

HOTLINE: Effective August 16, 2021

New Test **3004056** **Rheumatoid Arthritis Panel with Reflex to Rheumatoid Factors, RA PANEL R IgA, IgG, and IgM by ELISA**

Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/Quantitative Immunoturbidimetry
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Patient Prep: Fasting specimen preferred.

Collect: Serum separator tube (SST).

Specimen Preparation: Allow serum to clot completely at room temperature before centrifuging. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.8 mL) **Serum is the only acceptable specimen type for this test without a disclaimer.**

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, heat-inactivated, hemolyzed, icteric, or severely lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 24 hours; Refrigerated: 1 week; Frozen: 1 month (should not be thawed more than once)

Reference Interval:

Test Number	Components	Reference Interval
0055256	Cyclic Citrullinated Peptide (CCP) Antibody, IgG	19 Units or less
		Negative
		20-39 Units
		Weak positive
		40-59 Units
0050465	Rheumatoid Factor	Moderate positive
		60 Units or greater
		Strong positive
0051298	Rheumatoid Factors, IgA, IgG, and IgM by ELISA	0-14 IU/mL
3003992	Carbamylated Protein (CarP) Antibody, IgG	0-19 Units

Interpretive Data:

Anticyclic citrullinated peptide (anti-CCP) IgG antibodies are present in about 69-83 percent of patients with rheumatoid arthritis (RA) and have specificities of 93-95 percent. Anticarbamylated protein (anti-CarP) IgG antibodies are present in about 34-53 percent of patients with RA, have specificities of greater than 90 percent and can occur in RA patients seronegative for both rheumatoid factor and anti-CCP. Anti-CCP and anti-CarP autoantibodies may be present in the preclinical phase of disease, are associated with future RA development, and may predict radiographic joint destruction. Patients with weak positive results should be monitored and testing repeated.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: If CCP IgG is 20 units or greater and/or rheumatoid factor is 15 IU/mL or greater, then Rheumatoid Factor, IgG/IgM/IgA by EIA will be performed. Additional charges apply.

CPT Code(s): 86200; 86431; 83516 if reflexed, add 83516 x3

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.