

Quarterly HOTLINE: Effective November 12, 2018

**0050080**      **Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA, HEp-2 Substrate, IgG by IFA**      **ANA**

**Specimen Required:** Collect: Serum Separator Tube (SST).

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Non-serum, heat inactivated, grossly hemolyzed and severely lipemic specimens.

Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

**Reference Interval:**

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Test Number	Components	Reference Interval
	Antinuclear Antibodies (ANA), IgG by ELISA	None Detected
3000082	Antinuclear Antibody (ANA), HEp-2, IgG	Less than 1:80

**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, snRNP/Sm, Scl-70, Jo-1, centromere, and an extract of lysed HEp-2 cells. 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.

**Note:** ANA lacks diagnostic specificity, and is associated with a variety of diseases (cancers, autoimmune, infectious, and inflammatory conditions) and occurs in healthy individuals in varying prevalence. The lack of diagnostic specificity requires a confirmation of positive ANA by more-specific serologic tests, which may be guided by the pattern(s) observed.

If ANA are detected by ELISA, then Antinuclear Antibody (ANA), HEp-2, IgG by IFA will be added. Additional charges apply

ANA determined by indirect fluorescence assay (IFA) use HEp-2 substrate and IgG-specific conjugate at a screening dilution of 1:80. If positive, patterns reported include homogeneous, speckled, centromere, nucleolar, nuclear dots, or cytoplasmic. All positive results are reported with endpoint titers.

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.

Add reflex to 3000082, Antinuclear Antibody (ANA), HEp-2, IgG

Remove reflex to 0050639, ANA by IFA, IgG