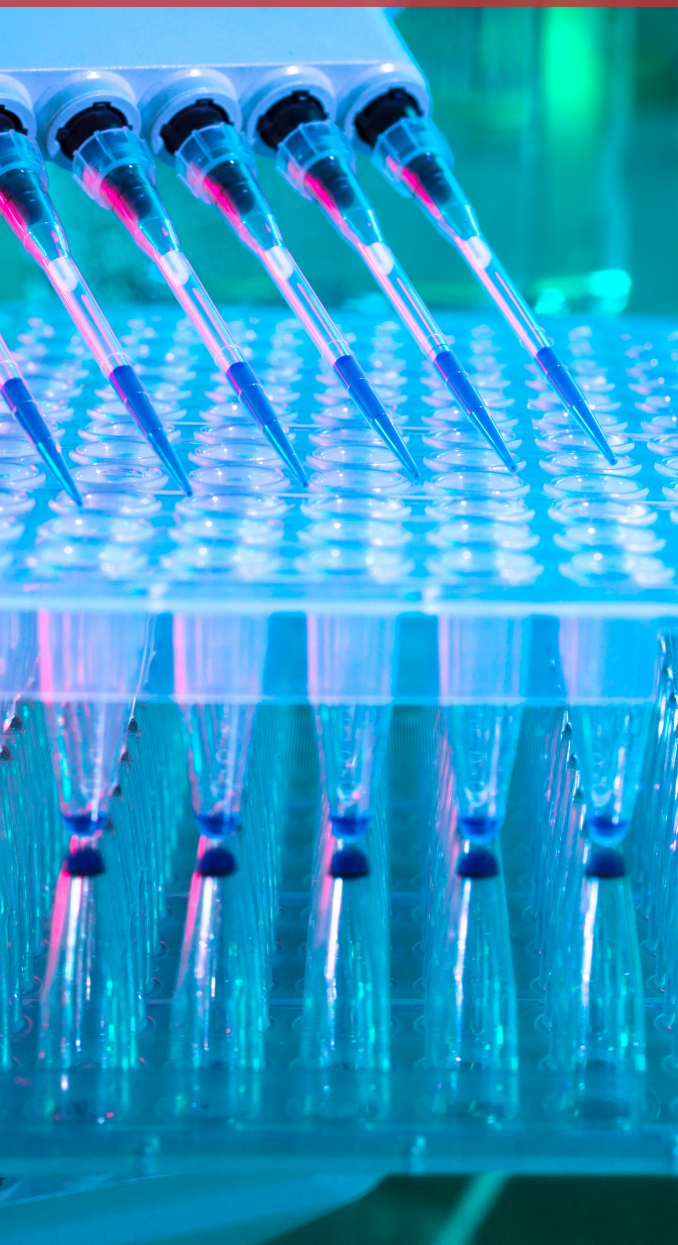
BioReference
LABORATORIES
an OPKO Health Company

COVID-19

Information for Healthcare Providers



NOVEL CORONAVIRUS DISEASE: COVID-19

The novel coronavirus disease (COVID-19) is a new virus of global health significance caused by infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic.

TRANSMISSION AND SYMPTOMS

According to the U.S. Centers for Disease Control and Prevention (CDC), COVID-19 is thought to spread from person to person in close contact through respiratory droplets. It is also possible that a person can catch COVID-19 by touching a surface or object that has the virus on it.

The CDC reports that the following symptoms may appear 2–14 days after exposure:

- Fever
- Cough
- Shortness of breath

DIAGNOSTIC TESTING FOR COVID-19

BioReference offers a real-time reverse-transcription polymerase chain reaction (real-time RT-PCR) assay, giving healthcare providers accurate and timely test results to ensure greater access to testing, promote earlier diagnosis and help limit the subsequent spread of infection. The test detects the presence of SARS-CoV-2 and is for use with patients who meet current guidance for evaluation of infection with COVID-19.

The test has been made available pursuant to the US Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for diagnostic testing in CLIA Certified high-complexity laboratories. The test has been validated, and is being performed at BioReference.

Please refer to the ICD-10 Coding Guidelines for more information on coding encounters related to 2019 novel coronavirus (COVID-19).

GUIDANCE FOR TESTING

The CDC has released criteria for healthcare providers for the evaluation of patients under investigation (PUI) of COVID-19. As of March 4, 2020 recommendations include testing for a wider group of symptomatic patients. Providers should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Decisions on which patients receive testing should be based on the local epidemiology of COVID-19, as well as the clinical course of illness.

Please refer to the most current CDC guidelines for further information. **www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html**

Healthcare providers should notify their local or state health department immediately in the event of a patient under investigation for COVID-19.

