MULTICENTER STUDY OF THE ANTINUCLEAR ANTIBODY VALIDATION (ANA) BY IFA IN THE AUTOMATED HELIOS® AND ANTIBODIES ANTI nDNA, LKS AND ANCA IN THE HELMED®

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AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS

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OBJECTIVE

To evaluate the performance of the ***AESKUSLIDES®*** ANA HEp-2, ***AESKUSLIDES®*** ANCA, ***AESKUSLIDES®*** nDNA and ***AESKUSLIDES®*** rLKS from AESKU.DIAGNOSTICS in the automated systems for indirect immunofluorescence (IIFA) HELMED® and HELIOS® (AESKU.SYSTEMS).

MATERIAL AND METHODS

A total of 436 samples were tested at three different reference laboratories in Colombia, comprising the following samples: 131 nDNA, 177 ANA, 64 ANCA and 64 rLKS.

All samples were tested on the automated systems HELMED® (ANCA, nDNA and rLKS) and HELIOS® (ANA). For the ANA slides, a manual reading was done with the in-house microscope in addition to the reading completed by HELIOS®.

The screening dilutions used in this study were 1/80 for ANA, 1/10 for nDNA and 1/20 for ANCA and rLKS. The results were compared to the daily routine method in which samples were run on the PhD system with Bio-Rad reagents.

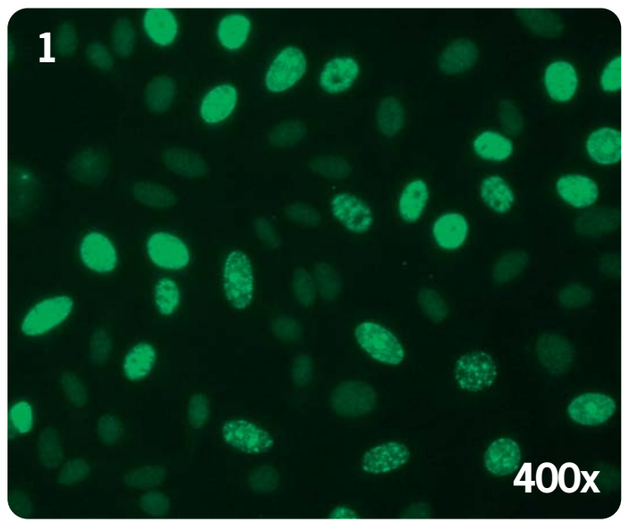
RESULTS

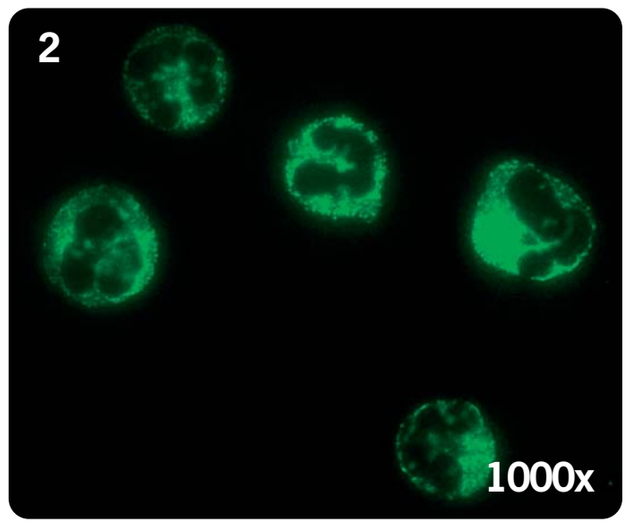
The results obtained for the ANA samples in the three different laboratories and between the two different commercial houses (AESKU® vs Bio-Rad) showed a correlation between 91.9% and 98.3%.

