Key Summary of Conference Abstract

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.

Poster Presentation at the 17th Annual Meeting of the Federation of Clinical Immunology

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References

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 May 10, 2017.