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:

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 # 25-15061PF) 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:

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room temperature</td>
<td>5 days</td>
</tr>
<tr>
<td>Frozen (-20 °C)</td>
<td>7 days</td>
</tr>
<tr>
<td>Refrigerated (2 °C–8 °C)</td>
<td>5 days</td>
</tr>
<tr>
<td>Frozen (-70 °C)</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

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)

- 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)

### 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)

### VCM (Diagnostic Hybrids)

- S06 Acceptable but not supplied by Quest

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

<table>
<thead>
<tr>
<th>Media Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| **UTM (Copan)** | 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)** | Combo collection kit nasopharyngeal and oropharyngeal 3 mL-220527  
- NP Collection Kit-220529  
- OP Collection Kit-220528  
- UTM medium 3 mL-220220 (1 mL-220244)  
- NP flocked swab-220252  
- OP flocked swab-220250 |
| **Cepheid® Xpert® Sample Collection Kit for Viruses** | B-100 NP  
F-100 OP |
| **Hardy Diagnostics Healthlink UTM** | 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) |
| **M4 (Fisher/Remel)** | Contains vancomycin, amphotericin B, and colistin and is suitable for transport of viruses, Chlamydiae, Mycoplasma and Ureaplasma) |
| **M4RT (Fisher/Remel)** | 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

<table>
<thead>
<tr>
<th>Media Type</th>
<th>Description</th>
<th>Available Sizes</th>
<th>Swabs Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>M5 (Fisher/Remel)</td>
<td>Similar to the M4, but it does not contain gelatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M6 (Fisher/Remel)</td>
<td>Contains gelatin, vancomycin, amphotericin B, and colistin for the transport of viruses, Chlamydiae, Ureaplasmas, and Mycoplasmas</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Puritan® UniTranz-RT Universal Transport Medium (UTM) with no swabs</strong></td>
<td>1 mL (UT 100); 3 mL (UT-300)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Puritan® UniTranz-RT UTM with flocked swabs for NP (1 mL)</strong></td>
<td>Minitip (UT-116)</td>
<td>Ultrafine flocked swabs (UT-117)</td>
<td>Elongated swab (UT-367)</td>
</tr>
<tr>
<td><strong>Puritan® UniTranz-RT UTM with flocked swabs for NP (3 mL)</strong></td>
<td>Ultrafine flocked swabs (UT-317)</td>
<td>Mini-tip Flock Swab (UT-316)</td>
<td></td>
</tr>
<tr>
<td><strong>Puritan® UniTranz-RT UTM with flocked swabs for OP</strong></td>
<td>Large flocked swab 1 mL (UT-106)</td>
<td>Elongated flocked swab 3 mL (UT-306)</td>
<td></td>
</tr>
<tr>
<td><strong>Puritan® UniTranz-RT UTM with Polyester swabs for OP (3 mL)</strong></td>
<td>One swab (UT-361)</td>
<td>Two swabs (UT-362)</td>
<td>NP and OP both 1 minitip and 1 standard (UT-366 and UT-302)</td>
</tr>
<tr>
<td><strong>Starplex™ Scientific Multitrans™ with flocked swabs from Fisher Scientific</strong></td>
<td>NP flocked: 23-038-096</td>
<td>NP and OP flocked: 22-046-450</td>
<td></td>
</tr>
</tbody>
</table>
### Acceptable (but not supplied by Quest) COVID-19 specimen transport media and swabs for test code 39448, continued

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Code Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Copan ESwab™</strong></td>
<td>Flocked swab with 1 mL of liquid Amies in a plastic, screw-cap tube</td>
<td>White cap (OP flocked swab): Cat#480C or 4C012S.A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Green cap (minitip flocked swab for NP): Cat#481C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Blue cap (wire shaft/flexible minitip for NP): Cat#482C</td>
</tr>
<tr>
<td><strong>BD ESwab™</strong></td>
<td>1 mL of modified liquid Amies medium packaged with a nylon flocked swab</td>
<td>White (reg flocked swab) OP: Cat#220245</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Green (minitip flocked swab) NP: Cat#220246</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Blue (flexible minitip) NP: Cat#220532</td>
</tr>
<tr>
<td><strong>Puritan® Opti-Swab™ 1 mL Liquid Amies Transport Medium w/ 6” elongated flock swabª</strong></td>
<td>Item # LA-106 for OP swab</td>
<td>Green-NP</td>
</tr>
<tr>
<td><strong>Puritan® Opti-Swab™ 1 mL Liquid Amies Transport Medium w/ 6” minitip flock swab®</strong></td>
<td>Item # LA-116 for NP swab</td>
<td>Blue-NP</td>
</tr>
<tr>
<td><strong>Puritan® Opti-Swab™ 1 mL Liquid Amies Transport Medium w/ 6” ultrafine flock swab¹¹</strong></td>
<td>Item # LA-117 for NP swab</td>
<td>White-OP</td>
</tr>
</tbody>
</table>
## 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)
- 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.

### BD EZ Swab (double swab)
- Product code 220105

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

### BD MaxV
- 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.

### BBL BD CultureSwab™—Liquid Stuart
**Mininip 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

<table>
<thead>
<tr>
<th>Description</th>
<th>Quest</th>
<th>Cepheid</th>
<th>Hardy/Healthlink</th>
<th>BD</th>
<th>DHI/Guidel</th>
<th>Fisher Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaver</td>
<td>S05</td>
<td>SWAB/B-100</td>
<td>3C038NHL</td>
<td>220526</td>
<td>402C</td>
<td>23001720</td>
</tr>
<tr>
<td>PrimeStore-MTM®</td>
<td>S03</td>
<td>SWAB/F-100</td>
<td>3C038NHL</td>
<td>220528</td>
<td>402C</td>
<td>23001722</td>
</tr>
<tr>
<td>Invoex transport media</td>
<td></td>
<td></td>
<td>330CHL</td>
<td>220244</td>
<td>330C.DHI</td>
<td>23001718</td>
</tr>
<tr>
<td>DNA/RNA Shield™</td>
<td>NA</td>
<td>NA</td>
<td>330CHL</td>
<td>220220</td>
<td>NA</td>
<td>23600952</td>
</tr>
<tr>
<td>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.</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
References