are inspected for evidence of any fluid leakage, consistent volume, and signs of possible contaminations, such as changes in turbidity, floating growth, and pH, as indicated by a color change of the medium. The swabs are examined for any tears in the packaging that could compromise the sterility of the swabs and for broken swabs. The swab size and flexibility are also noted (rigid versus pliable), as rigidity and large size both adversely affect patient comfort during specimen collection and dictate the collection methods possible (for example, nasopharyngeal swab versus nasal swab collection). This would be especially relevant to any three-dimensional (3D)-printed swabs under validation. The swabs must be both flexible enough to enter the nasal cavity and strong enough to withstand mechanical force against the mucosa or torsion without breaking. A manual assessment of the flexibility and the fragility of

TABLE 2 Culture media and incubation conditions used to assess sterility of the swabs and VTM

Culture medium	Targeted microorganisms	Incubation conditions
Blood agar plate	Routinely cultivable bacteria, e.g., *Enterobacteriaceae* and *Pseudomonas* species	35 ± 2°C in 5% CO_2 atmosphere for 48 h
Chocolate agar plate	Fastidious bacteria, e.g., *Haemophilus* species	35 ± 2°C in 5% CO_2 atmosphere for 48 h
BCYE agar plate	*Legionella* species (9, 10)	35 ± 2°C in 5% CO_2 atmosphere for 14 days
Thioglycolate broth	Fastidious bacteria and anaerobes	35 ± 2°C in 5% CO_2 atmosphere for 14 days
Sabouraud dextrose agar plate	Fungi	28°C for 14 days

the flocked or 3D-printed swabs should be performed compared to a reference swab. The flexibility of the head, the neck, and the breakpoint should be assessed (11). Any breakage of swabs outside the designated breakpoints or very inflexible swabs should be excluded from validation. Furthermore, any significantly compromised collection kits should be discarded and precluded from clinical use.

PHASE 2: EVALUATION OF THE SWABS

Sterility of the swabs. The sterility assessment of a new swab type has to ensure that the product is free of microbial contamination that could be introduced into the patient's nasopharyngeal mucosa during specimen collection. The swab should not harbor respiratory pathogens of concern (detailed in Table 2). Furthermore, the swabs should not contain any traces of microbial nucleic acids that could lead to false-positive results in downstream testing.

Following the recommendations outlined in the Centers for Disease Control and Prevention (CDC) protocol for the preparation of viral transport medium (12), a sample size of 10% or a minimum of 4 swabs of each lot number, whichever is greater, should be selected where a batch of up to 100 swabs is received. The swabs should be assessed for bacterial, fungal, and viral contaminants.

Each test swab is placed into 5 ml of sterile 0.85% saline solution (SS) and vortexed for 10 s. Subsequently, 100 μl of each SS is inoculated onto various culture media (Table 2) to target the growth of common bacterial and fungal contaminants. There should be no growth observed in any of the cultures.

To detect contamination with viral nucleic acids that could lead to false-positive results in downstream NAAT, the swabs should be tested for any viral targets that the collection device will be used for. Nucleic acids are extracted from each aliquot of the above-described prepared saline solutions and subsequently tested for the respective viral targets. Where available, the aliquots should be tested using an extended multiplexed respiratory panel if required. There should be no positive results for any of the targets tested.

***In vitro* performance of the swabs.** The ability of the swab to "transfer" viral particles is assessed and compared with the validated reference product, e.g., the Copan FLOQSwab. As viral culture techniques are not routinely available in frontline clinical laboratories, alternatively clinical specimens positive for the respective virus can be utilized. Dilutions of the specimens at different analyte concentrations are transferred with the swab, and the amount of virus transferred is then estimated by RT-PCR. This method was adapted from the swab elution method for bacterial suspensions, as outlined in the CLSI standard on the quality control of microbiological transport systems (8).

More precisely, two archived nasopharyngeal swab (NPS) specimens in Copan UTM with an initial cycle threshold (C_T) of around 20 cycles by RT-PCR are chosen: one specimen positive for SARS-CoV-2 and one specimen positive for another respiratory virus (influenza A, influenza B, or RSV). Each specimen undergoes serial 10-fold dilutions (10^{-1} to 10^{-4}) in sterile phosphate-buffered saline (PBS) to produce 4 primary dilutions. The C_T results of the 4 dilutions should fall between 25 and 35, depending on the dilution and original C_T (11). The test swab and reference swab, in parallel, are immersed into each dilution for 10 s, transferred into a tube containing 500 μl of sterile PBS (secondary dilution), swirled in the tube with PBS for 10 s, pressed against the sides of the tube, and then removed. In our experience, this swab transfer typically results in an additional 10-fold dilution of the primary

specimen dilution. Depending on the amount of swabs available for testing, this should be done in duplicate. For one additional aliquot of one dilution per sample (e.g., 10^{-3}), the swab should be left in the tube after the sample transfer. The swab should remain in the PBS for 24 h under refrigeration. This will reveal the possible presence of inhibitory substances being released from the swab into the medium, which could interfere with downstream PCR testing. This should be done with the reference swab in parallel.

