Coronavirus Shipping Solutions

The CDC has provided the following guidance:

"Packaging, shipping and transport of specimens from suspect cases or PUI's of 2019-nCoV infection must follow the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations."

"Follow shipping regulations for UN 3373 Biological Substance, Category B, when sending potential 2019-nCoV specimens.... Store specimens at 2 - 8 degrees C and ship overnight to CDC on ice pack...Complete CDC Form 50.34 for each specimen."

– Per January 17, 2020 CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV)

Complete Shipping Kits Designed Specifically For Use With the Coronavirus

INFECON® 6200 (½ Liter Vessel)
72 Hours @ -70°C with 22 lbs. Dry Ice
72 Hours @ 4°C with Gel Packs
Up to 6 Standard Tubes
Cat. No. INF-6200

INFECON® 6300 (1 Liter Vessel)
72 Hours @ -70°C with 22 lbs. Dry Ice
72 Hours @ 4°C with Gel Packs
Up to 20 Standard Tubes
Cat. No. INF-6300

Components May be Purchased Separately

INFECON® 2000
½ Liter Vessel, Carton, Bubble Pouch and Labels
Cat. No. INF-2000

INFECON® 3000
1 Liter Vessel, Carton, Bubble Pouch and Labels
Cat. No. INF-3000

INFECON® 6000
Overpack Cooler & Labels Only
76 Hours With 22 lbs. Dry Ice
Cat. No. INF-6000

INFECON® 5000
Dry Ice or Gel Pack Shipper
½ Liter Vessel - 60 Hrs With 5.6 lbs. Dry Ice
Cat. No. INF-5000

INFECON® 5500
Dry Ice or Gel Pack Shipper
1 Liter Vessel - 100 Hrs. With 16 lbs. Dry Ice
Cat. No. INF-5500

INFECON® Gel Packs
16 Oz. Reusable
Cat. No. INF-900

Com-Pac Shippers - Compliance, Convenience, Cost Effectiveness

- ✓ **Items Designated "For Category B Specimens" are UN Certified, Meet 49 CFR D.O.T. Regulations for Air & Ground Shipments, and Meet ICAO/IATA Packing Instruction 650.**
- ✓ **IItems Include All Accessories, Absorbents, Labels, Labeling Instructions and Shipping Declarations.**
- ✓ **Components Such As Boxes, Vessels, Labels and Absorbents May Be Purchased Separately for Refurbishment and Reuse.**

Check-Out Our Other Specimen Transport and Storage Products

BITRAN® LEAKPROOF SPECIMEN BAGS

3 Mil PE with No Printing
Leakproof Resealable Zipper
Cat. No. Based on Size

INFECON® LEAKPROOF SPECIMEN BAGS

3 Mil PE with Document Pouch
Leakproof Resealable Zipper
Biohazard Logo
Cat. No. Based on Size

INSPEX® TAMPER-EVIDENT ADHESIVE SPECIMEN BAGS

3 Mil PE with Biohazard Logo
Cat. No. 8022-XP 6.5" x 12"

BITRAN® BUBBLE POUCH BAG

Liquid-Tight Bitran Zipper Bag
With Document Pouch
6 Compartment Bubble Pouch
Cat. No. DA-1718 7" X 8"
Cat. No. DA-1912 9" X 12"

SAF-T-ZIP® SPECIMEN BAGS

6" X 9" 2.8 Mil PE Secondary Bag
Document Pouch, Resealable
Zipper & Biohazard Logo
Cat. No. Based on Zipper Color

New Product!

INSPEX® 95 kPa SPECIMEN BAG

6" X 9" Super-Tough Material
Tamper-Evident Adhesive Closure
Cat. No. XP-95-0609

Links to Helpful Websites on Coronavirus Specimen Packaging & Shipping

Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from PUI for 2019 Novel Coronavirus (2019-nCoV) (Jan.17, 2020):

https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidelines-clinical-specimens.html

Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV) (Jan.17, 2020):

https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Flab-biosafety-guidelines.html

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Your Specimen Containment & Shipping Experts for Over 30 Years....

