

Influenza A/B, SARS-CoV-2, Respiratory Syncytial Virus, PCR (Lab Tests and Diagnostic Procedures)

Comment

The FDA has noted that unauthorized **fraudulent** COVID-19 test kits are being sold online. The FDA advises consumers and health professionals to be cautious of websites and stores selling products that claim to prevent, diagnose, treat, or cure COVID-19 ([FDA Beware 2021](#)). Consumers and health care professionals can help by reporting suspected fraud to the [FDA's Health Fraud Program](#) or the [Office of Criminal Investigations](#).

Prior receipt of a COVID-19 vaccine will **not** affect viral testing for SARS-CoV-2.

Related Information

- [Influenza SARS-CoV-2 Multiplex Assay, PCR, CDC](#)
- [Influenza Virus, Molecular Detection](#)
- [Respiratory Panel, PCR, Nasopharyngeal](#)
- [Respiratory Syncytial Virus, Direct Detection, Molecular](#)

Overview

At the end of 2019, a novel coronavirus was identified as the cause of several cases of pneumonia in Wuhan City, Hubei Province, China. Initially linked to a large seafood and animal market suggesting animal-to-human spread, person-to-person transmission was quickly confirmed (Li Q 2020). The virus spread rapidly worldwide and in January 2020, the World Health Organization (WHO) declared the outbreak a "public health emergency of international concern." On March 11, 2020, the WHO publicly characterized COVID-19 as a pandemic. Currently, more than 400 million infections have been confirmed globally in over 200 countries and territories with over 6 million deaths ([WHO situation rept 2022](#)).

The novel virus has been named **severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)** and the disease it causes has been named **coronavirus disease 2019, or COVID-19**. The virus spreads by contact with respiratory fluids (droplets or aerosol) produced when an infected person exhales (eg, breathes, speaks, coughs, sneezes, or sings). These droplet/aerosol particles can be

- inhaled directly into lungs
- directly deposited on exposed mucous membranes (eyes, mouth, nose)
- transferred to mucous membranes by hands contaminated with virus-containing respiratory fluids or by indirectly touching surfaces with virus on them ([CDC SARS-CoV-2 Transmission 2021](#))

COVID-19 symptoms typically appear within 2 to 14 days (median of 5 days) of exposure and include **fever, chills, fatigue, cough, shortness of breath, myalgia, recent loss of taste or smell, vomiting or diarrhea, and/or sore throat**. Sickness ranges from a mild respiratory illness to severe disease including respiratory failure, septic shock, or other organ failure. Most fatalities have occurred in patients with underlying comorbidities, with overall global fatalities around 2 to 3 percent ([WHO](#)

[situation rept 2021](#)). The CDC currently estimates that about 30% of COVID-19 infections are asymptomatic, and 50% of transmission occurs prior to symptom onset ([CDC Pandemic Planning 2021](#)).

Nucleic acid amplification polymerase chain reaction testing has become the current gold standard method for diagnosis of SARS-CoV-2 infection (see [COVID-19, PCR, Respiratory Specimen](#)), and because COVID-19 symptoms can be similar to influenza and other respiratory infections caused by various pathogens, several panels have been developed for qualitative differentiation of nucleic acid from multiple organisms. The FDA has issued EUAs for SARS-CoV-2, Influenza A/B, and respiratory syncytial virus (RSV) detection/differentiation panels in nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens (manufacturer dependent) when determined necessary by a health care provider. EUAs include laboratory and point-of-care testing by prescription.

Use/Indications

Aid in the diagnosis of infection with SARS-CoV-2, Influenza A, Influenza B, and/or RSV

Test Includes

Rapid qualitative detection, differentiation, and identification of nucleic acid (RNA) from SARS-CoV-2, influenza A, influenza B, and/or RSV in upper respiratory specimens

Specimen

- Nasopharyngeal (NP) specimen collected by a trained health care professional.
- Anterior nasal swab (NS) specimen collected by a trained health care professional; both nares should be swabbed using the same swab.
- Nasal wash/aspirate (NW) specimen collected by health care professional.

