

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](http://www.interpathlab.com)

**Effective Date: July 24, 2017**

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In an effort to provide better and more comprehensive laboratory services to our clients regarding our autoimmune disease testing menu, we are pleased to announce our transition to a new test system vendor, Inova Diagnostics. Inova Diagnostics specializes in autoimmune technologies and diagnostic markers and will be an ideal partner as we seek to enlarge our autoimmune disease testing footprint.

Due to the complex nature of this transition, we will be transitioning our testing in three phases, the second commencing (July 24<sup>th</sup>, 2017). We appreciate your patience as we make these exciting changes.

Order Code	Test Name	NC	CC	CPT	SRC	RRC	NT	DT	AOE
		Name Change	Component Change	CPT Change	Specimen Requirements Change	Reference Range Change	New Test	Discontinued Test	Ask on Order Entry Questions
1443	Autoimmune Panel			◆		◆			
2331	Centromere Antibody			◆	◆	◆			
2372	ENA Antibody					◆			
2399	Histone Antibody			◆	◆	◆			
2393	JO-1 Antibody				◆	◆			
2369	Scleroderma Antibody				◆	◆			
2371	Sjogren Antibodies				◆	◆			
2366	Smith Antibody				◆	◆			

**1443 Autoimmune Panel**
**CPT/RRC**

<b>Specimen:</b>		
Collect:	<b>One SST</b> Also Acceptable One Red Top	
Submit:	<b>2 mL (Min:1 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>	
Special Handling:	Allow specimen to clot completely at room temperature Avoid Repeated Freeze/Thaw Cycles Separate from cells ASAP If the dsDNA Antibody is Positive, then the dsDNA AB Titer (Test# 2601) will be performed. Additional charges will apply.	
Rejection Criteria:	Grossly Hemolyzed Samples Heat inactivated Lipemic Samples Microbial Contamination Particulate matter	
Stability:	See Individual Components	
<b>Methodology:</b>	See Individual Components	
<b>Performed:</b>	Monday, Wednesday, Thursday	
<b>Reported:</b>	2-3 Day(s) Positive ANA Results will be titered and reported next day. Positive Anti DNA is confirmed with Crithidae.	
<b>CPT Codes:</b>	83516 86140 86235x7 86160x2	86038 86225 86431
<b>Interpretive Data:</b>		
<b>Components:</b>	2312 - ANA TITER 2600 - dsDNA ANTIBODY 2365 - SM/RNP AB 2368 - SJOGRENS B AB 2369 - SCLERODERMA AB 2320 - C-REACTIVE PROT 2357 - COMPLEMENT C4 2399 - HISTONE AB	2301 - ANA PATTERN 2366 - SMITH AB 2367 - SJOGRENS A AB 2331 - CENTROMERE AB 2337 - RHEUMATOID FACTOR 2356 - COMPLEMENT C3 2393 - JO-1 AB

**Please take note of reference range and CPT code changes.**

**Histone Ab Reference Range:**

<1.0 Units Negative  
 1.0-1.5 Units Weak Positive  
 1.6-2.5 Units Moderate Positive  
 >2.5 Units Strong Positive

**Sm/RNP Ab Reference Range:**

<20 Units Negative  
 20-39 Units Weak Positive  
 40-80 Units Moderate Positive  
 >80 Units Strong Positive

A positive Sm/RNP Ab result indicates the presence of antibodies reactive with the Smith (Sm) protein and/or ribonuclear protein (RNP). This Sm/RNP assay cannot distinguish between Anti-Sm and Anti-RNP activity, thus should be considered with the Sm Ab test result to determine clinical significance.

**dsDNA Ab Reference Range:**

<30	IU/mL	Negative
30-75	IU/mL	Equivocal
>75	IU/mL	Positive

**Sjogrens A/B Ab, Smith Ab, Jo-1 Ab, and Scleroderma Ab Reference Ranges:**

<20	Units	Negative
20-39	Units	Weak Positive
40-80	Units	Moderate Positive
>80	Units	Strong Positive

**Centromere Ab Reference Range:**

<20	Units	Negative
20-30	Units	Weak Positive
>30	Units	Moderate to Strong Positive

**ANA Reference Range:**

An ANA TITER of 1:160 or less may be seen in up to 4% of apparently healthy individuals, increasing in incidence with aging. These results should be considered in the context of clinical findings and criteria established by the American College of Rheumatology.