COLLECTION INSTRUCTIONS

Patients under investigation of COVID-19 and seeking evaluation of the disease will not be collected at BioReference Patient Service Centers. Specimen should be collected at physician offices, hospitals or other clinic settings. As of March 24, 2020, the FDA and CDC recommend collecting and testing an upper respiratory specimen with a nasopharyngeal collection (NP), as the preferred choice for swab-based SARS-CoV-2 testing. If a NP specimen cannot be collected, alternate collection sites are acceptable and detailed below. Refrigerate specimen at 2-8° C. Label with patient name. Place in specimen bag and label with "COVID-19" and submit to laboratory.

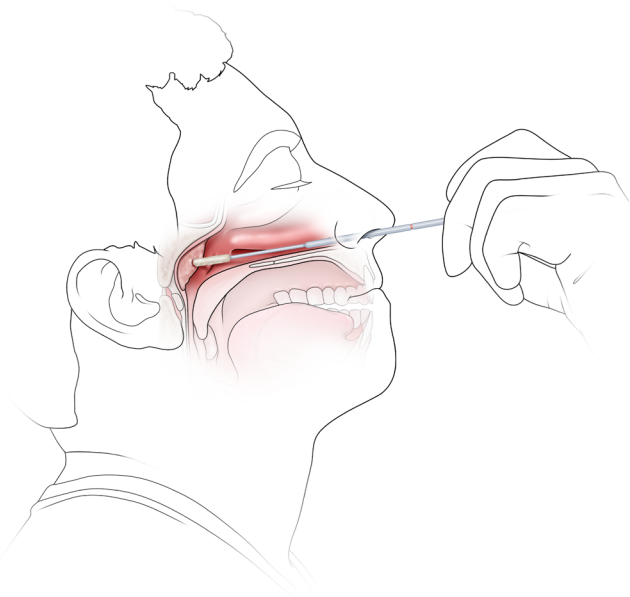
Flocked plastic NP swabs in universal or viral transport media (UTM/VTM) at 3 mL volume are preferred. The FDA has made alternative recommendations in the context of limited quantities of testing supplies during this public health crisis, based on the best available evidence and in consultation with outside experts. When considering alternate swab types, use only synthetic fiber swabs with plastic shafts, and transport in 3 mL of media. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

Please refer to the most current CDC guidelines for further information on collecting, handling, and testing clinical specimens. **www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html** and the FDA FAQs on Diagnostic Testing for SARS-CoV-2 "What If I Do Not Have...?" **www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2**

The COVID-19 assay provides you with accurate and timely test results to provide proper care and reduce subsequent spread of infection.

STANDARD PROCEDURES FOR NASOPHARYNGEAL COLLECTION

1. Tilt patients head so nasal passages are parallel to the palate.
2. Insert a swab into nostril. Leave the swab in place for several seconds to absorb secretions.
3. Slowly remove swab while rotating it.



TEST DETAILS

Test Code and Name:
TH68 Novel Coronavirus COVID-19 Nasopharynx
TH69 Novel Coronavirus COVID-19 Oropharynx
TH71 Novel Coronavirus COVID-19 Pooled N/NP/OP

Primary Container: Dacron-tipped plastic swab with universal transport media *(Speedy# 510)*
MAY INCLUDE ONE OF THE FOLLOWING:

- M6 MicroTip Flock Swab
- M4 MicroTip Flock Swab
- M6 Universal Flock Swab
- Star Swab

Alternate Container: Swab Viral Culturette *(Speedy# 509)*

Turn Around Time*: 3 Days

Transportation Temperature: Refrigerate (2-8˚ C)

Stability: 48 Hours (Refrigerated) 30 Days (Frozen)

Methodology: Real Time RT-PCR

Reference Range: Not Detected

Result Comments:

- **Positive 2019-nCoV** – Critical.
- **Presumptive Positive 2019-nCoV** – Critical. The viral concentration is likely to be near or below the limit of detection. Re-collection of a new sample is suggested, if clinically indicated.
- **Inconclusive** – Please consider re-collection of a new specimen, as clinically indicated.
- **Invalid** – Please consider re-collection of a new specimen, as clinically indicated.
- **Not Detected** – Please consider re-collection of a new specimen, as clinically indicated.

NOTE: All results will be reported to the respective state health departments or their designee. COVID-19 testing information is provided to the CDC and other federal agencies.

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AOEs: Source: ☐ Oropharyngeal ☐ Nasopharyngeal

Self-Pay Price: $55

CPT: 87635**

Clinical Utility: For the detection of the novel COVID-19, Coronavirus

** TAT is based upon receipt of the specimen at the laboratory.*
***CPT codes provided are based on AMA guidelines 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.*

SOURCES

US Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19). Last Accessed March 26, 2020. www.cdc.gov/coronavirus/2019-ncov/index.html

World Health Organization (WHO). Coronavirus disease (COVID-19). Last Accessed March 26, 2020. https://www.who.int/emergencies/diseases/novel-coronavirus-2019

US Food and Drug Administration (FDA). Coronavirus Disease 2019 (COVID-19). Last Accessed March 26, 2020. https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19

FOR MORE INFORMATION PLEASE VISIT

www.bioreference.com/coronavirus/

OR CALL 833-684-0508

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