Test Highlight

Antinuclear Antibody (ANA) by IFA

Effective November 13, 2018, the antinuclear antibodies (ANA) by indirect fluorescence assay (IFA) reference interval will change.

ARUP Laboratories will change the reference interval for ANA by IFA from 1:40 to 1:80. This change means that all patient samples will start with an initial screening dilution of 1:80.

The change in reference interval will reduce the positivity rate in individuals without autoimmune disease. A multicenter study reported that 31.7 percent of normal individuals were ANA positive at 1:40, which was decreased to 13.3 percent at 1:80 and 5.0 percent at 1:160 dilutions. At a screening titer of 1:80, the ANA prevalence in the U.S. population of individuals 12 years and older was reported to be 13.8 percent (95 percent confidence interval [95 percent CI] 12.2–15.5%).

The reference interval change is associated with the implementation of an FDA-cleared ANA IFA kit for use with manual microscope reading or an automated IFA reader. With this test system, all samples are read and approved by a medical technologist prior to release of results.

Key benefits associated with this change:

- Improved reliability in distinguishing between negative and positive results
- Image library to facilitate training and competence
- Potential to promote harmonization in the interpretation of results
- Potential for improved reproducibility
- Streamlined workflow
- Reduction in false-positive rates

ANA Testing

Test Code	Test Name
3000082	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA
3000601	Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA with Reflex by Pattern
0050080	Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA, HEp-2 Substrate, IgG by IFA
0050317	Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA HEp-2 Substrate, IgG by IFA and ENA Confirmation
3000479	Criteria Systemic Sclerosis Panel
3000480	Comprehensive Systemic Sclerosis Panel
2013993	Interstitial Lung Disease Panel

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Frequently asked questions (FAQ's)

1. Has the method for detecting ANA by IFA changed?
   The method for detecting ANA by IFA has not changed. The reference range of the kit has changed from 1:40 to 1:80. In addition, the HEp-2 slides with the reference range of 1:80 can be read using a manual microscope and automated IFA reader.
2. Why is ARUP making this change?
   The test kit requires an initial dilution of 1:80 as per FDA approval. In an effort to consolidate and automate ANA testing, ARUP Laboratories decided to make this kit change.
3. Was a study performed to demonstrate correlation between manual microscope and automated IFA reader at 1:80?
   Yes, correlation studies were performed as part of the validation process. A blinded panel of serum from 151 patients (88 pediatric and 63 adult) and 78 healthy adults were analyzed by manual microscopy and automated IFA reader in the Autoimmune Immunology Laboratory at ARUP Laboratories. The automated ANA IFA reader showed good qualitative agreement (95.6 percent) with manual microscopic evaluation. Pattern agreement between manual microscope reading and automated IFA reader ranged from 20.0–88.9 percent (for homogeneous, speckled, centromere, nucleolar, or nuclear dot pattern). The correlation studies showed that there was significant reduction in hands-on time when utilizing automation for processing ANA IFA testing, but an experienced technologist is required to interpret and validate results, sometimes manually.

References

1. Tan EM, et al. Range of antinuclear antibodies in "healthy" individuals. *Arthritis Rheum* 1997; 40:1601–11.
2. Satoh M, et al. Prevalence and sociodemographic correlates of antinuclear antibodies in the United States *Arthritis Rheum* 2012; 64(7):2319-27.
3. Tebo AE. Recent approaches to optimize laboratory assessment of antinuclear antibodies. *Clin Vaccine Immunol.* CVI.00270-17.

For more information:

- ARUP Consult®: https://arupconsult.com/search/site/ANA
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