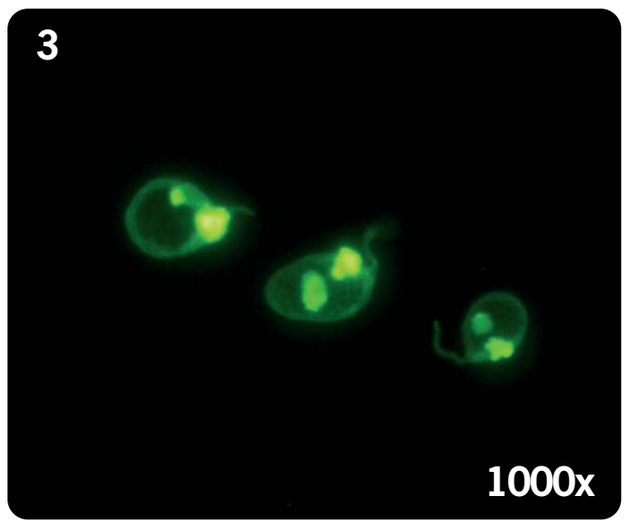
- A comparative titer discrepancy of one dilution for ANA was observed in 1.7% to 3.6% of the cases.
- Pattern differences were focused on non-observation of patterns on both sides and were found in 7.1% to 18.6% of the ANA samples.
- Cytoplasmic patterns on HEp-2 showed a difference between 1.8% to 5.1%.
- A concordance of 100% was obtained for both: ANCA and nDNA.
- The rLKS results obtained a correlation between 90.0% to 96.2% with the differences being that the ASMA and APCA patterns were not recognized.
- Following Kappa indexes were calculated: ANA 0.84-0.96, ANCA 1.0, nDNA 1.0 and rLKS 0.90-0.94. The interpretation of the kappa index was very good for all tests.

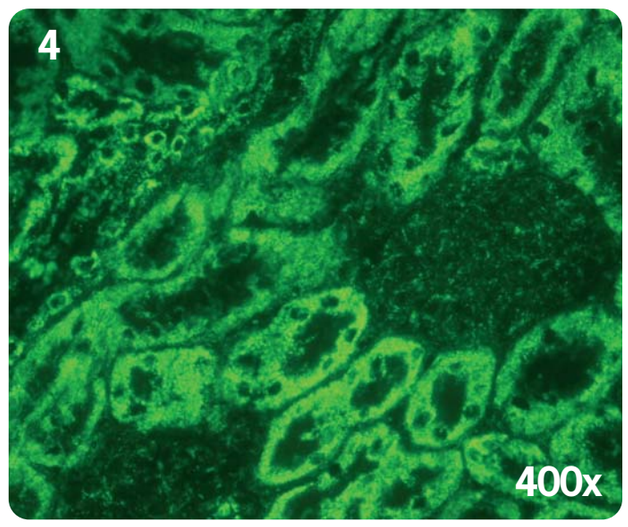
CONCLUSIONS

The performance of HELIOS® and HELMED® showed a very good correlation to the standard method in all laboratories for all tests. Thereby, both systems are able to simplify the daily routine workflow regarding their processing speed, precision, reliability and efficiency. The substrates showed excellent cell distribution, suitable cell size to verify details of patterns observed and no evidence of interference when reading cytoplasmic patterns which ensures correct pattern identification.









IMAGES
1 *ANA HEp-2;* ***2*** *ANCA;* ***3*** *nDNA;* ***4*** *rLKS*

ANA HEp-2		AESKU®		
		Pos	Neg	Total
Bio-Rad	Pos	108	7	115
	Neg	5	57	62
	Total	113	64	177

TABLE 1
93.2% Overall agreement

nDNA		AESKU®		
		Pos	Neg	Total
Bio-Rad	Pos	31	0	31
	Neg	0	100	100
	Total	31	100	131

TABLE 2
100% Overall agreement

ANCA		AESKU®		
		Pos	Neg	Total
Bio-Rad	Pos	4	0	4
	Neg	0	60	60
	Total	4	60	64

TABLE 3
100% Overall agreement

rLKS		AESKU®		
		Pos	Neg	Total
Bio-Rad	Pos	28	3	31
	Neg	2	31	33
	Total	30	34	64

TABLE 4
92.2% Overall agreement