

COVID-19 specimen collection guidelines

Quest specimen requirements and acceptable supplies for SARS-CoV-2 RNA (COVID-19), Qualitative NAAT (test code 39448)

Quest does not manufacture the collection supplies used in testing. Due to extraordinary demand, we are temporarily unable to accept online orders for upper respiratory specimen collection and transport supplies. Please call your local order entry team for more information. You do not have to use supplies from Quest to send us samples for testing. Please refer to the information below and to the Quest Test Directory at TestDirectory.QuestDiagnostics.com for a list of acceptable specimen collection and transport supplies for COVID-19 testing.

The tests performed under this test code are being offered under an Emergency Use Authorization (EUA) by the FDA. The EUA stipulates the tests may be used only by Quest laboratories and only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens. The authorization is valid only for the duration of the declaration that circumstances exist justifying the EUA for in vitro diagnostic tests for the detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act 21, U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

This guide is intended to describe the collection devices to be used for upper respiratory specimens for COVID-19.

For additional examples of acceptable swabs, visit the FDA website:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

NOTE: FOR TRANSPORT MEDIA, STRICTLY FOLLOW THIS GUIDE.

Information on samples from anterior nares:

Anterior nares specimen: Collected by a healthcare professional or a patient self-collected sample is acceptable when the patient is in an appropriate clinical setting (such as a drive-thru testing site).

Collection instructions: Use a single foam swab for collecting specimens from both nares of a symptomatic patient. Insert foam swab into 1 nostril straight back (not upwards). Once the swab is in place, rotate it in a circular motion 2 times and keep it in place for 15 seconds. Repeat this step for the second nostril using the same swab. Remove foam swab and insert the swab into an acceptable viral transport medium (including saline and PBS).

Acceptable foam swab: Puritan® 6" Sterile Standard Foam Swab w/ Polystyrene Handle (SKU # 25-1506 1PF) and Copan® Foam swab single wrapped (1C055S01)

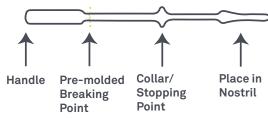


Information on mid-turbinate specimen:

Mid-turbinate specimen: Collected by a healthcare professional or a patient self-collected sample is acceptable when the patient is in an appropriate clinical setting (such as a drive-thru testing site).

Collection instructions: Use a collar/stopping point swab for collecting specimens from both nares of a symptomatic patient. Tilt patient head and insert swab into 1 nostril until the swab collar touches the outside of the nose. Once the swab is in place, rotate it in a circular motion 2 times and keep it in place for 15 seconds. Repeat this step for the second nostril using the same swab. Remove the swab and insert the swab into an acceptable viral transport listed in this guide (including saline and PBS). Break the swab shaft against the side of the tube, and close the lid.

Acceptable swabs: Contoured Adult Flocked Swab w/ Stopper with 80 mm Breakpoint Copan® FLOQSwab (56380CS01) and MDL® NasoSwab™ A362CS02





Specimen stability is as follows:

Room temperature: 5 days Frozen (-20 °C): 7 days

Refrigerated (2 °C-8 °C): 5 days Frozen (-70 °C): Acceptable

Specimens should be transported to your local Quest Diagnostics laboratory according to standard operating procedures. Cold packs/pouches should be used if placing specimens in a lockbox for courier pick-up. STAT pick-up cannot be ordered for these tests.

General comments for NP and/or OP specimens:

- Use only sterile Dacron® or rayon swabs with plastic shafts. Wired shaft swabs are acceptable.
- Flocked swabs are preferred.
- 3D-printed swabs are not acceptable.
- Note the stem/shaft must be flexible and long enough to collect the NP sample.
- Do not use calcium alginate swabs; swabs with wooden shafts; or swabs in bacterial culturette-type liquid or gel transports (see illustration on page 7 below), as they may contain substances that inhibit PCR testing.
- Saline has been indicated by the FDA in their FAQs as an acceptable transport medium that can be used in situations where commercial viral transport media are unavailable for molecular RT-PCR SARS-CoV-2 assays (such as those in use for the Quest tests). Note, the FDA believes that for saline, a sterile plastic vial containing between 1 mL and 3 mL of phosphate buffered saline (PBS) 1X pH 7.4 (range of pH 7.2-7.4) or saline (0.85% to 0.90%) is appropriate (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). The FDA believes that sample collection with a flocked swab is preferred. When options are limited, collection by a foam swab or spun synthetic swab is also acceptable, but may not be sufficient to rule out infection. Collection should be conducted with a sterile swab.
 - Quest Diagnostics will accept commercially available prefilled saline or PBS vials. In addition, for clients able to fill vials (using sterile laminar flow hood or a biological safety hood), Quest will accept 2-3 mL sterile PBS or sterile saline (0.85% or 0.9%) provided the vial filling process below is followed.

