TEST CHANGE

Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA HEp-2 Substrate, IgG by IFA and ENA Confirmation

0050317, ANA REF

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.0 mL serum to an ARUP standard transport tube.~~Standard Transport Tube.~~ (Min: 1.0~~.6~~ mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Nonserum~~Non-serum~~ specimens. Contaminated, grossly hemolyzed, heat-inactivated, severely lipemic, specimens, or inclusion of fibrin clots.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)
Methodology:	Qualitative Enzyme-Linked Immunosorbent Assay (ELISA) / Semi-Quantitative Indirect Fluorescent Antibody (IFA) / Semi-Quantitative Multiplex Bead Assay / Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)
Note:	ANA lacks diagnostic specificity, and is associated with in variety diseases (cancers, autoimmune, infectious, and inflammatory conditions) and occurs in healthy individuals in varying prevalence. The lack of diagnostic specificity requires confirmation of positive ANA by more-specific serologic tests, which may be guided by the pattern(s) observed. Specimens are screened for ANA using ELISA. If ANA IgG is detected by ELISA, then Antinuclear Antibody (ANA), HEp-2, IgG by IFA will be added. If ANA, IgG by IFA is confirmed positive with a titer of 1:80 or greater, then a titer and pattern will be reported. In addition, samples positive for ANA, IgG by IFA will reflex to Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA; Jo-1 Antibody, IgG; Smith/RNP (ENA) Antibody, IgG; Scleroderma (Scl-70) (ENA) Antibody, IgG; Smith (ENA) Antibody, IgG; SSA 52 and 60 (Ro) (ENA) Antibodies, IgG; and SSB (La) (ENA) Antibody, IgG. If Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA is detected, then Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae) will be added. Additional charges apply. ANA identified by indirect fluorescence assay (IFA) using HEp-2 substrate and IgG-specific conjugate at a screening dilution of

	1:80. Positive nuclear patterns reported include homogeneous, speckled, centromere, nucleolar, or nuclear dots. Positive cytoplasmic patterns reported include reticular/AMA, discrete/GW body-like, polar/golgi-like, rods and rings, or cytoplasmic speckled patterns. All positive results are reported with endpoint titers at no additional charge.
CPT Codes:	86038; if reflexed, add 86039; if reflexed, add 86235 x7 and 86225; if reflexed, add 86256
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Antinuclear Antibodies (ANA), IgG by ELISA: ANA specimens are screened using enzyme-linked immunosorbent assay (ELISA) methodology. All ELISA results reported as detected are further tested by indirect fluorescent assay (IFA) using HEp-2 substrate with an IgG-specific conjugate. The ANA ELISA screen is designed to detect antibodies against dsDNA, histone, SS-A (Ro), SS-B (La), Smith, Smith/RNP, Scl-70, Jo-1, centromeric proteins, and other antigens extracted from the HEp-2 cell nucleus. ANA ELISA assays have been reported to have lower sensitivities than ANA IFA for systemic autoimmune rheumatic diseases (SARD).

Negative results do not necessarily rule out SARD.

Reference Interval:

Test Number	Components	Reference Interval
	Anti-Nuclear Ab (ANA), IgG by ELISA	None detected