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OPKO Health Companies

Client Update

APRIL 8, 2020 – COVID-19

Test Name	Test Code	Effective Date
Novel Coronavirus COVID-19 Nasopharynx	**TH68-0**	**Immediately**
Novel Coronavirus COVID-19 Oropharynx	**TH69-8**	
Novel Coronavirus COVID-19- Pooled N/NP/OP	**TH71-4**	

As you are aware, we offer the **Novel Coronavirus COVID-19 (Test Codes TH68 TH69, and TH71) Test** for evaluating Patients under investigation of COVID-19.

Please be advised that when submitting specimen for testing, it MUST be received in 3 mL of universal or viral transport media (UTM/VTM), Roche cobas® PCR Media, liquid Amies media, or saline. Volumes lower than 3 mL increase the risk of Invalid results or Quantity Not Sufficient (QNS). For vials that contain less than 3 mL of media (e.g. e-Swabs), you will need to add normal saline to bring the media volume to 3 mL in the vial before sending in for testing.

Please refer to the table below for test information or visit us online at https://www.bioreference.com/coronavirus. Please 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 N/NP/OP
Primary Container	Dacron-tipped plastic swab with 3mL 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	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.
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), placed in 3 mL of transport media, as the preferred choice for swab based SARS-CoV-2 testing. If a NP specimen cannot be collected, alternate acceptable sites are oropharyngeal, nasal or mid-turbinate swabs, based on FDA guidance. Refrigerate specimen at 2-8° C. Label with patient name. Place in specimen bag and label with "COVID-19" and submit to laboratory.
AOE	Source: [ ] Oropharyngeal [ ] Nasopharyngeal
Price	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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