PHYSICIAN UPDATE

Expanded Testing for Antinuclear Antibodies Now Available

BioPlex 2200 Multiplex Immunoassay Platform Expands Options

BENEFITS

- Detects the most common clinically relevant autoantibodies associated with connective tissue disease
- Provides greater specificity compared to IFA
- Determines ANA antigenic specificities of specimens found positive using initial IFA ANA screening
- Increased ANA test menu, both individual autoantibodies and ANA panels
- Decreased turn-around time

SUMMARY

Beginning May 4, PeaceHealth Laboratories has expanded the BioPlex 2200 multiplex immunoassay test platform to our diagnostic services to provide a broader offering of in-house panels to our antinuclear antibodies (ANA) test menu. Additional options for individual autoantibodies and ANA panels will also be available.

ABOUT THE ASSAY

ANA testing performed on the BioPlex 2200 will provide more specific results than those seen in ANA by IFA. A negative ANA result by BioPlex 2200 rules out reactivity to the most commonly occurring specific autoantibodies and eliminates most of the false positive results that occur by IFA.

We first introduced this technology in January, 2010, when we began using the BioPlex 2200 for ANA screen, SSA, SSB, Sm, RNP and dsDNA testing. We will now add the following autoantibodies: Chromatin, Ribosomal P, Centromere B, SmRNP, Scl-70 and Jo-1. With this expanded offering, we will make available additional ANA panels and still continue to offer immunofluorescence (IFA) ANA screening.

The sensitivity/specificity for an ANA screen using the BioPlex 2200 and IFA were determined to be 80%/98% and 90%/66% respectively.

AUTOANTIBODY DISEASE ASSOCIATIONS

In 1975, specific autoantibodies occurring in connective tissue disorders were first characterized. Patients with Systemic lupus erythematosus (SLE), Sjögren’s syndrome, polymyositis, mixed connective tissue disease (MCTD) and rheumatoid arthritis were tested against specific antigens. These included double-stranded DNA, chromatin (soluble nucleoprotein), Smith (Sm) and ribonucleoprotein (RNP). Subsequently, other associations have emerged including: SS-A and SS-B with Sjögren’s syndrome, Jo-1 with polymyositis, and Scl-70 and centromere with systemic sclerosis.

continued on next page
Expanded Testing for ANA (continued)

The following table summarizes the individual test components now available using the BioPlex 2200 and also includes the antigen composition, associated disease(s) and related ANA IFA pattern.

Table 1 – Antinuclear Antibody Testing by Multiplex Flow Immunoassay

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Antigen Composition</th>
<th>Associated Disease(s)</th>
<th>ANA IFA Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>dsDNA</td>
<td>dsDNA synthesized by PCR</td>
<td>Systemic lupus erythematosus (SLE)</td>
<td>Homogeneous</td>
</tr>
<tr>
<td>SS-A (Ro)</td>
<td>Affinity purified antigen SS-A 60 and SS-A 52 recombinant antigen</td>
<td>Sjogren’s syndrome, SLE and other connective tissue diseases</td>
<td>Speckled</td>
</tr>
<tr>
<td>SS-B (La)</td>
<td>Affinity purified SS-B antigen</td>
<td>Sjogren’s syndrome, SLE and other connective tissue diseases</td>
<td>Speckled</td>
</tr>
<tr>
<td>Sm</td>
<td>Affinity purified Sm antigens</td>
<td>SLE</td>
<td>Speckled</td>
</tr>
<tr>
<td>RNP</td>
<td>Recombinant antigen RNP-68, recombinant antigen RNP-A</td>
<td>SLE, Mixed connective tissue disease (MCTD), Raynaud’s phenomenon, other connective tissue diseases</td>
<td>Speckled</td>
</tr>
<tr>
<td>SmRNP (new)</td>
<td>Sm/RNP purified antigen</td>
<td>SLE, MCTD, other connective tissue disease</td>
<td>Speckled</td>
</tr>
<tr>
<td>Chromatin (new)</td>
<td>Purified nucleohistone antigens</td>
<td>SLE, MCTD, other connective tissue disease</td>
<td>Homogeneous</td>
</tr>
<tr>
<td>Ribosomal P (new)</td>
<td>Ribosomal P affinity purified antigens</td>
<td>SLE</td>
<td>Cytoplasmic</td>
</tr>
<tr>
<td>Centromere B (new)</td>
<td>Recombinant Centromere B antigen</td>
<td>CREST (calcinosis, Raynaud’s phenomenon, esophageal dysfunction, sclerodactyly, telangiectasia) syndrome</td>
<td>Centromere</td>
</tr>
<tr>
<td>Scl-70 (new)</td>
<td>Recombinant Scl-70 antigen</td>
<td>Scleroderma, other connective tissue disease</td>
<td>Mixed</td>
</tr>
<tr>
<td>Jo-1 (new)</td>
<td>Recombinant Jo-1 antigen</td>
<td>Polymyositis, other connective tissue disease</td>
<td>Cytoplasmic</td>
</tr>
</tbody>
</table>

Autoimmune Individual and Panel Offerings

With the additional new ANA autoantibodies, we can now provide more comprehensive autoimmune panels in-house. Additionally, we have made name changes. Table 2 on page 3 describes the current autoimmune panels while Table 3 describes the new panels. As a result of the new panels, the laboratory report format will be fine-tuned to display “negative” and “positive” results with interpretive comments.
Table 2 – Current Autoimmune Panels