Aliquots of the secondary PBS dilution or the PBS containing the swabs undergo nucleic acid extraction and are tested by RT-PCR for the respective virus. The C_T values obtained using the test swab are compared with the reference swab and should not vary significantly from the reference swabs, e.g., should be no greater than 2 cycles (13). In our experience, for the majority of the swabs assessed using this method, the C_T difference between the test swab and the reference swab was less than 1 C_T and no more than 1.5 C_T for flocked swabs.

PHASE 3: EVALUATION OF THE VTM

Similar to the assessment of the swab, the VTM is examined for sterility, for the recovery and detection of viral nucleic acids at low analyte concentrations, and for the stability and recovery of viral nucleic acids under different storage conditions.

Sterility of the VTM. The sterility of the VTM needs to be ascertained to avoid overgrowth of the transport medium by organisms that could interfere with downstream testing. Furthermore, the VTM should be free of nucleic acids that could lead to false-positive test results. As described for the swabs, a sample size of 10% of each lot number of VTM received or a minimum of 4 VTM tubes should be selected (12).

Similar to the process for the sterility of the swabs, aliquots (100 μl) of the test VTM, including different lot numbers, are inoculated onto the above-listed culture media (Table 2). Additionally, a second aliquot of each VTM tube is extracted and subsequently tested by RT-PCR, as described for the sterility assessment of the swabs.

Recovery of viral nucleic acids from the VTM. The efficacy of nucleic acid recovery from the test VTM is evaluated over a range of different analyte concentrations. It is imperative to assess the VTM for analyte concentrations at the limit of detection of the respective assay used.

The test VTM is inoculated with archived patient specimens known to be positive for the respective respiratory virus. The inoculation of the VTM should be slightly above the limit of detection of the RT-PCR assay.

Specifically, 2 clinical NP samples positive for SARS-CoV-2 and 2 clinical NPS specimens positive for a different respiratory virus (influenza A, influenza B, or RSV) are selected. Each specimen is diluted 1:1,000 and 1:10,000 in the test VTM. If specimens with an original C_T value between 23 and 25 cycles are chosen, the dilutions should result in C_T values around 34 and 37 cycles, respectively, when tested by RT-PCR (14). These dilutions can be adjusted to reflect the respective assay C_T cutoff. Three aliquots of each dilution are extracted and tested by the respective RT-PCR. This is done in parallel with the reference UTM.

Overall, dilutions around the limit of detection for the respective assay should give comparable results for both the reference UTM and test VTM. The results should be in categorical agreement compared with the reference UTM. The C_T values might show some variation, which can be expected at low levels of analyte concentrations.

Stability and recovery of viral nucleic acids under different storage conditions. As many laboratories are centralized, the transportation of specimens from more remote collection sites is a factor to consider when choosing a collection device. The viral transport medium has to ensure that the specimen is preserved over prolonged periods of time. A stability study is performed to demonstrate the adequate recovery of viral nucleic acids from VTM stored for various periods of time and at different temperatures. Time points and temperatures are chosen that are representative of actual specimen storage and transport times (Table 3).

Four clinical NPS specimens are chosen: 2 specimens positive for SARS-CoV-2 and 2 specimens positive for a different respiratory virus (influenza A, influenza B, or RSV). The

TABLE 3 Storage temperatures and times used for stability study of test VTM

Time point	Storage temp and times
0	No storage, extract immediately (serves as the reference point)
1	Stored at room temp for 24 h
2	Stored at 4°C for 24 h
3	Stored at 4°C for 48 h
4	Stored at 4°C for 120 h
5	Stored at room temp for 120 h

original C_T values should fall between 25 to 28 cycles for the respective viral target. Each specimen is diluted 1:100 in the VTM and in the reference UTM, so that the resulting C_T value of the diluted specimens lies between 31 and 34 cycles (14). For each diluted sample, 6 aliquots are prepared. Each of the 6 aliquots is then subjected to one of the 6 storage conditions detailed in Table 3. Alternatively, each laboratory should validate the collection devices for their routine storage conditions. Nucleic acids from aliquots under each respective storage condition are extracted and tested by RT-PCR for the respective viral target. The resulting C_T values of the aliquots at different times and storage temperatures are compared for the test VTM and also between the test VTM and the reference UTM. C_T values should not be affected by the storage temperatures or times evaluated and should be comparable with the reference UTM, i.e., the C_T difference at the respective time point between the test VTM and reference VTM should be no greater than 2 cycles (13).