Container(s)

- Confer with testing laboratory for proper specimen container and collection.
- Nasal wash/aspirate: 0.6 mL in tube containing 3 mL VTM or 3 mL saline
- Nasopharyngeal or nasal swab: Flexible minitip nylon flocced swab in 3 mL UTM / VTM or flexible minitip flocced swab in 3 mL UTM / VTM

Volume / Minimum Volume

- 1 swab
- 0.6 mL nasal wash/aspirate

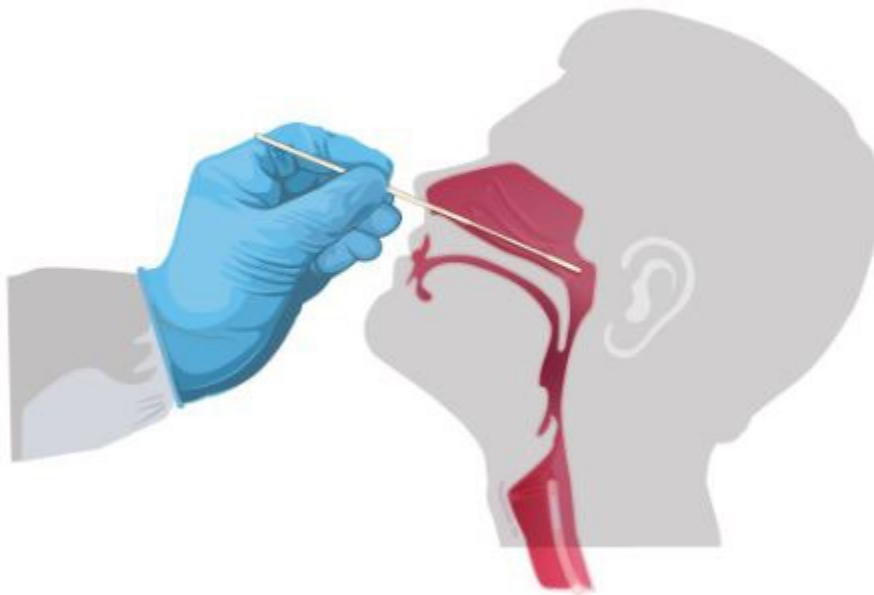
Collection

Prior to specimen collection, patient identity should be confirmed using two independent identifiers; use of a patient identification arm band or similar system is recommended. Specimen label(s) should include the two independent identifiers and the date of collection. There should be a method to identify the individual collecting the specimen. The specimen container(s) should be labeled in the presence of

the patient after specimen is collected. Container(s) should **not** be pre-labeled. Use computer-generated label(s), if available, to avoid transcription errors.

Collect specimen from patient as soon as possible, regardless of time of symptom onset. Health care professionals collecting specimens should use proper infection control techniques and wear personal protective equipment, including an N95 respirator (or facemask if respirator is not available), eye protection, gloves, and a gown.

- **NP swab:** Tilt patient's head back 70 degrees. Insert a minitip swab with flexible (wire or plastic) shaft through the nostril parallel to the palate (not upwards) until resistance is detected 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 swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. Place swab immediately into sterile tube containing 3 mL of universal transport media (UTM), viral transport media (VTM), or saline. See [CDC Nasopharyngeal Specimen Collection Steps](#).



CDC Interim Guidelines for Collecting 2021

- **NS (anterior nares):** Using a flocked or spun polyester swab, insert the tip of swab 0.5 to 0.75 inch (1 to 1.5 cm) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to

collect the sample. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with same swab. Place swab immediately into sterile tube containing 3 mL of universal transport media (UTM), viral transport media (VTM), or 3 mL saline. See [CDC How to collect Your Anterior Nasal Swab Sample for COVID-19 Testing](#).

