Variability in Method of Testing for Antinuclear Antibodies (ANA): A Survey of Participants in the College of American Pathologist’s (CAP) Proficiency Testing Program

Background

- Antinuclear antibodies (ANA) are an important diagnostic indicator of several autoimmune diseases, including systemic lupus erythematosus, systemic sclerosis, and mixed connective tissue disease.\(^1\)
- The American College of Rheumatology (ACR) recommends the indirect immunofluorescence assay (IFA) using HEP-2 cells as the “gold standard” for ANA testing.\(^1\)
- The ACR also recommends that clinical laboratories which do not use an ANA IFA assay specify their assay methods when reporting results.

Objective: The investigators conducted a survey of ANA testing methods in clinical laboratories to determine the extent of adoption of ACR recommendations among clinical laboratories.

Methods

- In 2016, 5,847 survey kits were distributed to clinical laboratories that participated in the College of American Pathologists (CAP) Proficiency Testing Program; these laboratories were located in the United States and other countries.
- The topics covered in the survey included ANA testing methods, cells used, slide preparation methods, and interpretation and reporting of results.

Results

- A total of 1,206 (21%) clinical laboratories (942 from the United States and 264 from other countries) responded to the survey.
- Survey responses are summarized below; response rates varied for each question.
  - 56% (669/1,206) of responding laboratories reported using an ANA IFA.
  - 80% (512/644) of laboratories that performed ANA IFA used HEP-2 cells; 18% used HEP-2-engineered cells.
  - 67% (435/646) of laboratories prepared slides manually; 33% (211) prepared slides on an automated platform.
  - 84% (210/251) examined slides by direct microscopy; 16% (41) examined slides on an automated platform.
  - 95% (607/636) interpreted IFA patterns manually; 4% (28) used both manual and automated interpretation.
  - 97% (624/641) reported a titer.

Conclusions

- Just over half of the clinical laboratories that responded to the survey use the “gold standard” assay recommended by the ACR.

References