



AUTOIMMUNE DISEASES

Comprehensive antinuclear antibodies testing options



The presence of antinuclear antibodies (ANA) represents a key diagnostic criterion for many autoimmune diseases and has been included in the classification criteria for systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD) and the European classification criteria for Sjögren syndrome.^{1,2}



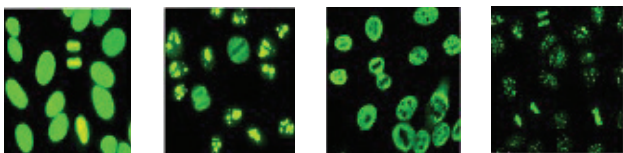
Labcorp's ANAs are performed by immunofluorescence assay (IFA) and offered as two different options when reporting the titer results to fit your preference: starting at either a 1:40 cutoff—with negative results confirmed with anti-Ro (SS-A) antibody—or at a 1:80 cutoff.

According to the American College of Rheumatology (ACR) ACR Task Force and the International Consensus on ANA Patterns (ICAP) recommendations, IFA remains the gold standard for ANA testing.^{3,4}

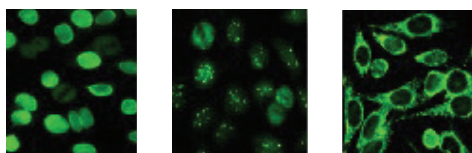
IFA system benefits

- **Consistency:** seven patterns are identified automatically, including the titer result⁵
- **High-quality results:** detailed review process, including technologist confirmation of all results

Automatic recognition of seven different ANA patterns



Homogeneous Nucleolar Speckled Centromeres



Nuclear membrane Nuclear dots Cytoplasmic
Rods and rings Speckled Fibrillar

While ANA by IFA is considered the hallmark of autoimmune rheumatic disease,^{6,7} ANA positivity is not specific; a positive ANA does not necessarily indicate autoimmune disease nor the likelihood of developing one.⁷ Positive ANA may occur in 13%-25% of healthy individuals who do not have a systemic autoimmune rheumatic disease (SARD) and who are unlikely to develop one, even out to four years.^{7,8}

A NOVEL MARKER ASSOCIATED WITH ABSENCE OF SARD

Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Antibodies may help identify individuals who do not have an ANA-associated autoimmune rheumatic disease (AARD) especially in the absence of significant clinical findings.⁹ Positivity by this monospecific immunoassay confirms the dense fine speckled (DFS) pattern observed on ANA by IFA with HEp-2 cells.¹⁰ This assay, when used in combination with an ANA reflex profile, may be utilized to include or exclude SARD.^{10,11}

Learn more about the Anti-DFS70 Antibodies:



ANA testing options and reflex profiles from Labcorp

Monospecific assays for individual autoantibodies provide diagnostic and potential prognostic utility for several autoimmune diseases.

