

COVID-19 specimen collection guidelines

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

Diagnostic Laboratory of Oklahoma (DLO) and Quest Diagnostics do 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 DLO or 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, which includes DLO, 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 swabs and media to be used for upper respiratory specimens for SARS-CoV-2 (COVID-19) molecular (NAAT) testing.

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

Swab sample collections

- It is important that the swab be appropriate for the anatomic site on which it is used, and that the swab type is compatible with that platform.
- Flocked swabs are preferred.
- Use only sterile Dacron®, polyester, or rayon swabs with plastic shafts. Wired shaft swabs are acceptable but must be trimmed using sterile scissors.
- 3D-printed swabs are not acceptable.
- Note the 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 (see https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).

The following specimen types are acceptable:

Collected by a healthcare professional (HCP):

- Nasopharyngeal (NP)
- Oropharyngeal (OP)

HCP-observed self-collection or HCP collected:

- Mid-turbinate (MT)
- Anterior nares (AN)

Note: The IDSA panel suggests collecting nasopharyngeal, or mid-turbinate, or nasal swabs rather than oropharyngeal swabs or saliva alone for SARS-CoV-2 RNA testing (https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/)

The current body of research shows mid-turbinate and anterior nares samples show greater sensitivity than oropharyngeal samples. ^{1,2} Multiple specimens from the same patient may be taken with a single swab. If a separate swab is used for collecting specimens from two different locations in the same patient, both swabs may be placed in the same vial in order to conserve collection and assay supplies.

Other swab specimens, such as tongue or saliva, have decreased sensitivity and are unacceptable. More data are necessary to better understand the validity of buccal swabs, saliva, specimens, or other specimen types for COVID-19 testing.

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Information on samples from anterior nares:

Anterior nares specimen collection instructions: Use a single swab for collecting specimens from both nares. Insert 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 swab and insert the swab into an acceptable viral transport medium (including saline or PBS).

Acceptable swabs: Puritan® 6" Sterile Standard Foam Swab w/ Polystyrene Handle (SKU # 25-1506 1PF) and Copan® Foam swab single wrapped (1C055S01). *Note: Other acceptable swabs include standard OP synthetic swabs w/ plastic/scored shaft.*



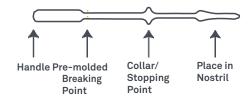
Information on mid-turbinate specimen:

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) and the collection is observed by the HCP.

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 DLO 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.

NOTE: FOR TRANSPORT MEDIA, STRICTLY FOLLOW THIS GUIDE.

All swabs must be submitted in liquid transport media, as outlined below.

- Dry swab submissions are unacceptable and will be rejected
- Any swab submitted in media containing guanidinium isothiocyanate, guanidinium thiocyanate, guanidine isothiocyanate, guanidine thiocyanate, or like component is unacceptable and will be rejected

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 (e.g., 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)



Vial filling process (continued):

- Use a sterile environment (e.g., 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 Liquid Amies Specimens can be stored in liquid Amies media for up to 72 hours at 4 °C.

Saline or Phosphate Buffered Saline (PBS)

The FDA has indicated saline and PBS as acceptable transport media in situations where commercial viral transport media are unavailable for molecular RT-PCR SARS-CoV-2 assays (such as those in use for the DLO and 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). Collection should be conducted with a sterile swab.

• DLO and 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), DLO and Quest will accept 2 mL to 3 mL sterile PBS or sterile saline (0.85% or 0.9%) provided the vial filling process below is followed.







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

VCM (Diagnostic Hybrids)4

NP kit ordering information:

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

Lesion swab kit ordering information (acceptable for OP):

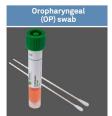
- PeopleSoft item #:142060
- PeopleSoft product ID #: S03
- Quanum product ID #:S03
- Ordered by the EA (each)

Note: both swabs in supply kit S03 are the same; only one is necessary for specimen collection.

The Nasopharyngeal and Oropharyngeal collection devices shown on this page are currently available to order from DLO. All other collection devices listed in this document ARE NOT available to order from DLO. You may submit specimens using these devices from inventory that you have on hand, but DLO cannot supply these devices.

*Only the nasopharyngeal VCM swab is accepted by the Oklahoma State Department of Health (OSDH)











Amies liquid elution swab (ESwab)

ESwab with 1 mL of Amies fluid in the transport vial

(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.)

Routine swab-OP/AN 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, ESwab (Amies liquid elution swab) routine, blue cap, Amies Medium, 1/each:

PeopleSoft #: 161558
PeopleSoft product ID #: S10
Quanum product ID #: S10
Ordered by the EA (each)

Not available to order from DLO

** DLO cannot process specimens on these ESwab collection devices in-house. All specimens submitted on these devices will be sent to Quest Diagnostics Infectious Disease (QDID) lab in San Juan Capistrano, Calif., for processing.

