RDL Reference Laboratory
10755 Venice Boulevard
Los Angeles, CA 90034
tel: 310.253.5455
800.338.1918
fax: 310.253.5466
www.rdlinc.com

January 1, 2017

Client Letter Test Update—January 2017

Dear Colleague:

Happy New Year and welcome to the new format of our monthly RDL client letter!

Each month we will share with you test updates, new test introductions and information we believe to be helpful to your everyday practice.

This month, in addition to CPT coding changes to our Myositis and Scleroderma testing, and a new test for the differential diagnosis of Dermatomyositis (DM), we are proud to introduce two new assays for a more comprehensive evaluation of Rheumatoid Arthritis (RA).

DM Antibody

The new SAE-1 Antibody exclusive to RDL, is highly specific (>95%) for DM and is available individually or as part of our expanded new MyoMarker™ Panel 3 PLUS (test code [1223].

RA Antibodies

The new CEP and Sa autoantibodies (test codes [178] and [177], respectively) can identify an additional 10% of seronegative RA patients (RF-IgM-negative, anti-CCP-negative). Combined with 14-3-3η protein, our new exclusive RAdx5™ panel (test code [1224]: 14-3-3η, anti-CEP, anti-Sa, RF-IgM, anti-CCP) not only can enhance the diagnosis of RA in early or established RA, but can also help predict disease severity. These two new autoantibodies are available exclusively from RDL.

We hope you find this monthly newsletter informative and helpful.
Please feel free to contact us with any questions or comments at 800-338-1918 or info@rdlinc.com.

Best Regards,

Dmitry Karayev, M.D., F.A.C.R.
Medical Director

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TEST CHANGES

Effective March 1, 2017, **several CPT codes** will be changing for components of both the **Myositis panel and Scleroderma Panel at RDL.**

Panel Test Code	Panel Name
1222	**MyoMarker™ Panel 3**
1223	**MyoMarker™ Panel 3 Plus**
1686	**Scleroderma Panel, Comprehensive**

Test Code: 1222 MyoMarker™ Panel 3
Test Code: 1223 MyoMarker™ Panel 3 Plus

Test Component	Method	Current CPT Code	New CPT Code (Effective 3/1/17)	1222 MyoMarker™ Panel 3	1223 MyoMarker™ Panel 3 Plus
Anti-Jo-1 Ab	EIA	86235	No Change	√	√
PL-7	RIPA	83516	No Change	√	√
PL-12	RIPA	83516	No Change	√	√
EJ	RIPA	83516	No Change	√	√
OJ	RIPA	83516	No Change	√	√
Anti-SS-A 52 kD Ab, IgG	EIA	86235	No Change	√	√
Anti-PM/Scl Ab	EIA	86235	No Change	√	√
Anti-U1 RNP Ab	EIA	86235	No Change	√	√
U2 snRNP	RIPA	83516	No Change	√	√
Anti-Fibrillarin (U3 RNP)	RIPA	83516	No Change	√	√
Mi-2	RIPA	83516	No Change	√	√
SRP	RIPA	83516	No Change	√	√
Ku	RIPA	83516	No Change	√	√
MDA-5(P140) (CADM)	EIA	83520	86235	√	√
NXP-2 (P140)	EIA	83520	86235	√	√
TIF1 GAMMA (P155/140)	EIA	83520	86235	√	√
Anti-SAE 1 IgG	EIA	83520	86235		√

NOTE: CPT codes for MyoMarker™ Panel 1 [1377] and MyoMarker™ Panel 2 [245] will not be affected by changes.

Test Code: 1686 Scleroderma Panel, Comprehensive

Test Component	Method	Current CPT Code	New CPT Code (Effective 3/1/17)	1686 Scleroderma Panel, Comprehensive
Anti-Nuclear Ab	IFA	86038 /86039	No Change	√
Anti-Scl-70 (Anti-Topoisomerase I)	EIA	86235	No Change	√
Anti-Centromere	IFA	86256	No Change	√
Anti-RNA Polymerase III	EIA	83520	86235	√
Anti-Th/To	RIPA	83516	No Change	√
Anti-U1 RNP	EIA	86235	No Change	√
Anti-Fibrillarian (U3 RNP)	RIPA	83516	No Change	√
Anti-PM/Scl Ab	EIA	86235	No Change	√

NEW TESTS

The following tests are available effective **January 1, 2017**

Order Code	Name	Type
176	**Anti-SAE 1 IgG**	**Individual Test**
1223	**MyoMarker™ Panel 3 Plus**	**Panel**
178	**Anti-CEP-1 IgG**	**Individual Test**
177	**Anti-Sa IgG**	**Individual Test**
1224	**RAdx5™**	**Panel**

Available Exclusively at RDL!