Viral transport media (VTM):

- 1 mL or 3 mL commercially available vials are acceptable (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).
- Only 3 mL vials of acceptable VTM may be split into 2 vials (1.5 mL each) using the vial filling process below.
- Clients interested in creating their own VTM should refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf) and should follow the vial filling process outlined below.

Vial filling process:

- Note: Add the VTM, PBS, or saline in the sterile container before collecting the patient sample.
- Label an empty sterile container (eg, 10 mL falcon tube or equivalent, conical or round bottom) by placing the label close to the top end of the tube, ensuring enough space for the lab label. The label should include:
 - Lot #, expiration date, and manufacturer (for commercially available VTM, PBS, or saline)
 - The date of manufacture, and expiration date, if known (for client created VTM)
- Use a sterile environment (eg, a laminar flow hood or biological safety hood) and add the appropriate volume of liquid to the sterile vial.
- Use 1.5 mL when splitting a 3 mL VTM tube (the mixing beads at the bottom of viral medium do not need to be transferred) or 2 mL to 3 mL of saline.
- Secure the lid of the tube until fully closed to prevent leakage.







Sterile plastic tube size–16 mm x 100 mm (NO GLASS TUBES OR SNAP CAP TUBES)

TUBES WITH CLOT ACTIVATOR ARE NOT ACCEPTABLE



Acceptable COVID-19 specimen transport media and swabs for test code 39448

Quest PBS (Phosphate Buffered Saline) NP Swab

Convenience kit 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)



VCM (Diagnostic Hybrids)1

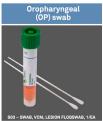
NP kit ordering information:

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

OP kit ordering information:

- PeopleSoft item #: 142060
- PeopleSoft product ID #: S03
- Quanum product ID #: S03
- Ordered by the EA (each)











Lesion swabs (Quest supply # S03) are preferred for oropharyngeal samples.

- Both swabs in supply kit S03 are the same; only one is necessary for specimen collection
- Cervical swabs (Quest supply # S06) are acceptable but only the smaller swab should be used for specimen collection

Amies liquid elution swab (ESwab)

ESwab with 1 mL of Amies fluid in the transport vial

Routine swab-OP swab Minitip swab-NP swab

Swab, ESwab (Amies liquid elution swab) routine, white cap, Amies Medium, 1/each:

PeopleSoft #: 164115 PeopleSoft product ID #: S12 Quanum product ID #: S12 Ordered by the EA (each)

SWAB, E-SWAB, (Amies liquid elution swab)

minitip, 1/each

PeopleSoft #: 161558 PeopleSoft product ID #: S10

Quanum product ID #: S10 Ordered by the EA (each)

Acceptable but not supplied by Quest



OP swab



Minitip-NP swab

VCM (Diagnostic Hybrids)1



S06: Acceptable but no longer able to be ordered through Quest



Acceptable (but not supplied by Quest) COVID-19 specimen transport media and swabs for test code 39448, continued

UTM (Copan)2

Combo collection kit nasopharyngeal and oropharyngeal 321 C

NP Collection Kit-305C OP Collection Kit-306C UTM medium 3 mL-330C NP flocked swab-503CS01 OP flocked swab-519CS01



UVT (BD)3

Combo collection kit nasopharyngeal and oropharyngeal 3 mL-220527

NP Collection Kit-220529 OP Collection Kit-220528

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

NP flocked swab-220252 OP flocked swab-220250



Cepheid® Xpert® Sample Collection Kit for Viruses⁴

B-100 NP F-100 OP





B-100 for NP

F-100 for OP

Hardy Diagnostics Healthlink UTM5

Hardy: 3C036NHL 3 mL: NP Hardy: 3C037NHL 3 mL: NP Hardy: 3C040NHL 1 mL: NP Hardy: 3C038NHL 3 mL: OP Hardy: 3C011NHL 1 mL OP

Hardy: 330CHL: 3 mL UTM

Hardy: 3C039NHL 3 mL (NP and OP)

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





Hardy: 3CO36NHL: NP

Hardy: 3C038NHL: OP

M4 (Fisher/Remel)6

Contains vancomycin, amphotericin B, and colistin and is suitable for transport of viruses, Chlamydiae, Mycoplasma and Ureaplasma)



M4RT (Fisher/Remel)⁶

Contains gentamicin and amphotericin B and is only suitable for transport of viruses and Chlamydiae





Acceptable (but not supplied by Quest) COVID-19 specimen transport media and swabs for test code 39448, continued

M5 (Fisher/Remel)6

Similar to the M4, but it does not contain gelatin



M6 (Fisher/Remel)6

Contains gelatin, vancomycin, amphotericin B, and colistin for the transport of viruses, Chlamydiae, Ureaplasmas, and Mycoplasmas



Puritan® UniTranz-RT® Transport System 1 mL

For the collection and preservation of Virus, Chlamydia, Mycoplasma and Ureaplasma.

