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 Dates: October 2 , 2017. October 9, 2017. October 16, 2017. October, 23, 2017.

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
*	Allergy Testing (All)					◆			
2606	Glucose, Fasting + 2 HR		◆						
2467	Influenza A/B Rapid				◆				
1090	Kappa Lambda Free Light Chain							◆	
91460	Kappa-Lambda Free Light Chains, Quantitative	◆							
2179	Testosterone					◆			
2126	Vitamin B12				◆	◆			

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Allergy Testing

Please take note of the following reference range change applicable to all allergy testing. Effective: October 16, 2017.

Allergen Reference Ranges:

Class 0:	**<0.1**	**kU/L**	**Absent or Undetected**
Class 0/1:	**0.10 - 0.34**	**kU/L**	**Clinical Relevance Undetermined**
Class 1:	**0.35 - 0.69**	**kU/L**	**Low**
Class 2:	**0.70 - 3.49**	**kU/L**	**Moderate**
Class 3:	**3.50 - 17.49**	**kU/L**	**High**
Class 4:	**17.5 - 49.9**	**kU/L**	**Very High**
Class 5:	**50.0 - 100**	**kU/L**	**Very High**
Class 6:	**>100**	**kU/L**	**Very High**

Allergens scoring in Class 0/1 have uncertain clinical relevance but could be a risk factor for future sensitization.

Allergens scoring in Class 2 or higher have an increasing probability of contributing to a total allergenic load and can be considered clinically relevant.

Test performed by 'ImmunoCAP Specific IgE Blood Test' technology.

See next page for list of components affected.

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Below is a list of all Allergy testing component names and test numbers.

80001	MILK, COWS [IGE]
80002	EGG WHITE [IGE]
80003	SOYBEAN [IGE]
80004	WHEAT [IGE]
80005	FISH, COD [IGE]
80006	PEANUT [IGE]
80007	CORN [IGE]
80008	WALNUT [IGE]
80009	SCALLOP [IGE]
80010	SHRIMP [IGE]
80011	CASHEW [IgE]
80013	HONEY BEE [IGE]
80014	YELLOW HORNET [IGE]
80015	PAPER WASP [IGE]
80016	YELLOW JACKET [IGE]
80017	WF HORNET
80020	SESAME SEED [IGE]
80021	PEA [IGE]
80022	HAZEL NUT [IGE]
80023	BRAZIL NUT [IGE]
80024	ALMOND [IGE]
80025	PECAN NUT [IGE]
80026	CRAB [IGE]
80027	TOMATO [IGE]
80028	PORK [IGE]
80029	BEEF [IGE]
80030	CARROT [IGE]
80031	ORANGE [IGE]
80032	POTATO [IGE]
80033	COCONUT [IGE]
80034	TUNA [IGE]
80035	SALMON [IGE]
80036	STRAWBERRY [IGE]
80037	YEAST [IGE]
80038	ONION [IGE]
80039	APPLE [IGE]

80040	RYE [IGE]
80041	BARLEY [IGE]
80042	OAT [IGE]
80043	LOBSTER [IGE]
80044	CHICKEN MEAT [IGE]
80046	MELONS [IGE]
80048	RICE [IGE]
80049	CHOCOLATE [IGE]
80051	GARLIC [IGE]
80052	EGG YOLK [IGE]
80055	CASEIN [IGE]
80056	GLUTEN [IGE]
80057	CHEESE, CHEDDAR [IGE]
80058	CHEESE, MOLD [IGE]
80059	MUSTARD [IGE]
80060	BANANA [IGE]
80061	TEA [IGE]
80062	CINNAMON [IGE]
80063	BEAN, WHITE-NAVY [IGE]
80064	CLAM [IGE]
80065	GREEN BEAN [IGE]
80066	TURKEY MEAT [IGE]
80067	PEACH [IGE]
80068	COFFEE [IGE]
80069	MALT [IGE]
80100	MAPLE/BOX ELDER [IGE]
80101	GRAY ALDER [IGE]
80102	COMMON BIRCH [IGE]
80103	OAK [IGE]
80104	COTTONWOOD [IGE]
80105	WALNUT, TREE [IGE]
80106	SYCAMORE [IGE]
80107	WILLOW [IGE]
80108	PINE, WHITE [IGE]
80109	MOUNTAIN JUNIPER [IGE]
80110	ELM [IGE]

