

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 dilution–with negative results confirmed with anti-Ro (SS-A) antibody–or at a 1:80 dilution.

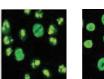
According to the American College of Rheumatology (ACR), ANA task force and the International Consensus on ANA Patterns (ICAP) recommendations, the IFA assay remains the gold standard for ANA testing.^{3,4}

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





Nuclear membrane



Nuclear dots Cytop Rods a

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 used to include or exclude SARD.^{10,11}

Learn more about the Anti-DFS70 Antibodies:



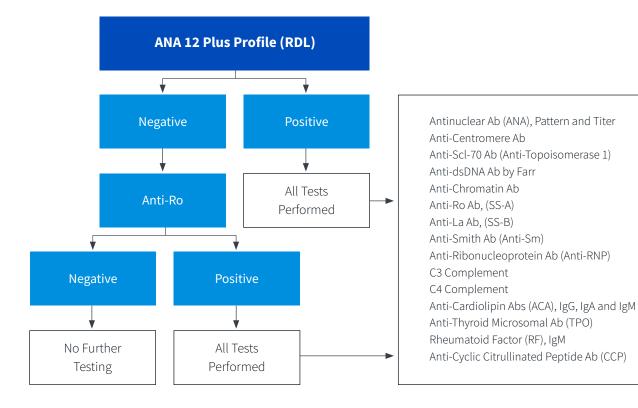
ANA testing options and reflex profiles from Labcorp

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

At a 1:40 dilution, negative ANA confirmed with Anti-Ro (SS-A)			At a 1:80 dilution				
520075	Antinuclear Antibodies by Indirect Fluorescent Antibody (IFA) (RDL)		164947	Antinuclear Antibodies (ANA), by IFA			
520180	ANA 12 Plus Profile (RDL)		340897	Antinuclear Antibodies (ANA) by IFA, Reflex to			
520175	ANA 12 Plus Profile, Do All (RDL)			9-biomarker profile by Multiplex Immunoassay (MIA			
520188	ANA 12 Profile (RDL)		382965	Antinuclear Antibodies (ANA) by IFA, Reflex to 11-biomarker profile by MIA			
520299	ANA 12 Profile, Do All (RDL)						

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

SLE	SS
ANA by IFA	Anti-Ro by ELISA
Tests with high specificity	Anti-La by ELISA
Anti-ds DNA by Farr	Rheumatoid arthritis (RA)
Anti-Sm by EIA	Anti-CCP (high specificity) by ELISA
Test with moderate specificity	Rheumatoid Factor (RF) by Turbidimetry
Anti-Ro by ELISA	MCTD
Anti-La by ELISA	Anti-U1 RNP by ELISA
Anti-Chromatin by EIA	Limited Scleroderma (CREST)
C3 and C4 Complements by Turbidimetry	Anti-Centromere B by IFA
Anti-Cardiolipin IgG, IgA and IgM by ELISA	Diffuse Scleroderma
Drug-Induced SLE	Anti-Scl-70 by EIA, confirmed by ID
Anti-Chromatin by EIA	Autoimmune Thyroid Disease
	Anti-Thyroid Microsomal (TPO) by CMIA



Test Name	Test No.	Test Components	Dilution	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)	NA 12 Profile (RDL)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 Turbidimetr 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 fiters and patterns		1:80		
Antinuclear Antibodies (ANA) by IFA, Reflex to 9-biomarker profile by MIA 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 MIAANA 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 Tests								
Antinuclear Antibodies by Indirect Fluorescent Antibody (IFA), Synovial Fluid (RDL)	520143	ANA by IFA (synovial fluid) with titers and patterns	1:40	•				
Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Ab	520313	Anti-DFS70 Ab						

References

Fenger M, Wiik A, Høier-Madsen M, et al. Detection of antinuclear antibodies by solid-phase immunoassays and immunofluorescence assays. Clin Chem. 2004;50(11):2141-2147. doi:10.1373/clinchem.2004.038422

Tebo AE. Recent approaches to optimize laboratory assessment of antinuclear antibodies. Clin Vaccine Immunol. 2017. 24(12):e00270-17. doi:10.1128/CVI.00270-17; PMID: 29021301 3

Meroni PL, Shur PH. ANA screening: an old test with new re commendations. Ann Rheum Dis. 2010;69(8):1420-1422. doi:10.1136/ard.2009.127100; PMID: 20511607 4. Chan EK, Damoiseaux J, Carballo OG, et al. Report of the first international consensus on standardized nomenclature of antinuclear antibody HEp-2 cell patterns 2014-2015. Front Immunol. 2015;6:412. doi:10.3389/fimmu.2015.00412; PMID: 26347739; PMCID: PMC4542633

EUROIMMUN Systems for full automation of IIFT. Euroimmun. January 2018

Mahler M, Hanly JG, Fritzler MJ. Importance of the dense fine speckled pattern on HEp-2 cells and anti-DFS70 antibodies for the diagnosis of systemic autoimmune diseases. Autoimmun Rev. 2012;11(9):642-645. doi:10.1016/j.autrev.2011.11.005; PMID: 22100330 6.

Mariz HA, Sato EI, Barbosa SH, et al. Pattern on the antinuclear antibody-HEp-2 test is a critical parameter for discriminating antinuclear antibody-positive healthy individuals and patients with autoimmune rheumatic diseases. 7. Arthritis Rheum. 2010;63(1):191-200. doi:10.1002/art.30084; PMID: 20954189

8. Agmon-Levin N, Damoiseaux J, Kallenberg C, et al. International recommendations for the assessment of autoantibodies to cellular antigens referred to as anti-nuclear antibodies. Ann Rheum Dis. 2014;73(1):17-23. doi:10.1136/ annrheumdis-2013-203863; PMID: 24126457

Conrad K, Röber N, Andrade LEC, Mahler M. The clinical relevance of anti-DFS70 autoantibodies. Clin Rev Allergy Immunol. 2017;52(2):202-216. doi:10.1007/s12016-016-8564-5; PMID: 27350273. 10. Mahler M, Parker T, Peebles CL, et al. Anti-DFS70/LEDGF antibodies are more prevalent in healthy individuals compared to patients with systemic autoimmune rheumatic diseases. J Rheumatol. 2012;39:2104-2110. doi:10.3899/ jrheum.120598; PMID: 22942262

I. Fitch-Rogalsky C, Steber W, Mahler M, et al. Clinical and serological features of patients referred through a rheumatology triage system because of positive antinuclear antibodies. PLoS One. 2014;9(4):e93812. doi:10.1371/journal. pone.0093812; PMID: 24705829; PMCID: PMC3976309

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