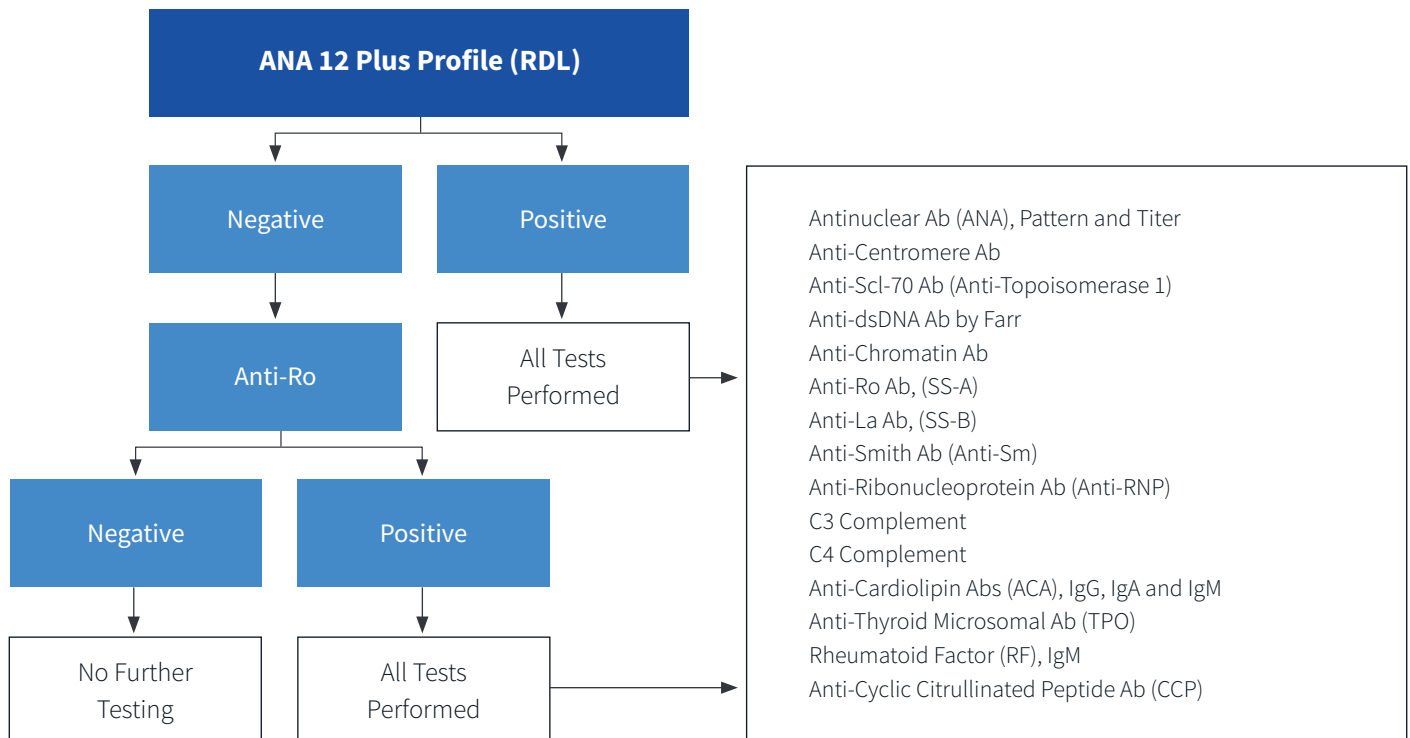
Reported at a 1:40 cutoff or higher, negative ANA confirmed with Anti-Ro (SS-A)	
520075	Antinuclear Antibodies by Indirect Fluorescent Antibody (IFA) (RDL)
520180	ANA 12 Plus Profile (RDL)
520175	ANA 12 Plus Profile, Do All (RDL)
520188	ANA 12 Profile (RDL)
520299	ANA 12 Profile, Do All (RDL)

Reported at a 1:80 cutoff or higher	
164947	Antinuclear Antibodies (ANA), by IFA
340897	Antinuclear Antibodies (ANA) by IFA, Reflex to 9-biomarker profile by Multiplex Immunoassay (MIA)
382965	Antinuclear Antibodies (ANA) by IFA, Reflex to 11-biomarker profile by MIA

ANA 12 Plus Profile (RDL) is a comprehensive diagnostic profile deliberately curated to aid in the differential diagnosis of eight autoimmune disease states:

SLE
ANA by IFA
Tests with high specificity
Anti-ds DNA by Farr
Anti-Sm by EIA
Test with moderate specificity
Anti-Ro by ELISA
Anti-La by ELISA
Anti-Chromatin by EIA
C3 and C4 Complements by Turbidimetry
Anti-Cardiolipin IgG, IgA and IgM by ELISA
Drug-Induced SLE
Anti-Chromatin by EIA

SS
Anti-Ro by ELISA
Anti-La by ELISA
Rheumatoid arthritis (RA)
Anti-CCP (high specificity) by ELISA
Rheumatoid Factor (RF) by Turbidimetry
MCTD
Anti-U1 RNP by ELISA
Limited Scleroderma (CREST)
Anti-Centromere B by IFA
Diffuse Scleroderma
Anti-Scl-70 by EIA, confirmed by ID
Autoimmune Thyroid Disease
Anti-Thyroid Microsomal (TPO) by CMIA