<table>
<thead>
<tr>
<th>Ordering Code</th>
<th>New PeaceHealth Laboratories’ Name</th>
<th>Former PeaceHealth Laboratories’ Name</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>10780</td>
<td>Autoimmune Panel 7 Only</td>
<td>ANA Reflex Profile</td>
<td>dsDNA, SSA, SSB, Sm, RNP, C3, C4</td>
</tr>
<tr>
<td>10770</td>
<td>ANA Screen plus Autoimmune Panel 7</td>
<td>ANA Plus ANA Profile</td>
<td>ANA Screen, ANA Titer*, dsDNA, SSA, SSB, Sm, RNP, C3, C4</td>
</tr>
<tr>
<td>69110</td>
<td>ANA Screen with reflex to Autoimmune Panel 7</td>
<td>ANA, reflex to Titer* and ANA Profile, if indicated</td>
<td>ANA Screen, ANA Titer*, if titer &gt;1:320 reflex: dsDNA, SSA, SSB, Sm, RNP, C3, C4</td>
</tr>
</tbody>
</table>

Table 3 – New Autoimmune Panels

<table>
<thead>
<tr>
<th>Ordering Code</th>
<th>PeaceHealth Laboratories’ Name</th>
<th>Former PeaceHealth Laboratories’ Name</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>10772</td>
<td>Autoimmune Panel 11 Only</td>
<td>ANAlyzer without ANA</td>
<td>dsDNA, SSA, SSB, Sm, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF</td>
</tr>
<tr>
<td>10782</td>
<td>Autoimmune Panel 15 Only</td>
<td>Not previously offered as a reference test</td>
<td>dsDNA, SSA, SSB, Sm, RNP, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF, Chromatin, Centromere B, Jo-1</td>
</tr>
<tr>
<td>10774</td>
<td>ANA Screen by IFA Plus Autoimmune Panel 11</td>
<td>ANA Lupus ANAlyzer Panel</td>
<td>ANA Screen by IFA, ANA Titer*, dsDNA, SSA, SSB, Sm, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF</td>
</tr>
<tr>
<td>10778</td>
<td>ANA Screen by IFA Plus Autoimmune Panel 11 without RF</td>
<td>ANAlyzer without RF</td>
<td>ANA Screen by IFA, ANA Titer*, if titer positive reflex: dsDNA, SSA, SSB, Sm, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF</td>
</tr>
<tr>
<td>10776</td>
<td>ANA Screen by IFA with reflex to Autoimmune Panel 11</td>
<td>ANA with reflex ANAlyzer</td>
<td>ANA Screen by IFA, ANA Titer*, if titer positive reflex: dsDNA, SSA, SSB, Sm, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF</td>
</tr>
<tr>
<td>10784</td>
<td>ANA Screen by IFA Plus Autoimmune Panel 15</td>
<td>Not previously offered as a reference test</td>
<td>ANA Screen by IFA, ANA Titer*, dsDNA, SSA, SSB, Sm, RNP, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF, Chromatin, Centromere B, Jo-1</td>
</tr>
<tr>
<td>10786</td>
<td>ANA Screen by IFA with reflex to Autoimmune Panel 15</td>
<td>Not previously offered as a reference test</td>
<td>ANA Screen by IFA, ANA Titer*, if titer positive reflex: dsDNA, SSA, SSB, Sm, RNP, C3, C4, SmRNP, Scl-70, Ribosomal P, Thyroid Peroxidase (TPO), RF, Chromatin, Centromere B, Jo-1</td>
</tr>
</tbody>
</table>

QUESTIONS?
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ordering information on back
Expanded Testing for ANA (continued)

ORDERING INFORMATION

Individual Tests

69115: Antinuclear Antibodies (ANA) Screen Only
69150: Antinuclear Antibodies (ANA) Titer Only
69100: Antinuclear Antibodies (ANA) Screen with reflex to titer
69105: Antinuclear Antibodies (ANA) Screen by IFA with reflex to titer
58210: Double Stranded DNA Antibody
58251: Sm
58252: RNP
58253: SmRNP
58270: Scl-70
58265: Ribosomal P
58254: Chromatin
58055: Centromere B
58260: Jo-1
58305: SSA
58310: SSB

Panels

10772: Autoimmune Panel 11 Only
10782: Autoimmune Panel 15 Only
10774: ANA Screen by IFA Plus Autoimmune Panel 11
10778: ANA Screen by IFA Plus Autoimmune Panel 11 without RF
10776: ANA Screen by IFA with reflex to Autoimmune Panel 11
10784: ANA Screen by IFA Plus Autoimmune Panel 15
10786: ANA Screen by IFA with reflex to Autoimmune Panel 15
10760: Extractable Nuclear Antigen (ENA) Panel, Sm, RNP, SS-A, SS-B

Methodology: Multiplex Flow Immunoassay (Luminex); Indirect Fluorescent Antibody (IFA)
Performed: Luminex daily; IFA Monday through Friday
Released: Same day as tested

SPECIMEN REQUIREMENTS

Collect: Individual Tests: One 7.5 mL serum separator tube (SST)
         Panels: Two 7.5 mL serum separator tubes (SST)
Stability: Please refer to online Test Directory for complete instructions (peacehealthlabs.org)
Standard Volume: Individual Tests: 1 mL serum; Panels: 2 mL serum (1 refrigerated, 1 frozen)
Transport: Refrigerated or frozen on dry ice
Comment: ANA specimens screened positive by Luminex or by IFA are titered using HEP-2 cells and the titer and pattern will be reported. Additional charges will be added for the titer.