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: March 11, 2024

Interpath Laboratory, Inc.
Test File Update

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
1153	Factor II (Prothrombin) Gene Mutation		◆						
1152	Factor V Leiden		◆						
2520	Fetal Fibronectin							◆	
3164	Group B Streptococcus by PCR				◆				
2706	Hepatitis C Genotype		◆						
2330	Lyme Antibody, Total							◆	
2788	Lyme Ab, Total						◆		
2699	MTHFR Mutation		◆						

1153 Factor II (Prothrombin) Gene Mutation **CC**
Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by Interpath Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.
Please take note of Added Comment.

1152 Factor V Leiden **CC**
Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by Interpath Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.
Please take note of Added Comment.

2520 Fetal Fibronectin **DT**
Please take note of Discontinued Test.

3164 Group B Streptococcus by PCR SRC

Specimen:	
Collect:	**Genital Swab in Culturette-Aerobic** Also Acceptable Cervical/Vaginal Smear in Culturette-Aerobic Endocervical Swab in Culturette-Aerobic Other in Culturette-Aerobic Rectal Swab in Culturette-Aerobic Urogenital Swab in Culturette-Aerobic Vaginal Secretions in Culturette-Aerobic
Submit:	**Genital Swab in Culturette-Aerobic. Submit Refrigerated.** Also Acceptable Vaginal Secretions in Culturette-Aerobic. Submit Refrigerated. Endocervical Swab in Culturette-Aerobic. Submit Refrigerated. Cervical/Vaginal Smear in Culturette-Aerobic. Submit Refrigerated. Urogenital Swab in Culturette-Aerobic. Submit Refrigerated. Rectal Swab in Culturette-Aerobic. Submit Refrigerated. Other in Culturette-Aerobic. Submit Refrigerated.
Special Handling:	Possible Sources: Urogenital, Vaginal or Rectal Specimen stable incubated in Todd Hewitt for 18-24 hrs. Swab can also be submitted in Todd Hewitt (LIM) Broth.
Rejection Criteria:	Specimen submitted frozen Wood Swabs Cotton Swabs Sample exposed to excessive heat Collection devices other than the dual rayon swab is not recommended.
Stability:	Ambient: 1 Day(s); Refrigerated: 2 Day(s); Frozen: Unacceptable; Incubated: Unacceptable
Methodology:	Automated Real-Time PCR by Cepheid GeneXpert
Performed:	Sun-Sat
Reported:	2-4 Day(s)
CPT Codes:	87653
Interpretive Data:	This test is performed by Cepheid GeneXpert. The use of collection devices other than the dual rayon swab is not recommended. Other specimen types have not been validated with the Xpert GBS test. False negative results may occur if the number of organisms in the sample is below the limit of detection. Test results may be affected by prior antibiotic therapy. DNA from non-viable organisms may be detected. A positive result is presumptive for the presence of GBS.

Please take note of changes to Stability.

2706 Hepatitis C Genotype CC

Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by Interpath Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Please take note of Added Comment.

2330 Lyme Antibody, Total DT

Please take note of Test discontinuation. Please refer to new test Lyme AB, Total (2788).

2788 Lyme Ab, Total NT

Specimen:	
Collect:	**One SST** Also Acceptable One Green Top (Li Heparin) One Lavender (EDTA) One Red Top One Plasma in Standard Transport Tube One Serum in Standard Transport Tube
Submit:	**1 mL (Min:0.5 mL) Serum in Standard Transport Tube. Submit Refrigerated. Submit in a Standard Transport Tube.** Also Acceptable 1 mL (Min:0.5 mL) Serum in Standard Transport Tube. Submit Refrigerated. Submit in a Standard Transport Tube. 1 mL (Min:0.5 mL) Plasma in Standard Transport Tube. Submit Refrigerated. Submit in a Standard Transport Tube. 1 mL (Min:0.5 mL) Plasma in Standard Transport Tube. Submit Refrigerated. Submit in a Standard Transport Tube.
Special Handling:	Seperate from cells as soon as possible. If the Lyme Antibody total is Positive, then the Lyme Antibodies, IgG/IgM by Western Blot (Test# 91156) will be performed. Additional charges will apply.
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Light blue (Citrate) Microbial Contamination
Stability:	Ambient: 8 Hour(s); Refrigerated: 7 Day(s); Frozen: 3 Month(s); Incubated: Unacceptable
Methodology:	Chemiluminescent Immunoassay
Performed:	Mon-Fri
Reported:	1-3 Day(s)
Interpretive Data:	General Reference Range : NOT DETECTED A negative result should not be used to exclude Lyme disease. Patients with early Lyme disease may have undetectable antibody titer. Additional serum samples, at varying intervals, should be tested to demonstrate a rise in titer, if clinically indicated. Early treatment may prevent the development of antibodies. Patients with antibodies against Human Ehrlichiosis (HGE), Tick-Borne Relapsing Fever (TBRF), Babesiosis, Parvovirus, and EBV infections may give false positive Lyme Ab Total results.

Please take note of New Test.

2699 MTHFR Mutation **CC**

Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by Interpath Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Please take note of Added Comment.