

HOTLINE: Effective August 17, 2020

0050317

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

ANA REF

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 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.

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

Add component 3002774, Cytoplasm Pattern to reflexive orderable 3000478