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

March 20, 2017

Client Letter Test Update—March 2017

Dear Colleague:

This month we are introducing a Laboratory Developed Test (LDT) alternative to the recently discontinued Scl-70 Immunodiffusion assay by INOVA. We have developed this quality LDT to ensure continuous reflex testing for positive Scl-70 EIA results. This change will be effective April 1, 2017.

We are also highlighting our T-SPOT.TB assay for *Mycobacterium tuberculosis* screening for your patients who are either initiating or undergoing treatment with immunomodulating therapies, or are at risk for latent or active TB. Recent data presented at EULAR 2016 indicate that the T-SPOT.TB assay has significantly fewer indeterminates, false-positives and false-negatives than the QuantiFERON-TB Gold assay ***(EULAR 2016 Abstract #53562 Kmeid J., et al. The utility of interferon-gamma release assays (IGRAs) for the diagnosis of Mycobacterium tuberculosis (Mtb) in cancer patients)***.

We hope you find this monthly letter 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

DISCONTINUED TESTS

The following TEST will be DISCONTINUED effective APRIL 1, 2016:

Old Code	**127**
Test Name	**Anti-Scl-70 Ab (ID)**
Effective Date	**04/01/2017**
Note:	**Panels that contain test code 127 as a component or as a reflex will be replaced with test code 2003, Anti-Scl-70 Ab (ID). See below for panels affected by changes.**
RECOMMENDED ALTERNATIVE	
Test Code	**2003**
Test Name	**Anti-Scl-70 Ab (ID)**
Effective Date	**04/01/2017**

PANELS AFFECTED BY TEST CODE # 127 CHANGES EFFECTIVE 04/01/2017:

Panel Code	Panel Name	Change
475	Interstitial Lung Disease Panel I	Test Reflex for any POS [577] Anti-Scl-70 Ab (EIA)
577	Anti-Scl-70 Ab (EIA)	
1022	ANA Profile II, Do All	
1020	ANA Profile II	
1201	ANA 12 Profile	
1206	ANA 12 Profile, Do All	
1228	ANA 12 Plus Profile	
1230	ANA 12 Plus Profile, Do All	
1686	Scleroderma Panel, Comprehensive	

The following PANELS will be DISCONTINUED effective APRIL 1, 2016:

Panel Code	Panel Name
626	CD4 Lymphocyte, Helper/Inducer Count
628	Helper/Suppressor Panel-Lymphocyte Immunophenotyping
629	T, B & NK Cell Panel-Lymphocyte Immunophenotyping
633	Natural Killer Cell 56/16-Lymphoctye Immunophenotyping
634	T & B Cell Panel-Lymphocyte Immunophenotyping
RECOMMENDED ALTERNATIVE	
Samples that will be received after April 1, 2017 will be referred to our SEND OUT Laboratory.	

TEST CHANGES

The following changes will be effective April 1, 2017

Order Code	Name	Type
2003	**Anti-Scl-70 Ab (ID)**	**Individual Test**

Available Exclusively at RDL!

[2003] Anti-Scl-70 Ab (ID)

Clinical Utility	Anti-Scl-70 antibodies are a specific marker for Systemic Sclerosis (SSc). They are associated with digital ulcers, pulmonary fibrosis, renal crisis and cardiac disease. These antibodies have classically been determined by double immunodiffusion (ID) techniques. However, ID is time consuming, requires multiple days and is difficult to automate. To circumvent this problem, techniques such as ELISA have been utilized for screening. However, when determined by ID, anti-Scl-70 antibodies are virtually never seen in healthy controls, non-affected relatives of patient with SSc, nor in patients with other connective tissue diseases or primary Raynaud's. Literature on non-ID techniques show a lower clinical specificity, especially in rheumatic disease controls. Differences in epitope recognition and/or antibody avidity and affinity in solid-phase and liquid-phase assays may explain this discrepancy or that the false positive results may be due to contamination of antigens or binding of anti-DNA/DNA complexes to topo-I. Due to its high specificity, RDL reflexes all EIA positive anti-Scl-70 antibodies to the double immunodiffusion technique (ID) to provide our clients the highest clinical specificity. ***References available upon request.***
Specimen Requirements	1 mL Serum; Ambient, Refrigerated or Frozen
Methodology	Immuno-double Diffusion (ID)
Setup/TAT	2 – 4 days
CPT Code	86331
Reference Range:	Negative, Positive
Result Notes:	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.

FEATURED TESTS OF THE MONTH

RDL's T-SPOT.TB for screening of latent or active *Mycobacterium tuberculosis* (Mtb) infection

RDL is proud to offer the T-SPOT.TB assay for the rapid and accurate screening for latent or active Mtb infection. This assay has superior test performance characteristics over the QuantiFERON-TB Gold assay and requires fewer collection tubes.