- **Nasal wash/aspirate (NW):** Sterile collection by health care provider. Attach catheter to suction apparatus. Have the patient sit with head tilted slightly backward. Instill 1 to 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.

For more information see: [CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing](#).

Methodology

Nucleic acid amplification testing (NAAT), with reverse-transcription polymerase chain reaction (RT-PCR)

Normal Values/Findings

Negative or not detected

Positive results are indicative of presence of the identified virus (active infection)

All positive SARS-CoV-2 results must be reported to local/state health departments.

Interpretative Information

- A positive result indicates the presence of organism-specific nucleic acid; results must be correlated with patient history and clinical symptoms. Positive results do not rule out infection with other pathogens (bacteria or coinfection with other pathogens not included in the panel). Positive results do not discern between viable and nonviable organisms.
- A negative test result means that SARS-CoV-2 RNA, influenza and/or RSV nucleic acid was not present in the specimen above the limit of detection, thus a negative result does not rule out the possibility of infection from any of the viruses and should not be used as the sole basis for patient management decisions.

Limitations

- Erroneous results may occur if a specimen is improperly collected, transported, or handled.
- Performance of assay(s) at the time of testing is dependent on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change overtime.
- False negative results may be the result of amplification inhibitor presence, the presence of organisms below the limit of assay detection, or mutation(s) within the target regions of SARS-CoV-2/Flu/RSV

- Individuals who received nasally administered influenza A vaccine (FluMist) may have inaccurate positive results
- Betacoronavirus genus, including SARS-CoV-1 may cause a false positive results (Xpert Xpress 2021).
- This assay cannot rule out infections caused by other bacterial or viral pathogens

Diagnostic Role

Similar to COVID-19 illness (and other respiratory infections caused by various pathogens), the most common symptoms of influenza and RSV are fever, chills, fatigue, cough, headache. Because treatment is available for some viral infections it is important to identify the correct pathogen and also investigate possible coinfection - which has been noted in some COVID-19 patients (Ding 2020; Kim 2020; Roh 2021).

Additional Information

Respiratory Syncytial viruses (RSV) cause respiratory illness in all ages and commonly present with cold-like symptoms. RSV is also associated with lower respiratory infections such as bronchiolitis and pneumonia. It is the most common cause of lower respiratory tract infection in children <1 year of age (Hall 2009). Severe disease occurs most commonly in infants, and children with underlying conditions.

Influenza A and B are seasonal viruses that appear in the winter and cause the seasonal flu. Influenza A viruses are divided into subtypes based on surface proteins: hemagglutinin (H) and neuraminidase (N). There are 18 different hemagglutinin subtypes and 11 different neuraminidase subtypes. The subtypes that are currently circulating and cause the flu are A(H1N1) and A(H3N2). Influenza A virus is known to cause flu pandemics. Influenza B viruses are divided into two lineages: B/Yamagata and B/Victoria; their proportions vary by geographic location. Both viruses (A and B) can present with fever, cough, headache, and general malaise.

For more information, guidance has been issued by the United States [CDC](#) and the [World Health Organization](#).

See: [Flu Symptoms and Diagnosis](#)

See: [Respiratory Syncytial Virus Infection \(RSV\)](#)

See: [COVID-19 Testing](#)

See: [COVID-19 Specimen Collection](#)

See: [COVID-19 Laboratories](#)

See: [COVID-19 Biosafety for Specimen Handling](#)

See: FDA [Emergency Use Authorizations](#)

Index Terms

COVID-19, Influenza, RSV PCR; Flu; Influenza A PCR; Influenza B PCR; Influenza, SARS-CoV-2, RSV PCR; Respiratory Syncytial Virus; RSV

Applies to

NeuMoDx™ Flu A-B/RSV/SARS-CoV-2 Vantage Assay; Pandemic; Seasonal Influenza; Xpert® Xpress SARS-CoV-2/Flu/RSV

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