

Automated Fluorescent Microscopy Shows Strong Correlation With Conventional Reading of Anti-Nuclear Antibody Tests



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ABSTRACT

Objective: We have previously shown that automated digital microscopy improves reproducibility of anti-nuclear antibody (ANA) results between scientists and from run-to-run for the same individual. In this study, we examined the agreement between automated fluorescent microscopy and conventional fluorescent microscopy for determination of ANA results.

Methods: We compared the Image Navigator system to conventional fluorescent microscopy in three laboratories, two in the United States and one in Europe. All of the medical laboratory scientists (MLS) who read these tests are experienced in reading ANA tests using conventional methods. They underwent a brief period of training for use of the Image Navigator system before the data were collected for the study.

The samples were routine serum samples submitted for ANA testing. In each laboratory, the samples were processed according to the normal routine of the laboratory using HEp-2000 cells, the samples were read by conventional microscopy, and then the slides were processed and read using the Image Navigator system.

Results: The results in the three laboratories showed overall agreement between the two methods of 98.7%, 99.0%, and 98.4%. Combining the data from the three sites the overall agreement was 98.7% with only 41 of 3185 samples showing discrepancy between the two methods.

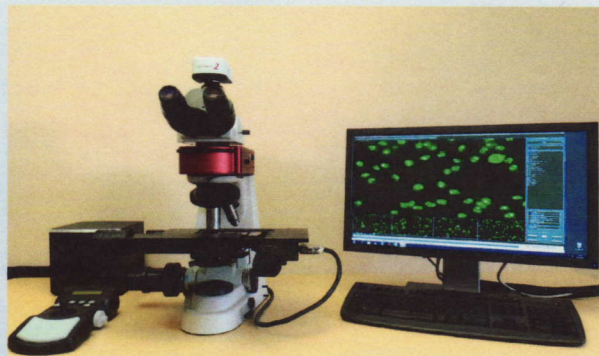
Conclusions: The Image Navigator system is a powerful tool for reproducible and accurate screening of fluorescent ANA tests. It automates many of the repetitive and tedious operations of reading the assays, while still allowing the MLS to make the final determination of the results.

METHODS

The Immuno Concepts Image Navigator system was compared to traditional manual reading of HEp-2000® indirect fluorescent antibody (IFA) anti-nuclear antibody (ANA) slides in three laboratories, two in the United States, and one in Europe. In all phases of the study, medical laboratory scientists who have extensive experience in reading IFA ANA tests were responsible for assessing the results by both the conventional method and the Image Navigator. The Principal Investigator examined and resolved all discrepant or controversial slides and images.

We have previously shown that the Image Navigator system enhances reproducibility of the ANA results, both from run-to-run by the same reader, and from reader to reader. In this study, we compared the Image Navigator system to conventional fluorescent microscopy in three laboratories, two in the United States and one in Europe. All of the medical laboratory scientists who read these tests are experienced in reading ANA tests using conventional methods. They underwent a brief period of training for use of the Image Navigator system before the data were collected for the study.

We assessed a total of 3185 serum samples at the three laboratories. The samples were routine serum samples submitted for ANA testing. In each laboratory, the samples were processed according to the normal routine of the laboratory using HEp-2000® cells, the samples were read by conventional microscopy, and then the slides were processed and read using the Image Navigator system.



RESULTS

Table 1. Comparison results from site 1, a university medical center in the United States.

		Image Navigator	
		Positive	Negative
Manual Reading	Positive	492	4
	Negative	20	1392

Positive Agreement: 99.2%
 Negative Agreement: 98.5%
 Overall Agreement: 98.7%

Table 2. Comparison results from site 2, a university medical center in the United States.

		Image Navigator	
		Positive	Negative
Manual Reading	Positive	207	2
	Negative	5	514

Positive Agreement: 99.0%
 Negative Agreement: 99.0%
 Overall Agreement: 99.0%

Table 3. Comparison results from site 3, a clinical laboratory in Europe.

		Image Navigator	
		Positive	Negative
Manual Reading	Positive	169	3
	Negative	7	433

Positive Agreement: 98.3%
 Negative Agreement: 98.4%
 Overall Agreement: 98.4%

Table 4. Combined data from sites one, two, and three.

		Image Navigator	
		Positive	Negative
Manual Reading	Positive	868	9
	Negative	32	2276

Positive Agreement: 99.0%
 Negative Agreement: 98.6%
 Overall Agreement: 98.7%

CONCLUSION

The Image Navigator is a highly reproducible and highly accurate instrument for the initial assessment of anti-nuclear antibody tests to determine positive and negative tests. The software has been designed to err toward false positive results so that a true positive will not be missed. The data presented here support this design in that less than 0.3% of the total samples examined at three different medical centers were considered "false negative."

The system allows the laboratory to use the highly sensitive HEp-2000® cell line for screening of ANA, while eliminating many of the repetitive and tedious operations of reading the assays. The Medical Laboratory Scientist makes the final determination of the results, so there remains a high level of confidence in the final results.