800 Industrial Park Road
Carbondale, Illinois 62901 USA
Tel: 800-824-0817

Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)

Summary of Recent Changes

Revisions were made on March 9, 2020. to reflect the following:

- Updates to all specimen storage guidelines for consistency with EUA IFU.
- Recommendation to include combined NP/OP specimens as an option for upper respiratory specimen collection.

March 9, 2020

Health care providers should contact their local/state health department immediately to notify them of patients with fever and lower respiratory illness who live in or have recently traveled to an affected area with sustained transmission or have been in close contact with a confirmed COVID-19 patient. Local and state public health staff will determine if the patient meets the criteria for a person under investigation (PUI) for COVID-19. Clinical specimens should be collected from PUIs for routine testing of respiratory pathogens at either clinical or public health labs. Note that clinical laboratories should NOT attempt viral isolation from specimens collected from COVID-19 PUIs.

Now that the CDC's diagnostic test has been authorized by FDA under the EUA, the International Reagent Resource (IRR) has begun to distribute the test to requesting laboratories.

Clinicians who have identified a potential PUI should immediately notify their state or local health department. Local and state public health staff will determine if the person is a PUI and whether testing for COVID-19 is indicated. The state and local health department will then assist clinicians to collect, store, and ship specimens appropriately, including during afterhours or on weekends/holidays.

Testing for other pathogens by the provider should be done as part of the initial evaluation and should not delay specimen shipping.

If a PUI tests positive for another respiratory pathogen, after clinical evaluation and consultation with public health authorities, they may no longer be considered a PUI. This may evolve as more information becomes available on possible COVID-19 co-infections.

Specimen Type and Priority

For initial diagnostic testing for COVID-19, CDC recommends collecting and testing upper respiratory (nasopharyngeal **AND** oropharyngeal swabs), and lower respiratory (sputum, if possible) for those patients with productive coughs. Induction of sputum is not recommended. Specimens should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset. Maintain proper infection control when collecting specimens.

General Guidelines

Store specimens at 2-8°C and ship overnight to CDC on ice pack. Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., serum) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted. In the upper left box of the form, 1)

for *test requested* select "Respiratory virus molecular detection (non-influenza) CDC-10401" and 2) for *At CDC, bring to the attention of* enter "Stephen Lindstrom: 2019-nCoV PUI".

I. Respiratory Specimens

A. Lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Sputum

Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

B. Upper respiratory tract

Nasopharyngeal swab AND oropharyngeal swab (NP/OP swab)

Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP and OP specimens may be kept in separate vials or combined at collection into a single vial.

Nasopharyngeal swab: Insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions.
Oropharyngeal swab (e.g., throat swab): Swab the posterior pharynx, avoiding the tongue.

Nasopharyngeal wash/aspirate or nasal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

II. Storage

Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

III. Shipping

Specimens PUI's must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations. Store specimens at 2-8°C and ship overnight to CDC on ice pack. If a specimen is frozen at -70°C ship overnight to CDC on dry ice. Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).

For additional information, consultation, or the CDC shipping address, contact the CDC Emergency Operations Center (EOC) at 770-488-7100.

Page last reviewed: March 9, 2020

Specimen Collection and Shipping Instructions

2019 Novel Coronavirus (COVID-19), NAA — Nasopharyngeal & Oropharyngeal Swabs

The LabCorp **2019 Novel Coronavirus (COVID-19), NAA [139900]** test is available for ordering by physicians or other authorized healthcare providers anywhere in the U.S. The test detects the presence of SAR-CoV-2, the virus that causes COVID-19, and is for use with patients who meet guidance for evaluation of COVID-19 infection.

LabCorp does not currently collect specimens for COVID-19 testing. Patients for whom testing has been ordered should not be sent to a LabCorp location to have a COVID-19 specimen collected.

Test ordering info

The test number for 2019 Novel Coronavirus (COVID-19), NAA is 139900. Test **must** be ordered, and specimen collected, by a physician or other authorized healthcare provider.

