Test Update
From Your Laboratory Service Provider, PathGroup Labs
Methodology change for Anti-CCP
Samuel Smith, MD Lab Director / Jeff Johnson, Clinical Operations Manager

This change will take effect October 11, 2010

Overview and Clinical Utility:
Effective October 11, 2010 PathGroup Labs will begin performing anti-CCP (Cyclic Citrullinated Peptides) on the Bio-Rad BioPlex 2200. Detection of CCP antibodies is used as an aid in the diagnosis of rheumatoid arthritis and should be used in conjunction with other clinical findings and laboratory results. Test code ordering will remain the same. Report format will also remain the same. Turnaround time will decrease with the new methodology, allowing for faster turnaround time for results.

Test Methodology:
The BioPlex™ 2200 Anti-CCP assay is a multiplex flow immunoassay intended for the semi-quantitative detection of IgG antibodies to Cyclic Citrullinated Peptide in human serum.

Ordering:

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test Name</th>
<th>CPT:</th>
<th>LOINC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCP</td>
<td>Anti-CCP (Cyclic Citrullinated Peptides)</td>
<td>86200</td>
<td>46437-0</td>
</tr>
</tbody>
</table>

Reference interval Anti-CCP:

<table>
<thead>
<tr>
<th>New Methodology: Multiplex Flow Immunoassay</th>
<th>Previous Methodology: ELISA</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 3.0 – Negative</td>
<td>&lt; 5.0 – Negative</td>
</tr>
<tr>
<td>&gt; 3.0 – Positive</td>
<td>&gt; 5.0 – Positive</td>
</tr>
</tbody>
</table>

Units: U/mL

Specimen Collection and Storage:
1) Collect specimen in a serum separator tube (SST).
   a) Allow serum tube to clot for 30 minutes.
   b) Spin serum separator tube 10-15 minutes @ 3500 rpm.
2) Serum specimens are stable refrigerated for 7 days or frozen for 30 days.

Test Performed:
Monday – Friday

Turnaround time:
24 Hours

For further questions, please contact Client Services at 615-562-9300 or 1-888-474-5227.