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80111	ASH [IGE]
80112	LOCUST [IGE]
80113	RUSSIAN OLIVE [IGE]
80114	MULBERRY [IGE]
80200	BERMUDA GRASS [IGE]
80201	REDTOP GRASS [IGE]
80202	BROME GRASS [IGE]
80203	CULTIVATED RYE [IGE]
80204	VELVET GRASS [IGE]
80205	CULTIVATED WHEAT [IGE]
80206	CORN POLLEN [IGE]
80207	ORCHARD GRASS [IGE]
80208	MEADOW FESCUE [IGE]
80209	RYE-GRASS [IGE]
80210	TIMOTHY GRASS [IGE]
80211	KENTUCKY BLUE [IGE]
80250	MUGWORT [IGE]
80251	RUSSIAN THISTLE [IGE]
80252	PIGWEED, COMMON [IGE]
80253	LAMB''S QUARTER [IGE]
80254	COCKLEBUR [IGE]
80255	FIREBUSH, KOCHIA [IGE]
80256	SHEEP SORREL [IGE]
80257	RAGWEED, WESTERN [IGE]
80258	RAGWEED, FALSE [IGE]
80259	ENGLISH PLANTAIN [IGE]
80260	SUGAR-BEET [IGE]
80261	RAGWEED, COMMON [IGE]
80262	SCALE [IGE]
80263	ALFALFA [IGE]
80264	SAGEBRUSH [IGE]
80265	MARSHELDER [IGE]
80267	NETTLE [IGE]
80268	GOLDENROD [IGE]
80269	SUNFLOWER [IGE]
80300	CAT DANDER EPITH [IGE]
80301	DOG DANDER [IGE]
80302	HORSE DANDER [IGE]
80303	COW DANDER [IGE]
80308	FEATHERS, MIXED [IGE]
80311	ARA H 1 [IGE]
80312	ARA H 2 [IGE]
80313	ARA H 3 [IGE]
80314	ARA H 8 PR-10 [IGE]
80315	ARA H 9 LTP [IGE]
80316	ALPHA-LACTALBUMIN [IGE]
80317	BETA-LACTOGLOBULIN [IGE]
80319	OVOMUCOID [IGE]
80320	OVALBUMIN [IGE]
80330	DERMAT. FARINAE [IGE]
80331	DERMAT. PTERO [IGE]
80339	HOUSE DUST, HOLLISTER [IGE]
80340	COCKROACH [IGE]
80350	ALTERNARIA TENUIS [IGE]
80351	PENICILLIUM CHRYS [IGE]
80352	CLADOSPORIUM [IGE]
80353	ASPERGILLIUS [IGE]
80354	MUCOR RACEMOSUS [IGE]
80355	CANDIDA ALBICANS [IGE]
80356	SETOMELAN. ROSTR. [IGE]
80357	BOTRYTIS [IGE]
80358	STEMPHYLLIUM [IGE]
80359	RHIZUPUS NIGRICAN [IGE]
80361	PHOMA [IGE]

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2606 Glucose, Fasting + 2 HR CC

