

Variability in Approach to Initial Antinuclear Antibodies (ANA) Testing and Follow-Up Testing: a Survey of Participants in the College of American Pathologists' Proficiency Testing Program

Background

- Antinuclear antibodies (ANAs) are key biomarkers of several rheumatic diseases, including systemic lupus erythematosus, systemic sclerosis, and mixed connective tissue disease.¹
- For diagnostic evaluation of these diseases, the American College of Rheumatology (ACR) recommends ANA testing using an indirect immunofluorescence assay (IFA), and that laboratories not using this method specify their testing method when reporting results.¹
- Determining the methods used by clinical laboratories could indicate if the ANA IFA is being used consistently.
- **Objective:** The aim of this study was to identify methods currently used by clinical laboratories for initial and follow-up ANA testing.

Methods

- In 2016, a survey about ANA testing methods was sent to 5,847 clinical laboratories that participated in the College of American Pathologists' proficiency testing program.
- A total of 1,206 (21%) clinical laboratories (942 from the United States, 264 from other countries) responded to the survey.

Results

- Among 1,206 responding laboratories, initial screening was conducted by the following methods:
 - 55% (669): ANA IFA
 - 21% (257): enzyme-linked immunosorbent assay (ELISA)
 - 11% (134): immunobeads
- Of 669 laboratories using ANA IFA for initial screening, 33% offered reflex testing following a positive result by the following methods:
 - 47%: ELISA with specific analytes
 - 25%: IFA with specific analytes
 - 25%: immunobeads with specific analytes
 - 6%: ELISA with nonspecific analytes
- Of 178 laboratories using ELISA for initial screening, reflex testing following a positive result was conducted by the following methods:
 - 69%: IFA
 - 24%: ELISA with specific analytes
 - 7%: IFA with specific analytes
 - 4%: immunobeads with specific analytes
- Of 133 laboratories using immunobeads for initial screening, 57% reflexed to specific analyte testing.

Conclusions

- There is substantial variation in the methods clinical laboratories use for initial screening of ANA and for follow-up testing of a positive result, which may affect the results reported.
- Clinical practice may benefit from the development of uniform laboratory guidelines and the use of more consistent ANA screening methods across clinical laboratories.

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Webpage

<https://www.aacc.org/science-and-practice/annual-meeting-abstracts-archive/2017-annual-meeting-abstracts>

Reference

1. American College of Rheumatology Position Statement. Available at: <http://www.rheumatology.org/Portals/0/Files/Methodology%20of%20Testing%20Antinuclear%20Antibodies%20Position%20Statement.pdf>. Updated 2015. Accessed August 8, 2017.