

Coronavirus Disease 2019 (COVID-19)

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

Updated April 14, 2020

Summary of Recent Changes

Revisions were made on April 14, 2020 to reflect the following:

 Clarify specimen collection procedures for all swab types and align with other respiratory disease specimen collection guidelines

Revisions were made on April 2, 2020 to reflect the following:

· Clarify the allowance for other swab types with new data and to align with FDA guidance

Revisions were made on March 24, 2020 to reflect the following:

- Allowance for self- or healthcare professional-collected nasal swabs as an acceptable specimen type if NP swab is not possible
- Allowance for self- or healthcare professional-collected nasal turbinate swabs as an acceptable specimen type if NP swab is not possible
- Updated infection control link to COVID-specific guidance

Revisions were made on March 21, 2020 to reflect the following:

 A new document, Guidelines For Submitting Specimens to CDC , has been posted that contains instructions for completing a specimen submission form (CDC Form 50.34), specimen collection, storage, and shipping to CDC laboratories.

Clinicians considering testing people with possible COVID-19 should work with their local and state health departments to coordinate testing through public health laboratories, or work with commercial or clinical laboratories using diagnostic tests granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration. CDC has guidance for who should be tested, but decisions about testing are at the discretion of state and local health departments and/or individual clinicians.

Healthcare providers should report positive results to their local/state health department. Clinical laboratories should NOT attempt viral isolation from specimens collected from people suspected to have COVID-19 unless this is performed in a BSL-3 laboratory. Testing for other pathogens by the provider should be done as part of the initial evaluation but should not delay testing for SARS-CoV-2.

Specimen Type and Priority

All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider. Nasopharyngeal (NP) swabs can be used for testing asymptomatic persons in a healthcare setting, including long-term care facilities. At this time anterior nares and mid-turbinate specimen collection are only appropriate for symptomatic patients and both nares should be swabbed. The guidance below addresses options for collection of specimens once a clinical determination has been made to pursue SARS-CoV-2 testing.

For initial diagnostic testing for SARS-CoV-2, CDC recommends collecting and testing an upper respiratory specimen. Nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- An oropharyngeal (OP) specimen collected by a healthcare professional, or
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab), or
- An anterior nares (nasal swab; NS) specimen collected by a healthcare professional or by onsite self-collection (using a flocked or spun polyester swab)
- Nasopharyngeal wash/aspirate or nasal aspirate (NA) specimen collected by a healthcare professional

For NS, a single polyester swab with a plastic shaft should be used to sample both nares. NS or NMT swabs should be placed in a transport tube containing either viral transport medium, Amies transport medium, or sterile saline. See the standard operating procedure for public health labs to create viral transport medium in accordance with CDC's protocol.

If both NP and OP swabs are collected, they should be combined in a single tube to maximize test sensitivity and limit use of testing resources.

CDC also recommends testing lower respiratory tract specimens, if available. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. When it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.

Specimens should be collected as soon as possible once a decision has been made to pursue SARS-CoV-2 testing, regardless of the time of symptom onset. Maintain proper infection control and use recommended personal protective equipment, which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens. See Biosafety FAQs for handling and processing specimens from suspected case patients.

General Guidelines

Proper collection of specimens is the most important step in the laboratory diagnosis of infectious disease. A specimen that is not collected correctly may lead to false negative test results. The following specimen collection guidelines follow standard recommended procedures.

I. Respiratory Specimens

A. Upper respiratory tract

Nasopharyngeal (NP) swab/oropharyngeal (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. In general CDC is now recommending collecting only the NP swab. If both swabs are used, NP and OP specimens should be combined at collection into a single vial. OP swabs remain an acceptable specimen type.

Nasopharyngeal swab: Insert flexible wire shaft minitip swab through the nares parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.

Oropharyngeal swab (e.g., throat swab): Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

Nasopharyngeal wash/aspirate or nasal aspirate (NA)

Attach catheter to suction apparatus. Have the patient sit with head tilted slightly backward. Instill 1 mL-1.5 mL of non-bacteriostatic saline (pH 7.0) into one nostril. Insert the tubing into the nostril parallel to the palate (not upwards). Catheter should reach depth equal to distance from nostrils to outer opening of ear. Begin gentle suction/aspiration and remove catheter while rotating it gently. Place specimen in a sterile viral transport media tube.

Nasal mid-turbinate (NMT) swab, also called Deep Nasal Swab

Use a flocked tapered swab. Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. For more information, see the CDC Influenza Specimen Collection Instructions. Note that these instructions are applicable for respiratory viruses in general, and not specific for influenza virus.

Anterior nares specimen (NS)

Using a flocked or spun polyester swab, insert the swab at least 1 cm (0.5 inch) inside the nares and firmly sample the nasal membrane by rotating the swab and leaving in place for 10 to 15 seconds. Sample both nares with same swab.

B. Lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate, pleural fluid, lung biopsy

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

Due to the increased technical skill and equipment needs, collection of specimens other than sputum from the lower respiratory tract may be limited to patients presenting with more severe disease, including people admitted to the hospital and/or fatal cases.

Sputum

Educate the patient about the difference between sputum and oral secretions (saliva). Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap 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 must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations .

If shipping samples to CDC: If specimens will ship without delay, store specimens at 2-8°C, and ship overnight to CDC on ice pack. If a delay in shipping will result in receipt at CDC more than 72 hours after collection, store specimens at -70°C or below and 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).

Samples may be shipped to CDC if repeated testing results remain inconclusive or if other unusual results are obtained. Please contact CDC at respvirus@cdc.gov prior to submitting samples.

Label each specimen container with the patient's ID number (e.g., medical record number), unique CDC or state-generated nCov 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."

Please refer to our instruction guidance for submitting CDC Form 50.34 found here: Guidelines For Submitting Specimens to CDC

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

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