Specimen:	
Collect:	**One Gray Top (2HR)** **One Gray Top (FAST)** Also Acceptable One SST (2HR) One SST (FAST)
Submit:	**Two 4 mL (Min:1 mL) Whole blood in Gray Top. Submit Refrigerated.** Also Acceptable Two 1 mL (Min:0.5 mL) Plasma. Submit Refrigerated. Submit in a Standard Transport Tube. Two 1 mL (Min:0.5 mL) Serum in SST. Submit Refrigerated.
Special Handling:	Draw fasting specimen, then give 75gm glucola (or 2 hours post meal). At 2 hour draw "2 HR" post sample. Label tubes "Fasting" and "2 HR". Other alternative samples: Green Top (Li Hep), Lavender EDTA, Pink EDTA, Red Top. If using alternative serum or plasma separate from cells ASAP. Serum or plasma stability: Ambient 8 hrs, RF 3 days, FZ 1 month
Rejection Criteria:	Hemolyzed specimens Microbially Contaminated Unlabled Specimens
Stability:	Ambient: 1 Day(s); Refrigerated: 3 Day(s); Frozen: Unacceptable; Incubated: Unacceptable
Methodology:	Colorimetric; Kinetic
Performed:	Mon-Fri
Reported:	1-3 Day(s)
CPT Codes:	82947 82950
Interpretive Data:	Please see report for interpretive data.
Components:	*2400 - GLUCOSE, FASTING* 2143 - GLUCOSE, POST

Please take note of change in components from 1023 Glucose to 2400 Glucose, Fasting. Effective: October 16, 2017.

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2467 Influenza A/B Rapid SRC

Specimen:	
Collect:	**Nasal Swab in Sterile Specimen Container** Also Acceptable Nasopharyngeal Swab in Sterile Specimen Container
Submit:	**Nasal Swab in Sterile Specimen Container. Submit Refrigerated.** Also Acceptable Nasopharyngeal Swab in Sterile Specimen Container. Submit Refrigerated.
Special Handling:	Use only the flocked swab provided in the kit. If transport is required, place the swab in Viral Transport Media and refrigerate. To perform Influenza A/B via DFA a separate nasopharyngeal swab, aspirate or washing needs to be collected and placed in Viral Transport Media.
Rejection Criteria:	Specimens collected from other sources. Swabs other than those provided in the ImmunoCard STAT! Flu A&B test kit.
Stability:	Ambient: 4 Hour(s); Refrigerated: 8 Hour(s); Frozen: Unacceptable; Incubated: Unacceptable
Methodology:	Solid Phase Immunoassay
Performed:	Mon-Fri
Reported:	1-2 Day(s)
CPT Codes:	87804
Interpretive Data:	Please see report for interpretive data.
Components:	2626 - INFLUENZA A 2627 - INFLUENZA B

Please take note of changes in collection, submission requirements, special handling, rejection criteria, stability, and methodology.
Effective: October 2, 2017

In an effort to improve the accuracy of rapid influenza testing, the U.S. Food and Drug Administration (FDA) recently announced the reclassification of these assays to ensure higher sensitivities, higher specificities and detection of currently circulating and newly emerging strains. Interpath Laboratory will be changing to a new rapid influenza diagnostic kit to meet these requirements.

Interpath Laboratory, Inc.
Test File Update

1090 Kappa Lambda Free Light Chain DT

Specimen:	
Collect:	**One SST** Also Acceptable One Red Top
Submit:	**1 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.**
Special Handling:	Allow for complete clot formation Avoid Repeated Freeze/Thaw Cycles Seperate from cells as soon as possible.
Rejection Criteria:	Hemolyzed specimens Lipemic Samples Microbially Contaminated Plasma
Stability:	Ambient: 2 Hour(s); Refrigerated: 3 Week(s); Frozen: 24 Month(s); Incubated: Unacceptable
Methodology:	Immunoturbidometric
Performed:	Tuesday, Thursday
Reported:	2-5 Day(s)
CPT Codes:	83883x2
Interpretive Data:	Please see report for interpretive data.
Components:	1091 - KAPPA 1092 - LAMBDA 1093 - K/L RATIO

Discontinuing test and replacing with 91460 Kappa-Lambda Free Light Chains, Quantitative. Effective: October 23, 2017.