Sample requirements

Nasopharyngeal (NP) or oropharyngeal (OP) specimens collected on swabs with synthetic tips are preferred. Swabs should be transported in Universal Transport Medium (UTM). For complete test details, including other acceptable specimen types, visit the LabCorp Test Menu.

Causes for rejection

Swabs with calcium alginate or cotton tips; swabs with wooden shafts; refrigerated samples greater than 72 hours old; room temperature specimen submitted; improperly labeled; grossly contaminated; broken or leaking transport device; collection with substances inhibitory to PCR including heparin, hemoglobin, ethanol, EDTA concentrations >0.01M.

Turnaround Time

Current turnaround time for COVID-19 testing is estimated between 3-4 days.

Supplies needed for collection

Nasopharyngeal swab collection — A Nasopharyngeal Dry Flocked Swab that is placed and transported in UTM is the preferred method. However, any synthetic swab (dacron, rayon, polyester) of appropriate size and configuration can be used.

For NP swab collection, discard the two swabs included in the UTM. UTM is for transport only.

Oropharyngeal swab collection — Specimen should be collected using a synthetic swab that is placed and transported in UTM.

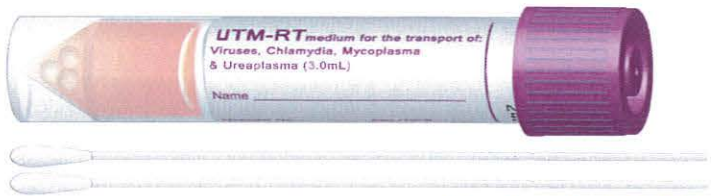
For OP swab collection, either UTM swabs or a synthetic swab can be used for specimen collection.

Specimen label and biohazard bag are also needed.

Preferred swab for NP sample collection. **Note:** Cap color may vary.

Supply order #: 93307

UTM tube for transport. Do **not** send swab dry.



Supply order #: 24674

LabCorp

March 10, 2020

Specimen Collection and Shipping Instructions

2019 Novel Coronavirus (COVID-19), NAA — Nasopharyngeal & Oropharyngeal Swabs

Nasopharyngeal (NP) collection

1. Assemble the supplies needed. For sample collection, have the synthetic swab (Nasopharyngeal Dry Flocked Swab preferred) and Universal Transport Medium (UTM), specimen label and biohazard bag available.
2. If the patient has a lot of mucous in the nose, this can interfere with collection. Have the patient use a tissue to gently clean the nasal passage before a swab is taken.
3. Open the swab package and remove the swab, taking care not to touch the tip to any surface or lay it down.
4. With the patient seated, if possible, tilt their head back 70 degrees, support the back of their head with your non-dominant hand.
5. Holding the swab in your hand, gently insert NP swab into the nostril along the septum floor of the nose extending straight back until the posterior nasopharynx is reached (distance from nostrils to external opening of ear). Rotate the swab several times while the swab it in contact with the nasopharyngeal wall.
6. Place NP swab into the UTM and break (snap) off at the indictor line on the swab. Replace cap and screw cap on securely.
7. Label sample and place in biohazard bag.
8. Freeze specimen and keep frozen.
9. Submit sample on one requisition, with test code 139900 — COVID-19.
10. To avoid delays in turnaround time when requesting multiple tests on frozen samples, **please submit separate frozen specimens for each test requested**.

Preferred swab for NP sample collection. **Note:** Cap color may vary.

Supply order #: 93307

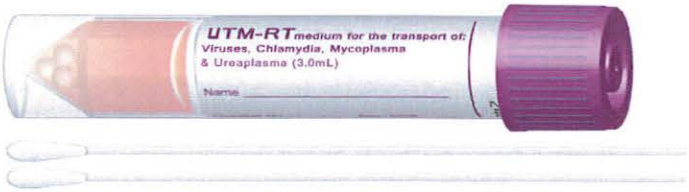
Oropharyngeal (OP) collection

1. Assemble the supplies needed. For sample collection, have Universal Transport Medium (UTM) with included swabs, specimen label and biohazard bag available.
2. Open the UTM package and remove one swab, taking care not to touch the tip to any surface or lay it down.
3. Holding the swab in your hand, gently insert swab into back of the throat and tonsillar area. Rub the swab over both tonsillar pillars and the posterior oropharynx and avoid touching the tongue, teeth, and gums.
4. Place swab into the UTM and break (snap) off at the indictor line on the swab. Replace cap and screw cap on securely.
5. Label sample and place in biohazard bag.
6. Freeze specimen and keep frozen.
7. Submit sample on one requisition, with test code 139900 — COVID-19.
8. To avoid delays in turnaround time when requesting multiple tests on frozen samples, **please submit separate frozen specimens for each test requested**.