**2331 Centromere Antibody**
**CPT/SRC/RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b>  Also Acceptable One Red Top
Submit:	<b>1 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Allow specimen to clot completely at room temperature Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday, Friday
<b>Reported:</b>	1-3 Day(s)
<b>CPT Codes:</b>	86286235
<b>Interpretive Data:</b>	

***Please take note of reference range, special handling, rejection criteria, stability, methodology, reported days, CPT codes, and LOINC code (see attached compendium) changes.***

**Centromere Ab Reference Range:**

<20 Units      Negative  
 20-30 Units    Weak Positive  
 >30 Units      Moderate to Strong Positive

**2372 ENA Antibody**
**RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b> Also Acceptable One Red Top
Submit:	<b>2 mL (Min:1 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday
<b>Reported:</b>	1-4 Day(s)
<b>CPT Codes:</b>	86235x2
<b>Interpretive Data:</b>	
<b>Components:</b>	2366 - SMITH AB <span style="float: right;">2365 - SM/RNP AB</span>

***Please take note of reference range change.***

**Smith Ab and Sm/RNP Ab Reference Ranges:**

<20 Units	Negative
20-39 Units	Weak Positive
40-80 Units	Moderate Positive
>80 Units	Strong Positive

A positive Sm/RNP Ab result indicates the presence of antibodies reactive with the Smith (Sm) protein and/or ribonuclear protein (RNP). This Sm/RNP assay cannot distinguish between Anti-Sm and Anti-RNP activity, thus should be considered with the Sm Ab test result to determine clinical significance.

**2393 Jo-1 Antibody**
**SRC/RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b> Also Acceptable One Red Top
Submit:	<b>1 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday
<b>Reported:</b>	1-4 Day(s)
<b>CPT Codes:</b>	86235
<b>Interpretive Data:</b>	

***Please take note of reference range, special handling, rejection criteria, stability, performed days, and LOINC code (see attached compendium) changes.***

**Jo-1 Ab Reference Range:**

<20	Units	Negative
20-39	Units	Weak Positive
40-80	Units	Moderate Positive
>80	Units	Strong Positive

**2399 Histone Antibody**
**CPT/SSC/RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b> Also Acceptable One Red Top
Submit:	<b>1 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Allow specimen to clot completely at room temperature Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday
<b>Reported:</b>	1-4 Day(s)
<b>CPT Codes:</b>	83516
<b>Interpretive Data:</b>	

***Please take note of reference range, special handling, rejection criteria, stability, performed days, CPT codes, and LOINC change (see attached compendium) changes.***

**Histone Ab Reference Range:**

<1.0	Units	Negative
1.0-1.5	Units	Weak Positive
1.6-2.5	Units	Moderate Positive
>2.5	Units	Strong Positive



**2369 Scleroderma Antibody**
**SRC/RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b> Also Acceptable One Red Top
Submit:	<b>1 mL (Min:0.5 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday
<b>Reported:</b>	1-4 Day(s)
<b>CPT Codes:</b>	86235
<b>Interpretive Data:</b>	

***Please take note of reference range, special handling, rejection criteria, stability, performed days, and LOINC code (see attached compendium) changes.***

**Scleroderma Ab Reference Range:**

<20 Units	Negative
20-39 Units	Weak Positive
40-80 Units	Moderate Positive
>80 Units	Strong Positive

**2371 Sjogren Antibodies**
**SRC/RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b> Also Acceptable One Red Top
Submit:	<b>2 mL (Min:1 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Allow specimen to clot completely at room temperature Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday
<b>Reported:</b>	1-4 Day(s)
<b>CPT Codes:</b>	86235x2
<b>Interpretive Data:</b>	
<b>Components:</b>	2367 - SJOGRENS A AB <span style="float: right;">2368 - SJOGRENS B AB</span>

***Please take note of reference range, submit requirements, special handling, rejection criteria, stability, performed days, and LOINC code (see attached compendium) changes.***

**Sjogrens A/B Ab Reference Range:**

<20 Units	Negative
20-39 Units	Weak Positive
40-80 Units	Moderate Positive
>80 Units	Strong Positive

**2366 Smith Antibody**
**SRC/RRC**

<b>Specimen:</b>	
Collect:	<b>One SST</b> Also Acceptable One Red Top
Submit:	<b>2 mL (Min:1 mL) Serum. Submit Refrigerated. Submit in a Standard Transport Tube.</b>
Special Handling:	Separate from cells ASAP
Rejection Criteria:	Grossly Hemolyzed Samples Grossly Lipemic Samples Heat inactivated Microbial Contamination Particulate matter
Stability:	Ambient: 8 Hour(s); Refrigerated: 2 Day(s); Frozen: 1 Month(s); Incubated: Unacceptable
<b>Methodology:</b>	Enzyme-Linked ImmunoSorbent Assay (ELISA)
<b>Performed:</b>	Monday, Wednesday, Thursday
<b>Reported:</b>	1-4 Day(s)
<b>CPT Codes:</b>	86235
<b>Interpretive Data:</b>	

***Please take note of reference range, special handling, rejection criteria, stability, performed days, and LOINC code (see attached compendium) changes.***

**Smith Ab Reference Range:**

<20	Units	Negative
20-39	Units	Weak Positive
40-80	Units	Moderate Positive
>80	Units	Strong Positive