Interpath Laboratory, Inc.
Test File Update

91460 Kappa-Lambda Free Light Chains, Quantitative NT

Specimen:	
Collect:	**One SST** Also Acceptable One Red Top
Submit:	**2 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.**
Special Handling:	Separate serum from cells ASAP or within 2 hours of collection
Rejection Criteria:	Plasma Specimen submitted at room temperature
Stability:	Ambient: 2 Hour(s); Refrigerated: 1 Week(s); Frozen: 2 Week(s); Incubated: Unacceptable
Methodology:	Quantitative Nephelometry
Performed:	Mon-Fri
Reported:	2-5 Day(s)
CPT Codes:	83883x2
Interpretive Data:	Please see report for interpretive data.
Components:	91461 - KAPPA QNT 91462 - LAMBDA 91463 - RATIO

New testing to replace 1090 Kappa Lambda Free Light Chain.

Please take note of differences in submission requirements, special handling, rejection criteria, stability, methodology and days performed changes.
Effective: October 23, 2017.

Interpath Laboratory, Inc.
Test File Update

2179 Testosterone — Reporting Change

Specimen:	
Collect:	**One SST** Also Acceptable One Green Top (Li Heparin) One Lavender (EDTA) One Pink Top (EDTA) One Red Top
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:	Allow specimen to clot completely at room temperature Avoid Repeated Freeze/Thaw Cycles Minimize air exposure Separate from cells ASAP Specimen should be collected between 6-10 a.m.
Stability:	Ambient: 8 Hour(s); Refrigerated: 1 Week(s); Frozen: 6 Month(s); Incubated: Unacceptable
Methodology:	Electrochemiluminescence Immunoassay (ECLIA)
Performed:	Mon-Fri
Reported:	1-3 Day(s)
CPT Codes:	84403
Interpretive Data:	

Male Reference Ranges		
0 - 11 year(s)	:	0-2.5 ng/dl
11 - 16 year(s)	:	2.5-778 ng/dl
16 - 20 year(s)	:	238-1048 ng/dl
20 - 49 year(s)	:	249-836 ng/dl
49 - 150 year(s)	:	193-740 ng/dl

Female Reference Ranges		
0 - 11 year(s)	:	2.5-7.49 ng/dl
11 - 16 year(s)	:	2.5-39.8 ng/dl
16 - 20 year(s)	:	2.5-31.1 ng/dl
20 year(s) - 49	:	8.4-48.1 ng/dl
49 - 150 year(s)	:	2.6-40.8 ng/dl

Results less than 12.0 ng/dL will be reported as <12.0 ng/dL due to limitations in testing methodology.
Effective: October 9, 2017.

To determine accurate levels of Testosterone below 12.0 ng/dL, order test 90203 (Testosterone LC/MS [Women, Children])

Interpath Laboratory, Inc.
Test File Update

2126 Vitamin B12 SRC/RRC

Specimen:	
Collect:	**One SST** Also Acceptable One Green Top (Li Heparin) One Green Top (Na Heparin) One Lavender (EDTA) One Pink Top (EDTA) One Red Top
Submit:	**1 mL (Min:0.5 mL) Serum. Submit Refrigerated.** Also Acceptable 1 mL (Min:0.5 mL) Plasma. Submit Refrigerated.
Special Handling:	Fasting Specimen is Preferred Minimize air exposure Protect from Light Separate from cells within 2 hours of collection SST collection stable for 24 hours.
Rejection Criteria:	Grossly Hemolyzed Samples Heat inactivated
Stability:	Ambient: 2 Hour(s); Refrigerated: 2 Day(s); Frozen: 2 Month(s); Incubated: Unacceptable
Methodology:	Electrochemiluminescence Immunoassay (ECLIA)
Performed:	Mon-Fri
Reported:	1-3 Day(s)
CPT Codes:	82607
Interpretive Data:	General Reference Range : 232-1245 pg/ml

Please take note of changes in collection, special handling, rejection criteria, stability, and reference range.
Effective: October 9, 2017.