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: November 28, 2022

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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
91495	Cytomegalovirus by Quantitative NAAT, Plasma		◆						
1153	Factor II (Prothrombin) Gene Mutation						◆		
1152	Factor V Leiden						◆		
94238	Factor V Leiden (F5) R506Q Mutation							◆	
2699	MTHFR Mutation						◆		
94235	MTHFR 2 Variants							◆	
90010	Nicotine, Serum				◆				
94230	Prothrombin (F2) (G20210A) Pathogenic Variant							◆	
91561	Seroquel				◆	◆			
91218	Trazodone				◆	◆			

91495 Cytomegalovirus by Quantitative NAAT, Plasma CC

Specimen:	
Collect:	**One Lavender (EDTA)** Also Acceptable One Pink Top (EDTA) One Standard Transport Tube
Submit:	**2 mL (Min:1 mL) Plasma. Submit Frozen.**
Special Handling:	Separate from cells within 24 hours of collection.
Rejection Criteria:	Serum Whole blood Respiratory specimens
Stability:	Ambient: Unacceptable; Refrigerated: 6 Day(s); Frozen: 3 Month(s); Incubated: Unacceptable
Methodology:	Quantitative Polymerase Chain Reaction
Performed:	Sun-Sat
Reported:	4-5 Day(s)
CPT Codes:	87497
Interpretive Data:	Please see report for interpretive data.
Components:	91676 - CMV QUANT 91678 - CMV QUANT LOG 91497 - CMV INTERP

Please take note of changes to components.

Component changes:

Remove: 91699 - CMV SOURCE; 91567 - CMV QUANT; 91496 - CMV QUANT

1153 Factor II (Prothrombin) Gene Mutation NT

Specimen:	
Collect:	**One Lavender (EDTA)** Also Acceptable One Pink Top (EDTA)
Submit:	**4 mL (Min:2 mL) Whole blood in Lavender (EDTA). Submit Refrigerated.** Also Acceptable 4 mL (Min:2 mL) Whole blood in Pink Top (EDTA). Submit Refrigerated.
Special Handling:	Variant analyzed: c.*97G>A, previously referred to as G20210A.
Rejection Criteria:	Shared samples - a separate sample must be collected for molecular testing (Testing for MTHFR, FACTOR V, and PT GENE MUTATION may be performed from same tube).
Stability:	Ambient: Unacceptable; Refrigerated: 1 Month(s); Frozen: Unacceptable; Incubated: Unacceptable
Methodology:	Mass Spectrometry Coupled with End-Point PCR
Performed:	Wednesday
Reported:	1-7 Day(s)
CPT Codes:	81240
Interpretive Data:	General Reference Range : negative Where appropriate, medical consultation and/or genetic counseling should be offered to patients to inform and explain the risk implications and genetic implications of these test results. Patient DNA is assayed for the Prothrombin G20210A mutation by polymerase chain reaction (PCR) and MOLDI-TOF mass spectrometry technology. The product of PCR is detected on the Agena Bioscience MassARRAY system. The expression of Factor II thrombophilia is impacted by coexisting genetic thrombophilic disorders, acquired thrombophilic disorders (eg, malignancy, hyperhomocysteinemia, high factor VIII levels), and circumstances including: pregnancy, oral contraceptive use, hormone replacement therapy, selective estrogen receptor modulators, travel, central venous catheters, surgery, and organ transplantation. The test result must be interpreted along with the patient's clinical history and other pertinent laboratory data. Variant analyzed: c.97G>A (G20210A), previously referred to as Factor II Gene Mutation.

Please take note of new test available for order.

1152 Factor V Leiden NT

Specimen:	
Collect:	**One Lavender (EDTA)** Also Acceptable One Pink Top (EDTA)
Submit:	**4 mL (Min:2 mL) Whole blood in Lavender (EDTA). Submit Refrigerated.** Also Acceptable 6 mL (Min:2 mL) Whole blood in Pink Top (EDTA). Submit Refrigerated.
Special Handling:	Variant analyzed: c.1601G>A (p.Arg534Gln), referred to as Factor V Leiden.
Rejection Criteria:	Shared samples - a separate sample must be collected for molecular testing (Testing for MTHFR, FACTOR V, and PT GENE MUTATION may be performed from same tube).
Stability:	Ambient: Unacceptable; Refrigerated: 1 Month(s); Frozen: Unacceptable; Incubated: Unacceptable
Methodology:	Mass Spectrometry Coupled with End-Point PCR
Performed:	Wednesday
Reported:	1-7 Day(s)
CPT Codes:	81241
Interpretive Data:	General Reference Range : negative Where appropriate, medical consultation and/or genetic counseling should be offered to patients to inform and explain the risk implications and genetic implications of these test results. Patient DNA is assayed for the Factor V Leiden G1691A mutation by polymerase chain reaction (PCR) and MOLDI-TOF mass spectrometry technology. The product of PCR is detected on the Agena Bioscience MassARRAY system. Other causes of activated protein C resistance and hereditary forms of venous thrombosis are not ruled out. The test result must be interpreted along with the patient's clinical history and other pertinent laboratory data.