Test Name	Test No.	Test Components	Reported Cutoff	Confirm Negative ANA with Anti-Ro (SS-A)	Non-Reflexive All components are tested regardless of ANA result
Antinuclear Antibodies by Indirect Fluorescent Antibody (IFA) (RDL)	520075	ANA by IFA with titers and patterns	1:40	•	
ANA 12 Profile (RDL)	520188	ANA by IFA, Anti-dsDNA Ab by Farr, Anti-Sm, Anti-U1 RNP, C3 Complement; C4 Complement, Anti-Cardiolipin Ab (IgG, IgA and IgM Isotypes), Anti-Centromere Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B), Anti-Scl-70 Ab, Anti-TPO (Thyroid Microsomal Peroxidase) Ab	1:40	•	
ANA 12 Profile, Do All (RDL)	520299	ANA by IFA, Anti-dsDNA Ab by Farr, Anti-Sm, Anti-U1 RNP, C3 Complement; C4 Complement, Anti-Cardiolipin Ab (IgG, IgA and IgM Isotypes), Anti-Centromere Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B), Anti-Scl-70 Ab, Anti-TPO (Thyroid Microsomal Peroxidase) Ab	1:40		•
ANA 12 Plus Profile (RDL)	520180	ANA by IFA, Anti-dsDNA Ab by Farr, Anti-Sm, Anti-U1 RNP, C3 Complement; C4 Complement, Anti-Cardiolipin Ab (IgG, IgA and IgM Isotypes), Anti-Centromere Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B), Anti-Scl-70 Ab, Anti-TPO (Thyroid Microsomal Peroxidase) Ab, Anti-Chromatin Ab, RF by Turbidimetry, Anti-CCP (Cyclic Citrullinated Peptide) Ab	1:40	•	
ANA 12 Plus Profile, Do All (RDL)	520175	ANA by IFA, Anti-dsDNA Ab by Farr, Anti-Sm, Anti-U1 RNP, C3 Complement; C4 Complement, Anti-Cardiolipin Ab (IgG, IgA and IgM Isotypes), Anti-Centromere Ab, Anti-Ro (SS-A) Ab, Anti-La (SS-B), Anti-Scl-70 Ab, Anti-TPO (Thyroid Microsomal Peroxidase) Ab, Anti-Chromatin Ab, RF by Turbidimetry, Anti-CCP (Cyclic Citrullinated Peptide) Ab	1:40		•
Antinuclear Antibodies (ANA), by IFA	164947	ANA by IFA with titers and patterns	1:80		
Antinuclear Antibodies (ANA) by IFA, Reflex to 9-biomarker profile by MIA	340897	ANA by IFA, and the following autoantibodies by Multiplex Immunoassay: Anti-dsDNA Ab, Anti-RNP Ab, Anti-Sm Ab, Anti-SS-A (Anti-Ro) Ab, Anti-SS-B (Anti-La) Ab, Anti-Scl-70 Ab, Anti-Chromatin Ab, Anti-Jo-1 Ab, Anti-Centromere B Ab	1:80		
Antinuclear Antibodies (ANA) by IFA, Reflex to 11-biomarker profile by MIA	382965	ANA by IFA, and the following autoantibodies by Multiplex Immunoassay: Anti-dsDNA Ab, Anti-RNP Ab, Anti-Sm Ab, Anti-SS-A (Anti-Ro) Ab, Anti-SS-B (Anti-La) Ab, Anti-Scl-70 Ab, Anti-Chromatin Ab, Anti-Jo-1 Ab, Anti-Centromere B Ab, Anti-Ribosomal P Ab, Sm/RNP Ab	1:80		

Additional Test		
Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Ab	520313	Anti-DFS70 Ab

References

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For more information, please contact your Labcorp representative or visit labcorp.com/rheumatology

