

SARS-CoV-2 (COVID-19)/Influenza A/B

Respiratory infectious disease molecular testing specimen collection guide

Test codes 31688, 31686, 31687

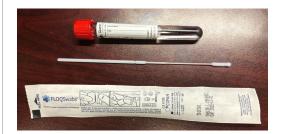
Acceptable media for **only** SARS-CoV-2 & Influenza A/B (TC 31688) **NP and AN acceptable**

Quest Phosphate Buffered Saline (PBS) NP and AN Swab

Convenience kits for collecting and transporting upper respiratory specimens

NP kit ordering information: PeopleSoft item #: 207128 PeopleSoft product ID: K162 Kit, PBS, Quest, 100/CA Ordered by the EA (each)

AN kit ordering information:
PeopleSoft item #: 207621
PeopleSoft product ID: K165 KIT,
ANTERIOR, NARES, PBS, 4PK
Ordered by the EA (each) in multiples
of 4 only. For example, ordering 8 EA
results in 2 kits of 4.





Acceptable media for the following Quest Diagnostics respiratory infectious disease molecular tests (codes):

SARS-CoV-2 RNA (COVID-19) and Influenza A and B, Qualitative NAAT (TC 31688)

- nasopharyngeal (NP) and anterior nares (AN) acceptable

SARS-CoV-2 RNA (COVID-19) and Respiratory Viral Panel (RVP), Qualitative NAAT (TC 31686) - NP only

SARS-CoV-2 RNA (COVID-19) and Respiratory Pathogen Panel (RPP), Qualitative NAAT (TC 31687) - NP only

VCM (Copan)1

NP kit ordering information:

- PeopleSoft item #: 142059
- PeopleSoft product ID #: S05
- Quanum product ID #: S05
- Ordered by the EA (each)





Acceptable for AN submissions

^{* 1} mL of volume may result in a Quantity Not Sufficient (QNS) if repeat testing of a specimen is needed. Therefore, 1 mL vials are not preferred and should only be used when other vials are not available.



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SARS-CoV-2 RNA (COVID-19) and Respiratory Viral Panel (RVP), Qualitative NAAT (TC 31686) - NP only

SARS-CoV-2 RNA (COVID-19) and Respiratory Pathogen Panel (RPP), Qualitative NAAT (TC 31687) - NP only

Copan UTM²

Combo collection kit NP, AN; 321 C NP Collection Kit-305C AN Collection Kit-306C

UTM medium 3 mL-330C or 3U044n NP flocked swab-503CS501

AN flocked swab-519CS501





BD UVT³

Combo collection kit nasopharyngeal and oropharyngeal 3 mL-220527

NP Collection Kit-220529 AN Collection Kit-220528

UTM medium 3 mL-220220 (1 mL*-220244)

NP flocked swab-220252 AN flocked swab-220250



Cepheid® Xpert® Sample Collection Kit for Viruses⁴

B-100 NP (new M-100 kit is equivalent) F-100 AN



B-100 for NP





Hardy Diagnostics Healthlink UTM5

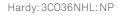
Hardy: 3CO36NHL 3 mL: NP Hardy: 3C037NHL 3 mL: NP Hardy: 3C040NHL 1 mL*: NP Hardy: 3C038NHL 3 mL: AN Hardy: 3C011NHL 1 mL*: AN

Hardy: 330CHL: 3 mL UTM

Hardy: 3C039NHL 3 mL (NP and AN)

Hardy: 302CHL 3 mL (2 AN with plastic applicator)







Hardy: 3C038NHL: OP/AN

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Puritan® UniTranz-RT Universal Transport

Medium (UTM) with no swabs⁶ 1 mL* (UT 100); 3 mL (UT-300)

Puritan® UniTranz-RT UTM with flocked swabs for NP (1 mL)*6

Minitip (UT-116)

Ultrafine flocked swabs (UT-117)

Elongated swab (UT-367)

Puritan® UniTranz-RT UTM with flocked swabs for NP (3 mL)6

Ultrafine flocked swabs (UT-317) Minitip flocked swab (UT-316)

Puritan® UniTranz-RT UTM with flocked swabs for OP/AN6

Large flocked swab 1 mL* (UT-106)

Elongated flocked swab 3 mL (UT-306)

Puritan® UniTranz-RT UTM with Polyester swabs for OP/AN (3 mL)⁶

One swab (UT-361)|

Two swabs (UT-362)

NP and AN both 1 minitip and 1 standard (UT-366 and UT-302)



Quest Diagnostics will also accept commercially available prefilled physiological 0.9% saline for AN swabs only.

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Swab considerations:

- Swab must be appropriate for the anatomic site on which it is used (NP or AN)
- Flocked swabs are preferred. Only sterile Dacron®, polyester, nylon, or rayon swabs with plastic/polystyrene shafts are acceptable. Cotton swabs are not acceptable. 3D-printed swabs are not acceptable.
- Swab stem/shaft must be flexible and long enough to collect the NP sample.
- If the applicator handle requires additional trimming, it is also important to perform the trimming with a sterile pair of scissors to prevent contamination of the sample.
- Calcium alginate swabs or swabs with wooden shafts are unacceptable as they may contain substances that inactivate some viruses and inhibit PCR testing

The products described in table 1 are equivalent products. They are manufactured in identical fashion with all raw materials being utilized in all products being equivalent and at the same ratios. Specifically, Copan Universal Transport Medium (UTM), BD UVT, Cepheid XPert Sample Collection Kit for Viruses, Hardy-HealthLink UTM, Puritan UniTranz, and Quest VCM transports are equivalent products.

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus, and influenza B virus, and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

References

- Simplify lab-related tasks for better practice workflow. Quest Diagnostics website. Published December 2018. Accessed September 13, 2020. https://hcpenroll.questdiagnostics.com/wp-content/uploads/2018/12/NEW-Quanum-for-HCP-Website-Brochure.pdf
- 2. Copan increases production of UTM COVID-19 sample collection kits. Medical Supply Company Ltd website. Published September 13, 2020. Accessed March 12, 2020. https://www.medical-supply.ie/2020/03/05/copan-increases-production-of-utm/
- $3. \quad \text{Beckton Dickinson website.} \\ \text{Accessed September 13, 2020.} \\ \text{https://products.copangroup.com/index.php/products/clinical/utm.} \\$
- 4. Cepheid product website. Accessed September 13, 2020. https://www.cepheid.com/?msclkid=e78ea74e94ed19d1538ef924e1b802e7&utm_source=bing&utm_medium=cpc&utm_campaign=USA%7CCepheid%7CBM&utm_term=%2BCepheid&utm_content=Cepheid
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- 6. Puritan UniTranz website. Accessed September 13, 2020. https://www.puritanmedproducts.com/ut-117.html

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