

MEMORANDUM

To: All Regional Medical Laboratory Clients

From: Patti Loykasek, HTL, QICH (ASCP), Manager of Immunology

Gerald C. Miller, Ph.D., Chief of Immunology and Microbiology

Date: March 26, 2018

Subject: Autoimmune Testing Changes

Regional Medical Laboratory, Inc. (RML) is pleased to announce implementation of new technology for fully automated, random access chemiluminescent autoimmune testing. This new technology brings workflow efficiencies and improved assay performance compared with existing enzyme-based technology. RML would like to make you aware of a few changes going into effect as a result of this implementation.

RML currently offers testing for several different extractable nuclear antigens, including Sjogren's Syndrome Antigen A (SS-A)/Ro. Antibodies to SS-A/Ro are found in 70 to 90 percent of patients with Sjogren's Syndrome and in about 35 to 50 percent of patients with Systemic Lupus Erythematosus (SLE). Two types of SS-A/Ro antibodies have been described: anti-SS-A 52 kDa (Ro52) and anti-SS-A 60 kDa (Ro60). Recent studies have shown Ro52 and Ro60 antibodies have different clinical associations. Ro52 antibodies are found more frequently in Sjogren's Syndrome than rheumatoid arthritis or SLE, whereas the Ro60 antibodies are more prevalent in Sjogren's Syndrome associated with SLE. A positive Ro60 antibody result is one of the three criteria as specified in the American College of Rheumatology Classification Criteria for Sjogren's Syndrome. Effective 3/26/18, RML will offer new, distinct tests for these antibodies to allow for each antibody to be ordered separately as well as part of a group.

Order Test Code	Test Name	LOINC	Result Code	Chart Name	Reference Range UOM
5599890	Sjogren's SSA Ro52 Antibody				
CPT 86235		56549-9	5599891	SSA Ro52	<20.0 CU
TAT = 2-4 days		n/a	5599892	SSA Ro52 Interp	Negative
Order Test Code	Test Name	LOINC	Result Code	Chart Name	Reference Range UOM
5599893	Sjogren's SSA Ro60 Antibody				
CPT 86235		63411-3	5599894	SSA Ro60	<20.0 CU
TAT = 2-4 days		n/a	5599895	SSA Ro60 Interp	Negative
Order Test Code	Test Name	LOINC	Result Code	Chart Name	Reference Range UOM
5599902	Sjogren's SSA Ro52/Ro60 Antibodies				
CPT 86235x2		56549-9	5599891	SSA Ro52	<20.0 CU
TAT = 2-4 days		n/a	5599892	SSA Ro52 Interp	Negative
		63411-3	5599894	SSA Ro60	<20.0 CU
		n/a	5599895	SSA Ro60 Interp	Negative

	Preferred: Collect a serum separator tube, spin, aliquot 1 mL of serum into a transport tube and freeze.			
Specimen	Alternate: Collect a serum separator tube, spin and refrigerate. Specimen must be received in the lab within			
	48 hours of collection.			
Stability	After separation from cells: Ambient: 8 hours; Refrigerated: 48 hours; Frozen: 30 days			

In addition to this change to SS-A testing, RML will also be changing the normal range for DNA Double Stranded Antibody (Test number 5572000). The new normal range for this test is <27 IU/mL.

Please visit the downloads section of RMLOnline.com to view the Livewire distributed on 2/26/2018 for more information regarding these test build changes including a complete list of impacted tests.

Please direct questions or concerns to Patti Loykasek, Manager of Immunology, or Gerald C. Miller, Ph.D., Chief of Immunology and Microbiology, at 918-744-2553.