# Antinuclear antibodies profiles

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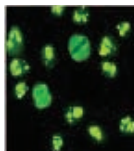
While ANA by IFA is considered the "hallmark" of autoimmune rheumatic disease,[6,7] ANA positivity is not specific; a positive ANA does not necessarily indicate autoimmune disease nor the likelihood of developing one.[7] Positive ANA may occur in 13%-25% of healthy individuals who do not have a systemic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

## IFA system benefits

- **Consistency**: seven patterns are identified automatically, including the titer result[5]
- **High-quality results**: detailed review process, including technologist confirmation of all results
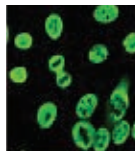
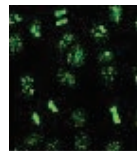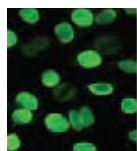## Automatic recognition of seven different ANA patterns
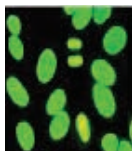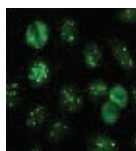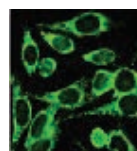


Homogeneous    Nucleolar    Speckled    Centromeres



Nuclear membrane    Nuclear dots    Cytoplasmic
Rods and rings
Speckled Fibrillar

### 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 reflex profiles from Labcorp

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

| | 340897 | 382965 | |
|---|---|---|---|
| | **ANA by IFA Reflex to 9-biomarkers profile** | **ANA by IFA, Reflex to 11-biomarkers profile** | **Clinical Associations** |
| ANA by IFA | ● | ● | A positive ANA test means autoantibodies are present. By itself, a positive ANA test does not indicate the presence of an autoimmune disease or the need for therapy. |
| Anti-dsDNA | ● | ● | Typically present in SLE, but may also be seen in SLE overlap syndromes and other autoimmune disease |
| Anti-RNP | ● | ● | Associated with MCTD when present as isolated, high titer autoantibody, but also associated with SLE and polymyositis (PM/DM) when other autoantibodies present |
| Anti-Sm | ● | ● | High specificity but low to moderate sensitivity for SLE |
| Anti-SS-A (Anti-Ro) | ● | ● | Associated with SS, but also with SLE and rheumatoid arthritis (RA). Associated with neonatal lupus syndrome when present in maternal blood |
| Anti-SS-B (Anti-La) | ● | ● | Associated with SS, and with SLE to a lesser degree |
| Anti-Scl-70 | ● | ● | Associated with scleroderma (diffuse and limited) |
| Anti-Chromatin | ● | ● | Mostly associated with SLE and drug-induced SLE |
| Anti-Jo-1 | ● | ● | Associated with PM/DM |
| Anti-Centromere B | ● | ● | Mostly associated with limited scleroderma including CREST syndrome (calcinosis, Raynaud phenomenon, esophageal dysmotility, sclerodactyly, telangiectasia) |
| Anti-Ribosomal P | | ● | Limited association with SLE. Seen in neuropsychiatric lupus |
| Sm/RNP | | ● | Mostly associated with MCTD |

## ANA by IFA test options for initial evaluation

| Test Name | Test No. |
|---|---|
| Antinuclear Antibodies (ANA), by IFA | **164947** |
| Antinuclear Antibodies (ANA) by IFA, Reflex to 9-biomarker profile by Multiplex Immunoassay | **340897** |
| Antinuclear Antibodies (ANA) by IFA, Reflex to 11-biomarker profile by Multiplex Immunoassay | **382965** |
| Anti-Dense Fine Speckled Protein 70 kDa (DFS70) Ab | **520313** |

**References**
1. 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
2. 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
5. EUROIMMUN Systems for full automation of IIFT. Euroimmun. January 2018
6. 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
7. 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. *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
9. 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
11. 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

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

# labcorp