[176] Anti-SAE 1 IgG (EIA)

Clinical Utility	Anti-SAE 1 IgG autoantibody can be used to assist in the diagnoses and characterization of a subset of dermatomyositis (DM) eients. It is highly specific for DM (>95%) and is present in 5-8% of the European DM population. Initial disease onset may consist of mild myopathic features with severe skin involvement; however, extensive myalgia and muscle disease with weakness can appear as the disease progresses. It is associated with dysphagia and systemic symptoms (i.e. fevers, weight loss, increased inflammatory markers). In one cohort, an association with ILD and cancer had been found. ***References available upon request.***
Specimen Requirements	1mL Serum or Plasma (EDTA, Heparin, Citrate); Ambient, Refrigerated or Frozen
Methodology	EIA

Setup/TAT	10 days
CPT Code	83520
Reference Range:	< 20 Units
Result Notes:	EIA Interpretation: <20 Units . . . . . Negative 20 - 39 Units. . . . . Weak Positive 40 - 80 Units. . . . . Moderate Positive >80 Units. . . . . Strong Positive This assay was developed and its performance characteristics validated by RDL. There is no FDA approved assay for the above test. As a lab developed test (LDT), approval or clearance by the FDA is not required. This test may be used for clinical purposes and should not be regarded as investigational or for research.

Available Exclusively at RDL!

[1223] MyoMarker™ Panel 3 PLUS (includes Anti-SAE 1 IgG)

Clinical Utility	The MyoMarker™ Panel 3 Plus can be used to assist in the diagnosis of dermatomyositis, polymyositis and the anti-synthetase syndrome. Furthermore, it allows characterization of various subsets of these disorders and offers prognostic information. ***References available upon request.***
Specimen Requirements	3.0 ml Serum or Plasma (EDTA, Heparin, Citrate): Ambient, Refrigerated or Frozen.
Methodology	RIPA,EIA
Setup/TAT	10-14 Days
CPT Code	83516 x 9, 86235 x 4, 83520 x 4
Reference Range:	

Test	Method	Reference Range
Anti-Jo-1 Ab	EIA	<20 Units
PL-7	RIPA	Negative
PL-12	RIPA	Negative
EJ	RIPA	Negative
OJ	RIPA	Negative
Anti-SS-A 52 kD Ab, IgG	EIA	<20 Units
Anti-PM/Scl Ab	EIA	<20 Units
Anti-U1 RNP Ab	EIA	<20 Units
U2 snRNP	RIPA	Negative
Fibrillarin (U3 RNP)	RIPA	Negative
Mi-2	RIPA	Negative
SRP	RIPA	Negative
Ku	RIPA	Negative
MDA-5(P140)(CADM-140)	EIA	<20 Units

		NXP-2 (P140)	EIA	<20 Units	
		TIF1 GAMMA (P155/140)	EIA	<20 Units	
		Anti-SAE 1 IgG	EIA	<20 Units	
Result Notes:	MyoMarker™ Panel 3 Plus, EIA Interpretation: <20 Units . . . . . Negative 20 - 39 Units. . . . . Weak Positive 40 - 80 Units. . . . . Moderate Positive >80 Units. . . . . Strong Positive This panel was developed and its performance characteristics validated by RDL. There is no FDA approved assay for the above tests. As a lab developed test (LDT), approval or clearance by the FDA is not required. This test may be used for clinical purposes and should not be regarded as investigational or for research.				

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[178] Anti-CEP-1 IgG (EIA)

Clinical Utility	Antibodies to Citrullinated α-Enolase Peptide 1 (CEP-1) predict onset of symptoms in preclinical rheumatoid arthritis (RA), confirm the diagnosis of RA, and provide insight into the potential pathogenic triggers of RA. ***References available upon request.***
Specimen Requirements	1mL Serum or Plasma (EDTA); Ambient, Refrigerated or Frozen
Methodology	EIA
Setup/TAT	3-4 days
CPT Code	83520
Reference Range:	< 20 Units
Result Notes:	Anti-CEP-1 IgG, EIA Interpretation: <20 Units . . . . . Negative 20 - 39 Units. . . . . Weak Positive 40 - 80 Units. . . . . Moderate Positive >80 Units. . . . . Strong Positive This test was developed and its performance characteristics validated by RDL. There is no FDA approved assay for the above tests. As a lab developed test (LDT), approval or clearance by the FDA is not required. This test may be used for clinical purposes and should not be regarded as investigational or for research.