Puritan® UniTranz-RT Universal Transport Medium (UTM) with no swabs

1 mL (UT 100); 3 mL (UT-300)

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

Minitip (UT-116) Ultrafine flocked swabs (UT-117) Elongated swab (UT-367)

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

Ultrafine flocked swabs (UT-317) Mini-tip Flock Swab (UT-316)

Puritan® UniTranz-RT UTM with flocked swabs for OP

Large flocked swab 1 mL (UT-106) Elongated flocked swab 3 mL (UT-306)

Puritan[®] UniTranz-RT UTM with Polyester swabs for OP (3 mL)

One swab (UT-361) Two swabs (UT-362) NP and OP both 1 minitip and 1 standard (UT-366 and UT-302)



Puritan* UniTranz-RT Transport System 3 m

For the collection and preservation of Virus.

Starplex™ Scientific Multitrans™ with flocked swabs from Fisher Scientific

NP flocked: 23-038-096

NP and OP flocked swab: 22-046-450





Acceptable (but not supplied by Quest) COVID-19 specimen transport media and swabs for test code 39448, continued

Copan ESwab™7

Flocked swab with 1 mL of liquid Amies in a plastic, screw-cap tube

White cap (OP flocked swab): Cat#480C or 4C012S.A Green cap (minitip flocked swab for NP): Cat#481C Blue cap (wire shaft/flexible minitip for NP): Cat#482C



White-OP
Green and blue-NP

BD ESwab™8

1 mL of modified liquid Amies medium packaged with a nylon flocked swab

The system is available in 3 flocked swab formats: regular (white), minitip (green) and flexible minitip (blue)

White (reg flocked swab) OP: Cat#220245 Green (minitip flocked swab) NP: Cat#220246 Blue (flexible minitip) NP: Cat#220532



White-OP
Green and blue-NP

Puritan® Opti-Swab™ 1 mL Liquid Amies Transport Medium w/ 6" elongated flock swab9

Item # LA-106 for OP swab



Green-NP

Puritan® Opti-Swab™ 1 mL Liquid Amies Transport Medium w/ 6" minitip flock swab¹0

Item # LA-116 for NP swab



Blue-NP

Puritan® Opti-Swab™ 1 mL Liquid Amies Transport Medium w/ 6" ultrafine flock swab¹¹

Item #LA-117 for NP swab





UNACCEPTABLE specimens for test code 39448

Calcium alginate swabs, wooden shafted swabs, charcoal medium, anaerobic swab/transport medium

Swab in Amies liquid transport

Amies in swabs is generally in a sponge so there is no fluid to test for ${\tt COVID-19}$

Single or double swab (red cap)
Twisted wire shaft swab (green cap)

Swab in Amies gel transport

Gel is not acceptable for PCR Single or double swab (blue cap) Twisted wire shaft swab (yellow cap)



BD EZ Swab (single swab)12

Product code 220093



Available with liquid Stuart or liquid Amies media in more than 15 swab and shaft configurations, BD CultureSwab products are designed to meet a wide range of transport needs³

BD EZ Swab (double swab)13

Product code 220105



BD BBL m CultureSwab m EZ II collection and transport systems are simple-to-use, media-free systems that contain a patented polyurethane foam swab

BD MaxV¹⁴

Product code 220235 (single swab, gel/no charcoal)

Product code 220236 (double swab, Amies gel/no charcoal)

Product code 220122 (dbl swab, Amies gel w/ charcoal)





The BD CultureSwab MaxV system is available with liquid Stuart or liquid Amies media, in single- or double-swab formats, for the transport of aerobes. Additionally, the BD CultureSwab MaxV (+) system is available in Amies gel medium without charcoal, in single- and double-swab formats, for the transport of aerobic and facultative anaerobic organisms⁵

BBL BD CultureSwab™-Liquid Stuart (minitip swab-green cap)

Product code 220133



BD ProbeTec[™] transport vials



Quidel urethral swab

PeopleSoft #:142058
PeopleSoft product ID #:S09
Quanum product ID #:S09
Mfg Part #:#99-08014-VCM







UNACCEPTABLE specimens for test code 39448, continued Calcium alginate swabs, wooden shafted swabs, charcoal medium, anaerobic swab/transport medium Beaver PrimeStore-MTM® Inveox transport media DNA/RNA Shield™

Ref: Equivalency-Copan Universal Transport Medium (UTM)

The products described in the accompanying table 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.

