Interpath Laboratory, Inc.
Test File Update

As an Interpath customer who receives electronic results or sends electronic orders you may need to be notified when we update our Service Manual. Although we try to keep these changes to a minimum, laboratory medicine is an evolving industry requiring changes to our technology from time to time. Depending on the requirements of your EMR or Hospital Information System you may be required to make similar changes to your system in order to correctly process inbound electronic results and create outbound electronic orders.

If you are uncertain that you are required to update your system we recommend that you contact your vendor for more information. As your laboratory service provider we are available to participate in the discussion with your vendor so that you clearly understand the impact of these changes.

Included in this email:

- This cover letter with a summary of the changes
- Microsoft Word® Document with the detail of these changes to our Service Manual
- Interpath Master Order/Result Compendium

Additional information including our most recent Service Manual and additional contact information can be found at www.interpathlab.com

Effective Date: May 19, 2020

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Order Code	Test Name	NC Name Change	CC Component Change	CPT CPT Change	SRC Specimen Requirements Change	RRC Reference Range Change	NT New Test	DT Discontinued Test	AOE Ask on Order Entry Questions
2870	**Anti-SARS-CoV-2 IgM and IgG**						◆		

2870 Anti-SARS-CoV-2 IgM and IgG NT

Specimen:	
Collect:	**One SST** Also Acceptable Green Top (Li Heparin)
Submit:	**1 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.** Also Acceptable 1 mL (Min:0.5 mL) Plasma. Submit Refrigerated. Submit in a Standard Transport Tube.
Rejection Criteria:	Heat inactivated Sample stabalized with azide.
Stability:	Ambient: 3 Day(s); Refrigerated: 7 Day(s); Frozen: 4 Week(s); Incubated: Unacceptable
Methodology:	Electrochemiluminescence Immunoassay (ECLIA)
Performed:	Mon-Fri
Reported:	1-4 Day(s)
Interpretive Data:	General Reference Range : non-reactive This test cannot be used by itself to diagnose an acute infection. Testing with a molecular diagnostic method (e.g., SARS-CoV-2 by PCR) should be performed to evaluate for active infection. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection. The individual immune response following SARS-CoV-2 infection (COVID-19) varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably. FOR INFORMATION ABOUT THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE EMERGENCY USE OF THIS SARS-COV-2 (COVID-19) ANTIBODY TEST, GO TO: www.fda.gov/media/137603/download (FOR HEALTHCARE PROVIDERS), OR: www.fda.gov/media/137604/download (FOR PATIENTS).

New test available for order. See attached COVID-19 testing document for further information.