

Quarterly HOTLINE: Effective November 12, 2018

0050317 Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA HEp-2 Substrate, IgG by IFA and ENA Confirmation ANA REF

Reference Interval:
Effective November 12, 2018

| Test Number | Components | Reference Interval | |
|-------------|--|-----------------------------|---|
| 0050080 | Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA, HEp-2 Substrate, IgG by IFA | Effective November 12, 2018 | |
| | | Test Number | Components |
| | | | Antinuclear Antibodies (ANA), IgG by ELISA |
| | | Reference Interval | None Detected |
| 3000082 | Antinuclear Antibody (ANA), HEp-2, IgG | Less than 1:80 | |
| 0050215 | Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA | Effective August 20, 2012 | |
| | | Test Number | Components |
| | | | Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA |
| | | Reference Interval | None Detected. |
| 2002693 | Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using <i>Crithidia luciliae</i>) | Less than 1:10 | |
| 0050470 | RNP (U1) (Ribonucleic Protein) (ENA) Antibody, IgG | 29 AU/mL or less | Negative |
| | | 30-40 AU/mL | Equivocal |
| | | 41 AU/mL or greater | Positive |
| 0050599 | Scleroderma (Scl-70) (ENA) Antibody, IgG | 29 AU/mL or less | Negative |
| | | 30-40 AU/mL | Equivocal |
| | | 41 AU/mL or greater | Positive |
| 0050085 | Smith (ENA) Antibody, IgG | 29 AU/mL or less | Negative |
| | | 30-40 AU/mL | Equivocal |
| | | 41 AU/mL or greater | Positive |
| 2012074 | SSA 52 and 60 (Ro) (ENA) Antibodies, IgG | Test Number | Components |
| | | | SSA-52 (Ro52) (ENA) Antibody, IgG |
| | | Reference Interval | 29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive |
| | | | SSA-60 (Ro60) (ENA) Antibody, IgG |
| | | Reference Interval | 29 AU/mL or Less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive |
| 0050692 | SSB (La) (ENA) Antibody, IgG | 29 AU/mL or less | Negative |
| | | 30-40 AU/mL | Equivocal |
| | | 41 AU/mL or greater | Positive |
| 0099592 | Jo-1 Antibody, IgG | 29 AU/mL or less | Negative |
| | | 30-40 AU/mL | Equivocal |
| | | 41 AU/mL or greater | Positive |

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 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**, RNP (U1) (Ribonucleic Protein) (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 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.

CPT Code(s): 86038; if reflexed, add 86039; if reflexed, add 86235 x7 and 86225; if reflexed, add 86256

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

Add reflex to 3000082, Antinuclear Antibody (ANA), HEp-2, IgG
Add reflex to 0050599, Scleroderma (Scl-70) (ENA) Antibody, IgG

Add reflex to 0099592, Jo-1 Antibody, IgG
Remove reflex to 0050639, ANA by IFA, IgG



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