Health PEI

Laboratory Medicine
PO Box 6600
Charlottetown
Prince Edward Island
Canada C1A 8T5

Santé Î.-P.-É.

Médecine de Laboratoire
C.P. 6600
Charlottetown
Île-du-Prince-Édouard
Canada C1A 8T5

M E M O R A N D U M

To: ALL PHYSICIANS and LABS

From: Dr. Marvin Tesch

Date: August 6, 2013

Re: **ANA AND VASCULITIS TESTING**

Effective August 8 2013, 2013, we will be moving ANA (anti-nuclear antigen) and ENA (extractable nuclear antigen) testing to the Immunocap 250 (Phadia reagents). Vasculitis testing will undergo a similar move late September 2013.

ANA will now be done as a screen first which will test for: SS-A, SS-B, Sm, RNP, Scl-70, Jo-1, dsDNA, Centromere B and the lesser ANA'S: Fibrillian, RNA Polymerase, Ribosommal P, PM-Scl, PCNA and MI-2. The screen will be reported as Negative, Equivocal or Positive. If Positive or Equivocal we will do reflex testing for the eight ENA's which will be reported with a numerical value. The interpretation of these ENA's remains the same and will be accompanied by an appropriate comment. These tests are an aid in the diagnosis of various systemic autoimmune disorders such as System Lupus Erythematosus (SLE), Scleroderma and its variant CREST (characterized by Calcinosis, Raynauds, Esophageal dysmotility, Sclerodactyly and Telangiectasia), polymyositis and dermatopolymyositis, Mixed Connective Tissue Disease (MCTD), and Sjogren's syndrome. If the ENA's are all negative one of the lesser ANA's maybe positive these still can indicate a connective disease or hepatitis

The ENA panel cannot be ordered on its own but you can now order dsDNA by itself if you suspect SLE or are monitoring disease activity (the test is highly specific for SLE and values correlate with disease activity)

Test Name:	ANA or dsDNA
Sample:	Sera (red-stoppered tube, can be kept at room temperature for 8 hours. If it cannot be delivered to the lab within 8 hours please refrigerate.
Turnaround:	Testing will be run weekly on Thursdays
Results:	The ANA screen will be reported as Negative, Equivocal or Positive. Positive or equivocal results will have reflex ENA testing done. These ENA's will reported as a numerical value (units = IU/ml)

ENA	Negative	Equivocal	Positive	Disease Association
SSA (Anti-Ro)	<7	7 to 10	>10	Sjogrens (75% of cases) and SLE (40%)
SSB (Anti-La)	<7	7 to 10	>10	Sjogrens (90%) and SLE (10%)
Sm	<5	5 to 10	>10	SLE (25%) *Can indicate more severe disease*
RNP	<5	5 to 10	>10	MCTD (95%) and SLE (35%)
Scl 70	<7	7 to 10	>10	Scleroderma (35%)
Jo 1	<7	7 to 10	>10	Polymyositis and Dermatomyositis (30%)
dsDNA	<10	10 to 15	>15	SLE (90%) *Especially with renal involvement*
Cent B	<7	7 to 10	>10	CREST (80%) and Scleroderma (70%)

Correlation studies have shown this new assay to be far more specific than the old assay which should limit the false positives that have plagued us. However, false positives can still be seen especially with increasing age, viral infections and some medications. These tests are **not** diagnostic but merely a predictive aid and must be viewed along with clinical context.

Along with ANA we will switch vasculitis testing: MPO (myleoperoxidase), PR3 (Proteinases 3) and GBM (Anti-glomerular basement antibody). MPO and PR3 will still be ordered as a vasculitis panel; however, GBM must be ordered by itself if you suspect Goodpastures. These tests are an aid in the diagnosis of various systemic vasculitides such as: Wegener's granulomatosis, Polyarteritis, Churg Strauss syndrome, Goodpastures and Idiopathic cresenteric glomerulonephritis. The results will be reported numerically (units = IU/ml)

Test Name: Vasculitis Panel (MPO & PR3) or GBM
Turnaround: Testing will be run weekly on Thursdays
Sample: Sera (red-stoppered tube), can be kept at room temperature for 8 hours.
If it cannot be delivered to the lab within 8 hours, please refrigerate.

Test	Negative	Equivocal	Positive	Disease Association
MPO (c-ANCA)	<3.5	3.5 to 5.0	>5.0	Polyarteritis (50%) or Churg Strauss (60%)
PR3 (p-ANCA)	<2.0	2.0 to 3.0	>3.0	Wegener's granulomatosis (75%)
GBM	<7.0	7.o to 10	>10	Goodpastures

Like ANA these tests should be more specific than the previous assay. However, these tests are **not** diagnostic as false positives can occur with other autoimmune diseases or infections and, as such, must be viewed as a predictive aid along with clinical context.

pc. Bill Bylhouwer
Jamie MacDonald