Autoantibodies to Extractable Nuclear Antigens

New Test ENA Panel: Test Code : ENAPNL includes RNP Antibody, SS-A Antibody, SS-B Antibody, Sm Antibody

New Test: SS-A/SS-B Panel: Test Code: SSABPL INCLUDES SmSS-A Antibody, SS-B Antibody,

On January 15, 2015, the Immunology Laboratory will begin to offer the INOVA Diagnostics (San Diego, CA) QUANTA Lite SS-A, SS-B, Sm, and RNP assays. These assays will be offered individually, the SS-A and SS-B will be offered as a panel and all four will be offered as part of an Extractable Nuclear Antibody Panel.

While the ANA test is an excellent screening test for SLE (a negative result virtually rules out SLE) it is by no means specific.

Autoantibodies to SS-A antigen are found in 40-60% of patients with Sjogren’s Syndrome and in 25-35% of patients with ANA positive Systemic Lupus Erythematosis (SLE). Autoantibodies to SS-B antigen are found in 5-15% of SLE patients and 25% of random Sjogren’s Syndrome patients. SS-B antibodies are found in approximately 60% of Sjogren’s patients with sicca complex. As with SS-A, these antibodies are often found in patients with clinical features of SLE, but are ANA negative. SS-B antibodies are usually found to occur simultaneously with SS-A, while SS-A can occur alone. Patients producing both SS-B and SS-A as opposed to SS-A alone generally have a milder disease with lower incidence of nephritis and antibodies to dsDNA.

Sm antibodies are highly specific for SLE and, as with antibodies to dsDNA, are considered a marker antibody. Sm antibodies have been included in the Arthritis and Rheumatism subcommittee criteria (REF?) for the classification of SLE and antibody titers were found to be a reliable measure of disease activity. Antibodies to RNP are found in up to 45% of patients with SLE and also in some other connective tissue diseases. RNP antibodies are associated with a relatively benign disease course with lower incidence of renal and CNS disease. RNP antigen contains epitopes or antibody sites that are unique to RNP but it also contains epitopes that are immunologically identical to free Sm. Since the RNP antigen coated onto the solid phase of this test has Sm antigenic epitopes, the

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patient Sm antibody response must be considered when interpreting the RNP results. A positive RNP result indicates the presence of antibodies reactive with the RNP/Sm complex but cannot distinguish between anti-Sm and anti-RNP activity. When the Sm antibody is measured in conjunction with the RNP antibody activity, the RNP antibody activity can be inferred. If a sample is negative in the Sm ELISA, but positive in the RNP ELISA, then the reactivity is largely or exclusively due to RNP antibodies. If the reactivity in the Sm ELISA is equivalent to the reactivity of the RNP, then the activity indicates the sample is a mixture of Sm and RNP antibodies. The RNP activity can be estimated by subtracting the Sm activity over the cut-off (i.e. over 20 Units) from the total RNP ELISA value.

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>&lt;20</td>
</tr>
<tr>
<td>Weak Positive</td>
<td>20-39</td>
</tr>
<tr>
<td>Moderate Positive</td>
<td>40-80</td>
</tr>
<tr>
<td>Strong Positive</td>
<td>&gt;80</td>
</tr>
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</table>

Reference values for SS-A, SS-B, Sm, and RNP will change from those used by Mayo Medical Laboratories and are listed in the table below.

<table>
<thead>
<tr>
<th>Test Name</th>
<th>SQ Code</th>
<th>CPT</th>
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<tbody>
<tr>
<td>RNP Antibody</td>
<td>RNPA</td>
<td>86235</td>
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<tr>
<td>SS-A Antibody</td>
<td>SSAA</td>
<td>86235</td>
</tr>
<tr>
<td>SS-B Antibody</td>
<td>SSBA</td>
<td>86235</td>
</tr>
<tr>
<td>Sm Antibody</td>
<td>SMAA</td>
<td>86235</td>
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Lab Division: Immunology
Method: ELISA
Sample Requirements: Collect 4 mL SST, process sample and send 0.5 mL serum frozen, minimum volume is 0.4 mL. SST must be spun within 8 hours, refrigerated serum must be received within 48 hours, for longer storage freeze.
Days Performed: Tuesday and Thursday
Analytical Time: Same day
Instrument: Inova Quantalyzer
NY Certified: Yes