 $Specifically, Copan \ Universal \ Transport \ Medium \ (UTM), \ BD \ UVT, \ Cepheid \ XPert \ Sample \ Collection \ Kit for \ Viruses, \\ Hardy-Health Link \ UTM \ and \ Quest \ VCM \ transports \ are \ equivalent \ products.$

Copan	Туре	Description	Quest	Cepheid	Hardy/ Healthlink	BD	DHI/Quidel	Fisher Healthcare
305C	Sample collection kit (nasopharyngeal)	Nasopharyngeal collection kit: flexible minitip flocked swab + 3 mL UTM® tube	S05	SWAB/B-100	3C036NHL	220526 /220531	403C	230001720
306C	Sample collection kit (oropharyngeal)	Oropharyngeal collection kit: regular flocked swab + 3 mL UTM® tube	S03	SWAB/F-100	3C038NHL	220528	402C	23001722
330C	Collection kit component	3 mL UTM® medium in 16x100 mm tube	NA	NA	330CHL	UVT 220244 /220220	330C.DHI	23001718
503CS01	Collection kit component	Flexible minitip (nasopharyngeal) flocked swab	NA	NA	NA	220252	503CS01.DHI	23600952
519CS01	Collection kit component	Regular (oropharyngeal) flocked swab	NA	NA	NA	220250	NA	23600957
321C	Combo collection kit nasopharyngeal and oropharyngeal	Flexible minitip flocked swab + regular flocked swab + 3 mL UTM® tube	NA	NA	3C039NHL	220527	99-08021	NA



References

- 1. Simplify lab-related tasks for better practice workflow. Quest Diagnostics website. Published December 2018. Accessed March 12, 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 March 5, 2020. Accessed March 12, 2020. https://www.medical-supply.ie/2020/03/05/copan-increases-production-of-utm/
- 3. Beckton Dickinson website. Accessed March 12, 2020. https://www.bing.com/images/search?view=detailV2&id=27BCDE77797251CA 0BFBA2B329E00DDA754FDA75&thid=0IP.4gENK8zrMNv1ViLpdJC6gwHaF-&exph=900&expw=1116&q=BD+viral+transport+media&sel ectedindex=5&ajaxhist=0&vt=0&sim=11
- 4. Cepheid product website. Accessed March 12, 2020. https://www.cepheid.com/?msclkid=e78ea74e94ed19d1538ef924e1b802e7&utm_source=bing&utm_medium=cpc&utm_campaign=USA%7CCepheid%7CBM&utm_term=%2BCepheid&utm_content=Cepheid
- 5. Universal transport medium. Hardy Diagnostics/Healthlink website. Accessed March 12, 2020. https://hardydiagnostics.com/industry_content/universal-transport-medium-2/
- Thermo Scientific Specimen Collection and Transport Solutions—US. Thermofisher catalog website. Published March 2017. Accessed March 12, 2020. https://assets.thermofisher.com/TFS-Assets/MBD/brochures/Collection-and-Transport-Solutions-Booklet(US).pdf
- 7. Copan Diagnostics product insert website. Accessed March 17, 2020. https://www.copanusa.com/wp-content/uploads/2019/07/ESwab-Package-Insert_HPC030_eSwab_copoliestere_Rev00_Date2016.02.pdf
- 8. Becton Dickinson website. Accessed March 17, 2020. https://www.bd.com/en-us/offerings/capabilities/specimen-collection/swab-based-specimen-collection/bd-eswab-collection-and-transport-system
- 9. Puritan Opti-Swab website. Accessed March 17, 2020. https://www.puritanmedproducts.com/diagnostics-specimen-collection/collection-transport-systems/la-106.html
- 10. Puritan Opti-Swab website. Accessed March 17, 2020. https://www.puritanmedproducts.com/la-116.html
- 11. Puritan Opti-Swab website. Accessed March 17, 2020. https://www.puritanmedproducts.com/la-117.html
- 12. Becton Dickinson website. Accessed March 17, 2020. https://www.bd.com/en-us/offerings/capabilities/specimen-collection/swab-based-specimen-collection/cultureswab-collection-and-transport-systems
- 13. Becton Dickinson website. Accessed March 17, 2020. https://www.bd.com/en-us/offerings/capabilities/specimen-collection/swab-based-specimen-collection/bd-bbl-cultureswab-ez-collection-and-transport-systems
- 14. Becton Dickinson website. Accessed March 17, 2020. https://www.bd.com/en-us/offerings/capabilities/specimen-collection/swab-based-specimen-collection/bd-cultureswab-maxv-collection-and-transport-systems