Overview

Useful For
Detecting or monitoring of monoclonal gammopathies and immune deficiencies

Testing Algorithm
See Celiac Disease Diagnostic Testing Algorithm in Special Instructions

Special Instructions
- Celiac Disease Diagnostic Testing Algorithm

Method Name
Nephelometry

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:
- Preferred: Serum gel
- Acceptable: Red top

Specimen Volume: 1 mL

Forms
If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>OK</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>28 days</td>
<td></td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information
The gamma globulin band as seen in conventional serum protein electrophoresis consists of 5 immunoglobulins. In normal serum, about 80% is immunoglobulin G (IgG), 15% is immunoglobulin A (IgA), 5% is immunoglobulin M (IgM), 0.2% is immunoglobulin D (IgD), and a trace is immunoglobulin E (IgE).

Elevations of IgG, IgA, and IgM may be due to polyclonal immunoglobulin production.

Monoclonal gammopathies of all types may lead to a spike in the gamma globulin zone seen on serum protein electrophoresis. Monoclonal elevations of IgG, IgA, IgD, and IgE characterize multiple myeloma. Monoclonal elevations of IgM occur in macroglobulinemia.

Decreased immunoglobulin levels are found in patients with congenital deficiencies.

Reference Values
IgG
- 0-<5 months: 100-334 mg/dL
- 5-<9 months: 164-588 mg/dL
- 9-<15 months: 246-904 mg/dL
- 15-<24 months: 313-1,170 mg/dL
- 2-<4 years: 295-1,156 mg/dL
- 4-<7 years: 386-1,470 mg/dL
- 7-<10 years: 462-1,682 mg/dL
- 10-<13 years: 503-1,719 mg/dL
- 13-<16 years: 509-1,580 mg/dL
- 16-<18 years: 487-1,327 mg/dL
- > or =18 years: 767-1,590 mg/dL

IgA
- 0-<5 months: 7-37 mg/dL
<table>
<thead>
<tr>
<th>Age Range</th>
<th>IgG (mg/dL)</th>
<th>IgM (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-&lt;9 months</td>
<td>16-50</td>
<td>26-122</td>
</tr>
<tr>
<td>9-&lt;15 months</td>
<td>27-66</td>
<td>32-132</td>
</tr>
<tr>
<td>15-&lt;24 months</td>
<td>36-79</td>
<td>40-143</td>
</tr>
<tr>
<td>2-&lt;4 years</td>
<td>27-246</td>
<td>46-152</td>
</tr>
<tr>
<td>4-&lt;7 years</td>
<td>29-256</td>
<td>37-184</td>
</tr>
<tr>
<td>7-&lt;10 years</td>
<td>34-274</td>
<td>37-224</td>
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<tr>
<td>10-&lt;13 years</td>
<td>42-295</td>
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<tr>
<td>13-&lt;16 years</td>
<td>52-319</td>
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</tr>
<tr>
<td>16-&lt;18 years</td>
<td>60-337</td>
<td>49-201</td>
</tr>
<tr>
<td>&gt; or =18 years</td>
<td>61-356</td>
<td>37-286</td>
</tr>
</tbody>
</table>

**Interpretation**

Increased serum immunoglobulin concentrations occur due to polyclonal or oligoclonal immunoglobulin proliferation in hepatic disease (hepatitis, liver cirrhosis), connective tissue diseases, acute and chronic infections, as well as in the cord blood of neonates with intrauterine and perinatal infections.

Elevations of immunoglobulin G (IgG), immunoglobulin A (IgA), or immunoglobulin M (IgM) may occur in monoclonal gammopathies such as multiple myeloma (IgG, IgA), macroglobulinemia (IgM), primary systemic amyloidosis, monoclonal gammopathy of undetermined significance, and related disorders.
Decreased levels are found in patients with primary or secondary immune deficiencies.

**Cautions**

Electrophoresis is usually required to interpret an elevated immunoglobulin class as polyclonal versus monoclonal. Immunofixation is usually required to characterize a monoclonal protein.

If there is a discrete M-peak, the monoclonal protein can be monitored with quantitative immunoglobulins. If immunoglobulin quantitation is used to monitor the size of a monoclonal protein that is contained in a background of polyclonal immunoglobulins, changes in the immunoglobulin quantitation may reflect changes in the background immunoglobulins. In these situations, serum protein electrophoresis should therefore be used to monitor the monoclonal protein.

**Clinical Reference**


**Performance**

**Method Description**

In this Siemens Nephelometer II method, the light scattered onto the antigen-antibody complexes is measured. The intensity of the measured scattered light is proportional to the amount of antigen-antibody complexes in the sample under certain conditions. If the antibody volume is kept constant, the signal behaves proportionally to the antigen volume.

A reference curve is generated by a standard with a known antigen content on which the scattered light signals of the samples can be evaluated and calculated as an antigen concentration. Antigen-antibody complexes are formed when a sample containing antigen and the corresponding antiserum are put into a cuvette. A light beam is generated with a light emitting diode (LED), which is transmitted through the cuvette. The light is scattered onto the immuno-complexes that are present. Antigen and antibody are mixed in the initial measurement, but no complex is formed yet. An antigen-antibody complex is formed in the final measurement.

The result is calculated by subtracting value of the final measurement from the initial measurement. The distribution of intensity of the scattered light depends on the ratio of the particle size of the antigen-antibody complexes to the radiated wavelength. (Unpublished Mayo method; instruction manual: Siemens Nephelometer II, Siemens, Inc, Newark, DE, Version 3, 2008)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Saturday; Continuously until 3 p.m.

**Analytic Time**
1 day

**Maximum Laboratory Time**
3 days

**Specimen Retention Time**
14 days

**Performing Laboratory Location**
Rochester

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**Fees and Codes**

**Fees**
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

**Test Classification**
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

82784 x 3

**LOINC® Information**

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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</thead>
<tbody>
<tr>
<td>IMMG</td>
<td>Immunoglobulins IgG,A,M, S</td>
<td>34550-4</td>
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</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGA</td>
<td>Immunoglobulin A (IgA), S</td>
<td>2458-8</td>
</tr>
<tr>
<td>IGM</td>
<td>Immunoglobulin M (IgM), S</td>
<td>2472-9</td>
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<tr>
<td>IGG</td>
<td>Immunoglobulin G (IgG), S</td>
<td>2465-3</td>
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