March 2, 2018

Mercy Clinical Laboratory has added a new multiplex immunoassay platform, the Biorad BioPlex® which will expand our in-house testing capabilities while simultaneously reducing turnaround time. This method utilizes color-coded fluorescent microsphere beads, coated with antigens or antibodies particular to a specific assay. When test serum is incubated with the bead mixture, antihuman IgG antibody joined to a second fluorophore, detects antibodies bound to the beads. Beads then pass through a flow cytometer that analyzes and quantifies the signal.

On March 7th we will begin performing antinuclear antibody testing (ANA screen) on the Bioplex®. This methodology detects autoantibodies for the following protein targets:

- Double-stranded DNA (dsDNA)
- Chromatin
- Ribosomal P
- SSA
- SSB
- Smith
- RNP
- Sci-70
- Jo-1
- Centromere B

A negative result means that the patient’s serum shows no reactivity for these most common clinically relevant antibodies associated with connective tissue diseases. In some cases, nuclear components not part of this screen can contribute to the presence of anti-nuclear antibodies. If the ANA screen is negative and there is still a high degree of clinical suspicion for the presence of anti-nuclear antibodies, consider a rheumatology consult. All positive ANA screens will reflex to an ANA IFA to provide both the titer and cellular staining pattern.
The following tests can be ordered individually:
- Double –stranded DNA (dsDNA) (reflexed to dsDNA IFA)
- SSA
- SSB
- Smith
- RNP
- Scl-70
- Jo-1
- Centromere B
- Cyclic citrullinated peptide (CCP)
- Myeloperoxidase Ab (MPO)
- Proteinase 3 Ab (PR3)
- Glomular Basement Membrane (GBM)

Panels available include:

**ENA Panel**
- SSA
- SSB
- RNP
- Smith
- Jo-1
- Scl-70

**Vasculitis Panel**
- Myeloperoxidase Ab (MP)
- Proteinase 3 Ab (PR3)
- ANCA IFA

Test Name: Antinuclear Antibody Screen, reflex Confirmation

**New Order**

Performing Laboratory: MCL

CPT: 86038

Specimen Requirements: Serum from Gold SST or Red top

Minimum Volume: 1 ml

Stability: Refrigerated 7 days, Frozen 1 month

Rejection Criteria: hemolysis

Test Methodology: Immunoassay

Normal Range: Negative

Reportable Range: Negative, Positive, Equivocal

Client List Price: $34.00

Patient/Insurance Price: $37.00

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Order Code</th>
<th>Internal Code</th>
<th>CPT Code</th>
<th>Result code</th>
<th>Result 9 character translation code</th>
<th>LOINC code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antinuclear Antibody Screen, reflex Confirmation</td>
<td>ANASCRN</td>
<td>86038</td>
<td>ANA Screen</td>
<td>ANASCRN</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Test Name:**  Extractable Nuclear Antigen Ab  
**Performing Laboratory:** MCL  
**CPT:**  86235 x 6  
Specimen Requirements: Serum from Gold SST or Red top, Plasma from Lavender top (ETDA), or Green top (Lithium Heparin)  
Minimum Volume: 1 ml  
Stability: Refrigerated 7 days, Frozen 1 month  
Rejection Criteria: hemolysis  
Test Methodology: Immunoassay  
Normal Range: <1.0 Al  
Reportable Range: 0.2 Al to 8.0 Al  

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Order Code</th>
<th>CPT</th>
<th>Result code</th>
<th>Result 9 character translation code</th>
<th>LOINC code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extractable Nuclear Antigen Ab</td>
<td>ENA</td>
<td>86235</td>
<td>SSA Ab</td>
<td>SSA Ab</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>86235</td>
<td>SSB Ab</td>
<td>SSB Ab</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>86235</td>
<td>RNP Ab</td>
<td>RNP Ab</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>86235</td>
<td>Smith Ab</td>
<td>Smith Ab</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>86235</td>
<td>JO 1 Ab</td>
<td>JO 1 Ab</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>86235</td>
<td>SCL70 Ab</td>
<td>SCL70 Ab</td>
<td></td>
</tr>
</tbody>
</table>

**Test Name:**  Vasculitis Panel  
**Performing Laboratory:** MCL  
**CPT:**  86256, 86255, 83516, 83516  
Specimen Requirements: Serum from Gold SST or Red top  
Minimum Volume: 1 ml  
Stability: Refrigerated 7 days, Frozen 1 month  
Rejection Criteria: hemolysis  
Test Methodology: Immunoassay (MPO and PR3), IFA (ANCA PC)  
Normal Range: MPO and PR3 (< 1.0), ANCA PC (Negative)  
Reportable Range: MPO and PR3 (0.2-8.0), ANCA PC (Negative, Positive)  

<table>
<thead>
<tr>
<th>Test Description</th>
<th>CPT Code</th>
<th>Result code</th>
<th>Result 9 character translation code</th>
<th>LOINC code</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPO Ab</td>
<td>86256</td>
<td>$26.50</td>
<td>$26.50</td>
<td></td>
</tr>
<tr>
<td>PR3</td>
<td>86255</td>
<td>$26.50</td>
<td>$26.50</td>
<td></td>
</tr>
<tr>
<td>ANCA PC Screen</td>
<td>83516</td>
<td>$45.00</td>
<td>$45.00</td>
<td></td>
</tr>
<tr>
<td>ANCA PC Titer</td>
<td>83516</td>
<td>$55.50</td>
<td>$55.00</td>
<td></td>
</tr>
<tr>
<td>Test Description</td>
<td>Order Code</td>
<td>Internal HL7 Interface Code</td>
<td>CPT Code</td>
<td>Result code</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------</td>
<td>-----------------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Careset Parent Order</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vasculitis Panel</td>
<td></td>
<td>VASCPAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Careset Children Orders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti Neutrophil Cytoplasmic Ab, P and C</td>
<td>ANCA</td>
<td></td>
<td><strong>86255</strong></td>
<td>ANCA PC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ANCA PC Pat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>86256</strong></td>
<td>ANCA PC Titer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ANCA PC Interp</td>
</tr>
<tr>
<td>Myeloperoxidase Antibody</td>
<td>MPO AB</td>
<td></td>
<td><strong>83516</strong></td>
<td>Myeloperox Ab</td>
</tr>
<tr>
<td>Proteinase-3 Autoantibody</td>
<td>PR3</td>
<td></td>
<td><strong>83516</strong></td>
<td>Proteinase 3 Ab</td>
</tr>
</tbody>
</table>

Thank you for choosing MCL.