In a recent presentation at EULAR 2016*, a side-by-side comparison between the T-SPOT and QuantiFERON-TB Gold performed at MD Anderson Cancer Center demonstrated that the T-SPOT had a 2% indeterminate rate compared to 40% with the QuantiFERON-TB Gold. Furthermore, 2 out of 157 patients who tested negative on QuantiFERON-TB Gold developed active TB; there were also 3 active TB cases out of 118 patients that tested indeterminate on QuantiFERON-TB Gold. When compared to T-SPOT, none of the 420 patients who tested negative on T-SPOT developed TB. The T-SPOT cohort had only 9 borderline results and none of those cases developed TB.

Advantages of the T-SPOT.TB assay:

- Higher sensitivity and similar specificity than QuantiFERON-TB Gold with fewer indeterminates*
- Fewer collection tubes than QuantiFERON-TB Gold.
- Rapid, reliable blood screening for latent or active Mtb infections
- Performed by ELISPOT (interferon-gamma release assay[IGRA])
- Prompt Turnaround time of 3 days

**EULAR 2016 Abstract #53562 Kmeid J., et al. The utility of interferon-gamma release assays (IGRAs) for the diagnosis of Mycobacterium tuberculosis (Mtb) in cancer patients.*

Test Code:	**288**
Test Name:	**T-SPOT TB Test**
Clinical Utility:	Substantiation for latent Tuberculosis testing is based on multiple studies showing higher incidence of TB following anti-TNFα therapy and other immunomodulating therapies. Testing for latent TB is done via the T-Spot TB assay, which is an FDA approved Interferon Gamma Release Assay (IGRA). When compared to the QuantiFERON-TB Gold, multiple studies show a more favorable sensitivity, similar specificity and less indeterminate results.
Specimen Requirements	2 Lithium Heparin (green top), 6 mL each at room temperature **Must be at RDL within 32 hours.** ***Patients can only be drawn Monday–Thursday for clients outside of Los Angeles due to short stability.*** *1) Draw two lithium heparin [green top] tubes [6 mL each].* *2) Invert gently ten times to mix. Do not centrifuge.* *3)Date and time of draw must be written on both tubes in addition to the required unique identifiers.*

	4) Samples must be shipped the same day to avoid cancellation. *5) Keep the specimen ambient, at room temperature until the RDL courier or FEDEX courier picks it up. NEVER REFRIGERATE OR FREEZE.*
Methodology	ELISPOT (IGRA)
Setup/TAT	3 Days
CPT Code:	86481
Reference Range:	
Result Notes:	*Testing for latent TB is done via the T-Spot assay, which is an FDA approved Interferon Gamma Release Assay (IGRA). When compared to QuantiFERON TB Gold, multiple studies show a more favorable sensitivity, similar specificity, and less borderline results with the T-Spot TB Test.*

Test Name	Reference Range
T-Spot TB Test	Negative
Negative Control Spot Count	<5
Panel A Spot Count	<5
Panel B Spot Count	<5
Positive Control Spot Count	>20

DID YOU KNOW ? ? ?

Patients with Dermatomyositis (DM) who have anti-NXP2 antibodies have a distinct and often severe systemic phenotype. A recent publication from Stanford University (2017) found an association between anti-NXP2 antibodies and adult DM, male gender, dysphagia, myalgia, peripheral edema, calcinosis and were less likely to be clinically amyopathic. 25% of anti-NXP2 positive DM patients had an associated internal malignancy. ***References available upon request.***

Test Code:	**174**
Test Name:	**NXP-2 (P140)**
Clinical Utility:	Anti-NXP-2 antibodies are present in 2-30% of adult DM and 18-25% of JDM. In JDM they are only associated with cutaneous calcinosis cutis. In adult DM, they are significantly associated with the presence of cancer (cancer was found in 13.6% of Anti-NXP-2 positive DM patients).
Specimen Requirements	1 mL serum, ambient, refrigerated or frozen
Methodology	EIA
Setup/TAT	7 Days
CPT Code:	83520
Reference Range:	< 20 Units
Result Notes:	NXP-2 (P140) EIA Interpretation: <20 Units . . . . . Negative 20 - 39 Units. . . . . Weak Positive 40 - 80 Units. . . . . Moderate Positive >80 Units. . . . . Strong Positive

	Anti-NXP-2 antibodies are present in 2-30% of adult DM and 18-25% of JDM. In JDM they are only associated with cutaneous calcinosis cutis. In adult DM, they are significantly associated with the presence of cancer (cancer was found in 13.6% of Anti-NXP-2 positive DM patients). This test was developed and its performance characteristics validated by RDL. There is no FDA approved assay for the above test's 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.