Test Definition: FRGAM
Rheumatoid Factor IgG, IgA, IgM

Overview

Method Name
Enzyme Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube: Red-top tube

Acceptable: SST tube

Specimen Volume: 1.50 mL

Collection Instructions: Draw blood in a plain, red-top tube(s) or a serum-gel tube(s). Spin down and send 1.50 mL of serum refrigerated in a plastic vial.

Specimen Minimum Volume
0.50 mL

Reject Due To

<table>
<thead>
<tr>
<th>Reject Due To</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>NA</td>
</tr>
<tr>
<td>Lipemia</td>
<td>NA</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>Whole blood unspun greater than 5 days old</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>5 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>365 days</td>
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</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>5 days</td>
<td></td>
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</table>

Clinical and Interpretive

Reference Values
Rheumatoid Factor (RF) levels IgG:
Test Definition: FRGAM
Rheumatoid Factor IgG, IgA, IgM

Negative: <20 EU/mL
Borderline/Equivocal: 20-25 EU/mL
Positive: >25 EU/mL

Rheumatoid Factor (RF) levels IgA:
Negative: <20 EU/mL
Borderline/Equivocal: 20-25 EU/mL
Positive: >25 EU/mL

Rheumatoid Factor (RF) levels IgM:
Negative: <10 IU/mL
Borderline/Equivocal: 10-12.5 IU/mL
Positive: >12.5 IU/mL

Interpretation
The presence of abnormal levels of all three rheumatoid factor (RF) isotypes has a specificity of 99% for Rheumatoid Arthritis. IgA-RF alone can occur in Henoch Schoenlein purpura. RF in any isotype combination may be found in hepatitis C, Sjogren Syndrome, and other chronic infections.

Borderline/Equivocal RF results warrant redraw & retesting to confirm.

Performance

PDF Report
No

Day(s) Performed
Once per week

Report Available
7 to 18 days

Performing Laboratory Location
IMMCO Diagnostics, Inc.

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 developed and performance parameters have been validated by IMMCO Diagnostics, Inc. This
test has not been approved by the U.S. Food and Drug Administration (FDA); however, US FDA approval is not
required for clinical use. It is not intended that clinical diagnosis and patient management decisions be made using
these results alone. This test has been validated using serum samples. The manufacturer has not determined the
efficacy of this when performed on CSF, plasma, joint or pleural fluid specimens. The performance characteristics of
this test were determined by IMMCO Diagnostics Inc.

CPT Code Information
83520 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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<tbody>
<tr>
<td>FRGAM</td>
<td>Rheumatoid Factor IgG, IgA, IgM</td>
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<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>Z5623</td>
<td>Rheumatoid Factor IgG</td>
<td>33314-6</td>
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<tr>
<td>Z5624</td>
<td>Rheumatoid Factor IgA</td>
<td>33313-8</td>
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<tr>
<td>Z5625</td>
<td>Rheumatoid Factor IgM</td>
<td>11573-3</td>
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