[177] Anti-Sa IgG (EIA)

Clinical Utility	Anti-Citrullinated Vimentin (Sa) antibodies are highly specific for rheumatoid arthritis (RA). They are found in early polyarthritis, can identify patients who are anti-CCP and RF-Igm antibody negative, and predict a more aggressive RA disease course. Disappearance of anti-Sa antibodies 3 months after initiation of aggressive treatment is associated with less radiographic progression. ***References available upon request.***
Specimen Requirements	1mL Serum or Plasma (EDTA); Ambient, Refrigerated or Frozen
Methodology	EIA
Setup/TAT	3-4 days
CPT Code	83520
Reference Range:	< 20 Units
Result Notes:	Anti-Sa IgG, EIA Interpretation: <20 Units . . . . . Negative 20 - 39 Units. . . . . Weak Positive 40 - 80 Units. . . . . Moderate Positive >80 Units. . . . . Strong Positive This test was developed and its performance characteristics validated by RDL. There is no FDA approved assay for the above tests. As a lab developed test (LDT), approval or clearance by the FDA is not required. This test may be used for clinical purposes and should not be regarded as investigational or for research.

Available Exclusively at RDL!

[1224] RAdx5™

Clinical Utility	The RAdx5™ is a novel comprehensive diagnostic and prognostic panel for rheumatoid arthritis available exclusively at RDL. It combines 3 novel markers (14-3-3η, anti-CEP-1 and anti-Sa) with 2 traditional markers (anti-CCP and RF-IgM) to not only enhance the diagnosis of RA in early or established disease, but also to help predict disease severity. If 14-3-3η and/or anti-Sa positivity is present, the disappearance or decrease of these antibodies with treatment is associated with less radiographic progression. In pre-clinical RA, positivity of anti-CEP-1 along with anti-CCP antibodies significantly raises the risk of imminently developing clinical RA. ***References available upon request.***
Specimen Requirements	3mL (1 mL min) Serum or Plasma; Ambient, Refrigerated or Frozen
Methodology	EIA, TURB
Setup/TAT	3-4 days
CPT Code	83520 x3; 86200, 86431

Reference Range:

Test	Method	Reference Range
14-3-3η Protein (EIA)	EIA	<0.2 ng/mL
Anti-CEP 1 IgG (EIA)	EIA	<20 Units
Anti-Sa IgG (EIA)	EIA	<20 Units
Rheumatoid Factor IgM	TURB	<=6 IU
Anti-CCP Ab (EIA)	EIA	<20 Units

Result Notes:

RAdx5™, EIA Interpretation:
<20 Units . . . . . Negative
20 - 39 Units. . . . . Weak Positive
40 - 80 Units. . . . . Moderate Positive
>80 Units. . . . . Strong Positive

This panel was developed and its performance characteristics validated by RDL. There is no FDA approved assay for the above tests. As a lab developed test (LDT), approval or clearance by the FDA is not required. This test may be used for clinical purposes and should not be regarded as investigational or for research.

DID YOU KNOW ? ? ?

In October of 2016, ACR/EULAR published a new Sjogren's syndrome classification criteria.

The Table below summarizes the new criteria:

American College of Rheumatology/European League Against Rheumatism classification criteria for primary Sjogren's syndrome: The classification of primary Sjogren's syndrome (SS) applies to any individual who meets the inclusion criteria,does not have any of the conditions listed as exclusion criteria, and has a score of ≥4 when the weights from the 5 criteria items below are summed.

Item	Weight/Score
Labial salivary gland with focal lymphocytic sialadenitis and focus score of ≥1 foci/4 mm	3
Anti-SSA/Ro positive	3
Ocular Staining Score ≥5 (or van Bijsterveld score ≥4) in at least one eye	1
Schirmer's test ≤5 mm/5 minutes in at least one eye	1
Unstimulated whole saliva flow rate ≤0.1 ml/minute	1

For more information please refer to:

Shiboski, C. H., Shiboski, S. C., Seror, R., Criswell, L. A., Labetoulle, M., Lietman, T. M., Mariette, X. (2016). 2016 American College of Rheumatology/European League Against Rheumatism Classification Criteria for Primary Sjögren's Syndrome: A Consensus and Data-Driven Methodology Involving Three International Patient Cohorts. Arthritis & Rheumatology, 69(1), 35-45. doi:10.1002/art.39859