OP/AN swab

Minitip-NP swab



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

UTM (Copan)⁵

Combo collection kit NP, OP/AN

321 C

NP Collection Kit-305C

OP/AN Collection Kit-306C

UTM medium 3 mL-330C or 3U044n

NP flocked swab-503CS501 OP/AN flocked swab-519CS501

Not available to order from DLO

*Also accepted by the OSDH

UVT (BD)6

Combo collection kit nasopharyngeal and oropharyngeal 3 mL-220527

NP Collection Kit-220529

OP/AN Collection Kit-220528

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

NP flocked swab-220252 OP/AN flocked swab-220250

Not available to order from DLO

Cepheid® Xpert® Sample Collection Kit for Viruses7

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

F-100 OP/AN

Not available to order from DLO

Hardy Diagnostics Healthlink UTM⁸

Hardy: 3CO36NHL 3 mL: NP Hardy: 3CO37NHL 3 mL: NP Hardy: 3CO40NHL 1 mL*: NP

Hardy: 3C038NHL 3 mL: 0P/AN Hardy: 3C011NHL 1 mL*: 0P/AN

Hardy: 330CHL: 3 mL UTM

Hardy: 3C039NHL 3 mL (NP and OP/AN)

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

Not available to order from DLO

M4 (Fisher/Remel)9

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

and Ureaplasma)

Not available to order from DLO

M4RT (Fisher/Remel)9

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

Not available to order from DLO











B-100 for NP

F-100 for OP/AN





Hardy: 3CO36NHL: NP

Hardy: 3C038NHL: OP/AN





^{*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.



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

M5 (Fisher/Remel)9

Similar to the M4, but it does not contain gelatin

Not available to order from DLO



M6 (Fisher/Remel)9

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

Not available to order from DLO



Puritan® UniTranz-RT Universal Transport Medium (UTM) with no swabs¹⁰

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

Puritan® UniTranz-RT UTM with flocked swabs for NP (1 mL)* 10

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

Puritan® UniTranz-RT UTM with flocked swabs for NP (3 mL)¹⁰

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

Puritan® UniTranz-RT UTM with flocked swabs for OP/AN¹0

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)¹⁰

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

Not available to order from DLO

Starplex™ Scientific Multitrans™ with flocked swabs from Fisher Scientific¹¹

NP flocked: 23-038-096

NP and OP/AN flocked swab: 22-046-450

Not available to order from DLO





^{*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.



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

Copan ESwab™12**

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

White cap (OP/AN 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

Not available to order from DLO

BD ESwab™13**

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/AN: Cat#220245 Green (minitip flocked swab) NP: Cat#220246 Blue (flexible minitip) NP: Cat#220532

Not available to order from DLO



White-OP/AN
Green and blue-NP

White-OP/AN

Green and blue-NP

Puritan® Opti-Swab™ 1 mL* Liquid Amies Transport Medium w/ 6" elongated flock swab¹⁴

Item # LA-106 for OP/AN swab

Not available to order from DLO



Green-NP

Puritan® Opti-Swab™ 1 mL* Liquid Amies Transport Medium w/ 6" minitip flock swab¹⁵

Item # LA-116 for NP swab

Not available to order from DLO

Puritan® Opti-Swab™ 1 mL* Liquid Amies Transport Medium w/ 6" ultrafine flock swab¹6

Item #I A-117 for NP swab

Not available to order from DLO



** DLO cannot process specimens on these ESwab collection devices in-house. All specimens submitted on these devices will be sent to Quest Diagnostics Infectious Disease (QDID) lab in San Juan Capistrano, Calif., for processing.

*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.



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-HealthLink UTM and Quest VCM transports are equivalent products.

Copan	Туре	Description	DLO/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 (OP/AN)	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 (NP and OP/AN)	Flexible minitip flocked swab + regular flocked swab + 3 mL UTM® tube	NA	NA	3C039NHL	220527	99-08021	NA

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 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)¹⁷

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 needs 17

BD EZ Swab (double swab)18

Product code 220105

BD BBL $^{\infty}$ CultureSwab $^{\infty}$ EZ II collection and transport systems are simple-to-use, media-free systems that contain a patented polyurethane foam swab



UNACCEPTABLE specimens for test code 39448, continued

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

BD MaxV¹⁹

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 organisms 19

BBL BD CultureSwab[™]-Liquid Stuart (minitip swab-green cap)²⁰

Product code 220133



BD ProbeTec[™] transport vials²¹



Quidel urethral swab

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





Beaver



PrimeStore-MTM®22



Inveox transport media²³



DNA/RNA Shield™24



ImproViral™NAT VTM²⁹



UNACCEPTABLE specimens for test code 39448, continued

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

Ruhof kits²⁵ Abbott Multi-Collect²⁶ **Babio VTM** MANTACC UTM²⁷ BIOER Technology RNAsafeguard Reagent/SARS-CoV-2 collection kit NEST VTM²⁸



References

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