NP & OP Storage/Shipping requirements

Samples/specimens **should** be shipped frozen due to limited stability at 2°-8°C. Refrigerated swabs submitted within 72 hours will be accepted.

UTM tube for transport. Do **not** send swab dry.



Supply order #: 24674

LabCorp

www.LabCorp.com

March 10, 2020

Quest Diagnostics

SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR NEW

Test Code

39433

CPT Code(s)*

Please reach out to client services

Clinical Significance

SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR - The SARS-CoV-2 Real-time RT-PCR test is a qualitative molecular diagnostic test that aids in the diagnosis of COVID-19.

This test is intended to be performed only using respiratory specimens collected from individuals who meet Centers for Disease Control and Prevention (CDC) clinical and/or epidemiological criteria for COVID-19 testing. CDC COVID-19 criteria for testing on human specimens are available at the CDC's webpage Information for Healthcare Professionals: Coronavirus Disease 2019 (COVID-19) (https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html).

A Detected result is considered a presumptive positive test result for COVID-19. This result indicates that RNA from SARS-CoV-2 (formerly 2019-nCoV) was detected, and that the patient is presumptively infected with the virus and presumed to be contagious. Specimens with Presumptive Positive or Inconclusive results will be referred to the appropriate Public Health laboratory for additional testing.
A Not Detected (negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for patient management decisions.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

Test Resources

Fact Sheet
Healthcare Provider Fact Sheet

Test Details

Methodology

Real-Time Reverse Transcriptase Polymerase Chain Reaction

Assay Category

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics. It has not been cleared or approved by the FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes. This test is pending the Food and Drug Administration's Emergency Use Authorization.

Reference Range(s)

Not detected

Alternative Name(s)

SARS,Novel Coronavirus,nCOV,COVID-19,COVID,Wuhan,Coronavirus

LOINC® Codes, Performing Laboratory

⚠ *Service Area must be determined*

Preferred Specimen(s)

1 nasopharyngeal or oropharyngeal swab in M4, V-C-M or UTM media

Alternative Specimen(s)

0.85 mL bronchial lavage/wash, nasopharyngeal aspirate/wash, sputum/tracheal aspirate sample in a plastic sterile leak-proof container

Minimum Volume

1 swab • 0.35 mL

Collection Instructions

Read the Healthcare Provider Fact Sheet:
https://www.questdiagnostics.com/dms/Documents/covid-19/SARSCoV-2_HCP_Fact_Sheet.pdf

Order SARS-CoV-2 RNA, RT PCR separately from other tests on a separate requisition. The SARS-CoV-2 test

will be prioritized if submitted on a shared requisition. One specimen will be tested per order.

IMPORTANT: If sample is being shipped directly to the performing laboratory by an overnight air courier, then transport it frozen on dry ice.

Shipping and storage: -70° C is acceptable

Transport Container

Swab

Transport Temperature

Refrigerated (cold packs)

Specimen Stability

Room temperature: Unacceptable
Refrigerated: 72 hours
Frozen -70° C: See Collection Instructions

Reject Criteria

Calcium alginate swab • Cotton swabs with wooden shaft • Received refrigerated more than 72 hours after collection

Setup Schedule

⚠ *Service Area must be determined*

Reference ranges are provided as general guidance only. To interpret test results use the reference range in the laboratory report.

* The CPT codes provided are based on AMA guidance and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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The tests listed by specialty and category are a select group of tests offered. For a complete list of Quest Diagnostics tests, please adjust the filter options chosen, or refer to our Directory of Services.