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Client Update

MARCH 17, 2020 - COVID-19

To Our Valued Clients,

As you know, BioReference released information on Monday, March 16 about the availability of our Real-Time Reverse Transcription Polymerase Chain Reaction (Real-Time RT-PCR) COVID-19 assay.

Since that update was sent, new information has been released relating to specimen stability and results reporting. Of note, the stability of refrigerated specimen has been updated to 48 hours, and the stability of frozen specimen is 30 days. Additionally, any "Positive" results will be a critical value that is called to clients.

Additionally, we would like to inform you that when ordering swabs for COVID-19 testing, you will also receive a lime green specimen bag label. Upon collection, please adhere this label to the outside of each specimen bag prior to submission to the laboratory.

Please refer to page two of this client notification for full test information about the **Novel Coronavirus COVID-19 (Test Codes TH68, TH69, and TH71)**, including the changes made in the stability and reporting.

New York Clients: As you may know, in partnership with the New York State Department of Health, BioReference is providing testing for the public drive-through testing facility in New Rochelle, NY. Additional satellite testing sites will continue to open across the state in the coming weeks and will be announced accordingly. A new hotline for New York residents, established and run by the State of New York, is now available for patients to call if they believe they are impacted by COVID-19 to schedule an appointment for the drive-thru. Please have patients call: 1-888-364-3065.

BioReference Leadership continues to closely monitor the evolving situation pertaining to COVID-19, and will be in touch with further updates.

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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OPKO Health Companies







Client Update

MARCH 17, 2020 - COVID-19

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	48 Hours (Refrigerated); 30 Days (Frozen)
Methodology	Real-Time RT-PCR
Reference Range	Not Detected
Result Comments	Positive - Critical
	Presumptive Positive 2019-nCoV – Critical. Re-Collection is Advised
	Inconclusive – Consider Re-Collection As Clinically Indicated
	Invalid – Consider Re-Collection 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: 1 1 :	t of the consistent at the laboratory.

^{*} TAT is based upon receipt of the specimen at the laboratory.

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^{**}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.