PHASE 4: EVALUATION OF CLINICAL PERFORMANCE

Lastly, if the first three phases of the evaluation result in a satisfactory outcome and the sterility and performance of the new collection device are ensured, the clinical performance of the test swab and VTM should be compared to the reference collection kit. Both collection devices are used to obtain samples from patients known to be positive for SARS-CoV-2 or another respiratory virus, such as influenza. In this phase, per the recently published Canadian regulations, at least 30 patients should be recruited for the clinical performance evaluation (13). Alternatively, the collection device can be used on a few volunteers first to evaluate the comfort of the swab during collection. For each patient or volunteer, one nasopharyngeal swab using the reference collection device and one sample using the collection device to be tested will be collected sequentially from each nostril during one session. Nucleic acid extraction and RT-PCR for SARS-CoV-2 (or respective respiratory virus) are performed per the respective laboratory protocol. Categorical agreement is assessed between the reference collection device and the test device. Some variability between the C_T values of the two devices might occur due to sampling effects, especially in patients with lower viral loads.

Summary of assessment results. Our experience with the assessment of collection devices from manufacturers that are not currently registered or listed with the respective governing body exposed the problems that can arise from using collection devices with uncertain quality assurance parameters and highlights the need to perform a thorough evaluation of any new swab and VTM type prior to use. This systematic approach allowed us to quickly reject or approve new collection devices.

Since the design of this protocol, our laboratory has assessed more than 10 different collection kits consisting of VTM and a flocked swab, 3 different brands of VTM only, and 2 different types of 3D-printed swabs.

Generally, we observed acceptable results for the assessment of the flocked swabs. All flocked swabs passed the first phase of visual inspection and the flexibility, size, and position of breakpoints were comparable with the reference flocked swab. For one brand, growth was observed on cultures from 3 out of 10 swabs tested. Scant growth of *Bacillus megaterium* and *Dermacoccus nishinomiyaensis* (on BAP plates) and *Staphylococcus hominis* and *Haemophilus parainfluenzae* (on buffered charcoal yeast extract [BCYE] plates) was observed. The respective VTM of this collection kit also resulted in moderate to heavy growth of *Pseudomonas putida*, *Arthrobacter woluwensis*, *Sphingomonas parapaucimobilis*,

TABLE 4 Examples of issues encountered during the various phases of the validation protocol

Manufacturer	Device description	Protocol phase	Summary of issues
1	VTM with flocked swab	Swab sterility	3/10 swabs with growth observed in cultures (BAP and BCYE plates)
		VTM sterility	In 10/10 VTM moderate to heavy growth was observed in all culture media
2	VTM with flocked swab	Device integrity	13% of VTM containers with visible leakage or inconsistent vol
3	VTM with flocked swab	Device integrity	4% of VTM containers with visible leakage or inconsistent vol
4	VTM with flocked swab	Device integrity	Visible growth, discoloration, and leakage in a no. of VTM containers
5	3D printed swab	Integrity	Breakage of stem outside break point, limited flexibility
		In vitro performance of swab	Poor transfer effectiveness, C_T values 3–4 cycles higher than reference flocked swab

and *Rhizobium radiobacter* on all culture plates and broth inoculated with the VTM (Table 4). The efficacy of the flocked swabs in their ability to transfer viral particles was good overall, with minor differences observed between the reference swab and the test swab. In contrast, for both of the 3D-printed swabs that we assessed, the C_T values of the transferred samples were overall higher (between 3 and 4) compared with the reference flocked swab, suggesting that this swab type is less effective at transferring viral particles. One of the 3D-printed swabs exhibited breakage of the shaft and swab head and had very poor flexibility, causing severe discomfort when tried on volunteer testers. However, we have limited experience with 3D-printed swabs and others recently have reported good performance for various 3D-printed swabs (11, 15).

The majority of the VTM brands performed well and were free of contamination. The first phase of visual inspection of the device integrity resulted in the quick rejection of several collection devices. For 3 brands, we observed leakage of the VTM containers and/or visibly inconsistent volumes in the container in up to 13% of the kits received. All brands of VTM tested were supposedly sterilized by the manufacturer; however, one brand showed visible turbidity, discoloration, and leakage in a number of VTM containers received and was not further assessed for this reason. A different brand of VTM, which had passed the initial visual inspection and was seemingly clean, did result in moderate to heavy growth on all culture plates and thioglycolate broth.

We did not observe any problems with the stability of samples or the recovery of viral nucleic acids in any of the VTM tested.

CONCLUSIONS

The quality control of swabs is not expected to be routinely done by frontline laboratories per CLSI standard M40-A2. This article describes a systematic method to evaluate swabs and VTM from unregistered manufacturers. This approach allows the assessment of the quality of new viral specimen collection devices using methods available in most frontline laboratories, which prevents large purchases of nonsuitable swabs that do not meet quality criteria for diagnostic testing. This method is broadly applicable, as microbiology laboratories are faced with assessing collection devices that do not yet have clearance or approval from relevant federal or local regulatory bodies for respiratory viral testing. The components consist of inspection of device integrity, determination of swab and VTM sterility and effectiveness, determination of the stability of the VTM, and examination of the clinical performance of the device. As this pandemic evolves, it will be important to consider the question of routine quality control of swabs and VTMS that are from unlicensed manufacturers.

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