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OPKO Health Companies

Client Update

MARCH 16, 2020 – COVID-19

To Our Valued Clients,

The 2019 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). COVID-19 is thought to spread from person to person in close contact through respiratory droplets. On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic.

Our priority remains in the health and safety of our employees, and the healthcare providers and patients we serve. COVID-19 testing is imperative in aiding healthcare providers identify infected patients more quickly, and BioReference has been working expeditiously to develop and offer a test that will yield high quality and accurate results.

BioReference is pleased to offer a Real-Time Reverse Transcription Polymerase Chain Reaction (Real-Time RT-PCR) assay to ensure patients and providers have greater access to testing to promote earlier diagnosis and help limit spread of infection. On the following page of this client notification, you will find full test information about the availability of the **Novel Coronavirus COVID-19 (Test Codes TH68 TH69, and TH71)**. 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.

Please visit https://www.bioreference.com/coronavirus/ for more information. Please contact your Account Executive or call Customer Service at 833-684-0508 with any questions. Please notify your local or state health department immediately in the event of a patient under investigation for COVID-19.

Regards,

James Weisberger, M.D.
Senior Vice President | Chief Medical Officer | Laboratory Director

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Test Name	Test Code	Effective Date
Novel Coronavirus COVID-19 Nasopharynx	**TH68**	**March 13, 2020**
Novel Coronavirus COVID-19 Oropharynx	**TH69**	
Novel Coronavirus COVID-19- Pooled NP/OP	**TH71**	

To aid in identifying novel coronavirus disease (COVID-19) and ensure greater access to testing, **Novel Coronavirus COVID-19 (Test Codes TH68 TH69, and TH71)**, a Real-Time RT-PCR assay, is now available for testing at BioReference. 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 Note: 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.

Please refer to the table below for test information, and contact your Account Executive or Customer Service at 833-684-0508 with any questions.

	Test Information
Test / Name	TH68 Novel Coronavirus COVID-19 Nasopharynx TH69 Novel Coronavirus COVID-19 Oropharynx TH71 Novel Coronavirus COVID-19- Pooled 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 Temp	Refrigerate at 2-8 C
Stability	3 days (Refrigerated at 2-8 C)
Methodology	Real-Time RT-PCR
Reference Range	Not Detected
Result Comments	Presumptive Positive 2019-nCoV – *Critical Call* Inconclusive – *Recommend Repeat Testing As Clinically Indicated* Invalid – *Recommend Repeat Testing As Clinically Indicated* Not Detected - *Consider Re-Collection As Clinically Indicated* **NOTE:** All results, positive, negative and inconclusive, will be reported to the respective state health departments through ELR (Electronic Laboratory Reporting).
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 13, the CDC recommends collecting only the upper respiratory nasopharyngeal (NP) swab. Collection of an oropharyngeal (OP) specimen is a lower priority, and, if collected, should be combined in the same tube as the NP swab and immediately place in 2-3 mL of viral transport media. Refrigerate specimen at 2-8° C. Label with patient name. Place in specimen bag and label with "COVID-19" and submit to laboratory. NOT TO BE USED FOR BACTERIAL TRANSPORT.
AOE	Source: [ ] Oropharyngeal [ ] Nasopharyngeal
Price	List $150, Self-Pay $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.

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