Please take note of new test available for order.

94238 Factor V Leiden (F5) R506Q Mutation DT

Please take note test is being discontinued. Instead see test 1152 Factor V Leiden.

2699 MTHFR Mutation NT

Specimen:	
Collect:	**One Lavender (EDTA)** Also Acceptable One Pink Top (EDTA)
Submit:	**4 mL (Min:2 mL) Whole blood in Lavender (EDTA). Submit Refrigerated.** Also Acceptable 6 mL (Min:2 mL) Whole blood in Pink Top (EDTA). Submit Refrigerated.
Special Handling:	Variant analyzed: c.665C>T (p. Ala222Val), previously referred to as C677T. Variant analyzed: c.1286A>C (p. Glu429Ala), previously referred to as A1298C.
Rejection Criteria:	Shared samples - a separate sample must be collected for molecular testing (Testing for MTHFR, FACTOR V, and PT GENE MUTATION may be performed from same tube).
Stability:	Ambient: Unacceptable; Refrigerated: 1 Month(s); Frozen: Unacceptable; Incubated: Unacceptable
Methodology:	Mass Spectrometry Coupled with End-Point PCR
Performed:	Wednesday
Reported:	1-7 Day(s)
CPT Codes:	81291
Interpretive Data:	Please see report for interpretive data.
Components:	2707 - C677T MUTATION 2708 - A1298C MUTATION

Please take note of new test available for order.

94235 MTHFR 2 Variants DT

Please take note test is being discontinued. Instead see test 2699 MTHFR Mutation.

90010 Nicotine, Serum SRC

Specimen:	
Collect:	**One Red Top** Also Acceptable One Green Top (Li Heparin) One Lavender (EDTA) One Pink Top (EDTA)
Submit:	**4 mL (Min:1 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.** Also Acceptable 4 mL (Min:1 mL) Plasma. Submit Refrigerated. Submit in a Standard Transport Tube.
Rejection Criteria:	Specimens exposed to repeat freeze/thaw cycles
Stability:	Ambient: 1 Week(s); Refrigerated: 2 Week(s); Frozen: 24 Month(s); Incubated: Unacceptable
Methodology:	Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry
Performed:	Sun-Sat
Reported:	2-5 Day(s)
CPT Codes:	80323
Interpretive Data:	Please see report for interpretive data.
Components:	90012 - COTININE 90013 - NICOTINE

Please take note of changes to collect requirements (removal of SST).

94230 Prothrombin (F2) (G20210A) Pathogenic Variant DT

Please take note test is being discontinued. Instead see test 1153 Factor II (Prothrombin) Gene Mutation.

91561 Seroquel SRC/RRC

Specimen:	
Collect:	**One Red Top** Also Acceptable One Lavender (EDTA) One Pink Top (EDTA)
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.
Special Handling:	Separate from cells within 2 hours of collection
Rejection Criteria:	Use of separator tubes
Stability:	Ambient: 1 Day(s); Refrigerated: 2 Day(s); Frozen: 4 Month(s); Incubated: Unacceptable
Methodology:	Liquid Chromatography Tandem Mass Spectrometry
Performed:	Wednesday
Reported:	2-9 Day(s)
CPT Codes:	80342

Please take note of changes to stability, methodology, and reference range.
Reference Range changes:
Therapeutic range: 100-1000 ng/mL
Toxic: >1000 ng/mL

91218 Trazodone RRC/SRC

Specimen:	
Collect:	**One Red Top** Also Acceptable One Lavender (EDTA) One Pink Top (EDTA)
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.
Special Handling:	Separate from cells ASAP Timing of specimen collection: Pre-dose (trough) draw - At steady state concentration.
Rejection Criteria:	Use of separator tubes Whole blood
Stability:	Ambient: 1 Day(s); Refrigerated: 2 Week(s); Frozen: 4 Month(s); Incubated: Unacceptable
Methodology:	Liquid Chromatography Tandem Mass Spectrometry
Performed:	Wednesday
Reported:	2-9 Day(s)
CPT Codes:	80338

Please take note of changes to stability, methodology, performed and reported dates, and reference range.
Reference Range changes:
Therapeutic range: 800-1600 ng/mL
Toxic: Not well estabilised