

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.

Reject Due To

Hemolysis	NA
Lipemia	NA
Icterus	NA
Other	Whole blood unspun greater than 5 days old

Specimen Minimum Volume

0.50 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	5 days	
	Frozen	365 days	
	Ambient	5 days	

Clinical & Interpretive**Reference Values**

Rheumatoid Factor (RF) levels IgG:

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

Performing Laboratory Location

IMMCO Diagnostics, Inc.

Fees & Codes**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

Test ID	Test Order Name	Order LOINC Value
FRGAM	Rheumatoid Factor IgG, IgA, IgM	Not Provided

Result ID	Reporting Name	LOINC®
Z5623	Rheumatoid Factor IgG	33314-6
Z5624	Rheumatoid Factor IgA	33313-8
Z5625	Rheumatoid Factor IgM	11573-3