

A COMPARATIVE STUDY ON THE RELIABILITY OF THE NEW AUTOMATED HELIOS® SYSTEM FOR EVALUATION OF INDIRECT IMMUNOFLUORESCENCE

G. Giuliani, G. Garelli, S. Pastori, E. Fornara, T. Caldarulo

AIM:

To evaluate the reliability of the fully-automated **HELIOS®** system (**AESKU.SYSTEMS**) for the detection of anti-nuclear antibodies (ANA), anti-double stranded DNA antibodies (dsDNA) on *Crithidia luciliae*, anti-endomysium (EMA), anti-mitochondrial, anti-smooth muscle, anti-parietal cell antibodies (LKS) and anti-neutrophil cytoplasmic antibodies (ANCA) by indirect immunofluorescence (IIF). To compare the diagnostic performance of automated IIF reading using the **HELIOS®** system with the traditional visual interpretation of IIF by a laboratory expert.

METHODS:

A total number of 210 samples with suspected autoimmune diseases were collected for ANA (n=108), dsDNA ab (n=24), LKS (n=19), EMA (n=33) and ANCA (n=26) testing. ANA, dsDNA, LKS, EMA and ANCA were determined by IIF employing corresponding **BIORAD KALLESTAD** slides and **AESKUSLIDES®** (**AESKU.DIAGNOSTICS**), interpreted visually, and using the automated interpretation of the **HELIOS®** platform.

TABLE: Agreement between **HELIOS®** and expert interpretation of samples

	HELIOS®			EXPERT			n
	Positive	Negative	Low titer	Positive	Negative	Low titer	
ANA	40	55	13	40	51	17	108
Anti dsDNA	8	14	2	8	15	1	24
LKS	8	10	1	8	9	2	19
EMA	9	23	1	9	23	1	33
ANCA		26			26		26
Total n.	65	128	17	65	124	21	210

CONCLUSIONS:

The **HELIOS®** system was shown to be able to correctly discriminate ANA, anti-dsDNA, LKS, ANCA, EMA positive/negative samples when compared to manual microscopic IIF performed independently by an

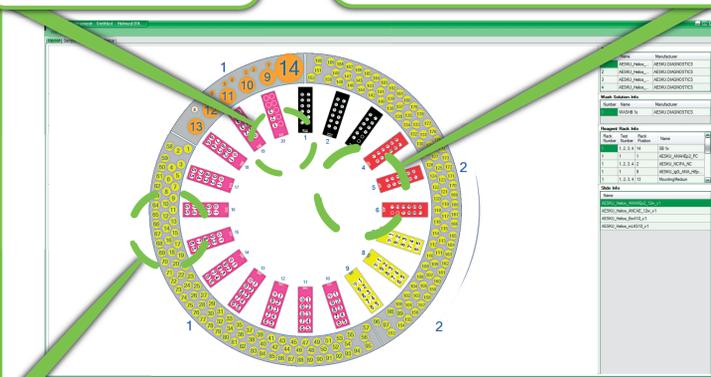
RESULTS:

In total 124 routine samples and 86 selected samples with known autoantibody levels were analyzed to assess the performance of the **HELIOS®** system with regard to positive/negative discrimination. Five of the 86 samples showed a discrepant reading between the **HELIOS®** and visual expert (table). Four of the discrepant samples were classified as weak speckled positive by visual examination and negative by the **HELIOS®**. Moreover, one LKS sample was discrepant negative by **HELIOS®** reading and weak positive by visual expert interpretation. Discrepant results consisted only of samples in the low titer category and this was subject to variables related to the characteristics of the substrate, of the conjugate used and to differences in a cut-off setting.

expert. The in-house validation of the system, in which over 1000 serum samples were measured, showed a 98.4% correlation of results when compared to the manual IIF procedure and visual interpretation. The negative predictive value was 100%. Automation of the IIF method provides the opportunity of reducing the variability of results between laboratories, increasing accuracy of the results and improving the correlation of staining patterns with corresponding autoantibody reactivities.

up to 20 slides

up to 4 different assays



up to 190 samples with Barcode

SLIDE BARCODE READER

Slide barcode reader ensures slide traceability. **AESKUSLIDES® IFA** reagents are barcoded with relevant manufacturing information (reference, lot, expiry date etc.), including a unique serial number. This increases process assurance for laboratory regulation compliance.

IMAGE CAPTURE

The built-in camera uses advanced autofocus algorithms to generate ultra-clear pictures which are automatically stored with patient results.

BUILT-IN LED MICROSCOPE

The integrated microscope (incorporating Nikon-based optics) is complemented by the **AESKU®** engineered motor which ensures both accuracy and speed.

SAMPLE BARCODE READER

The sample barcode reader ensures sample traceability, and eliminates hands-on processing time and transcription error.

IFA PROCESSING

Based on the **HELMED®** platform, the **HELIOS®** system is capable of performing all IFA processing steps automatically, uniquely including mounting medium dispensation, enabling complete IFA processing without human intervention.

Full traceability

No darkroom needed

Integrated slide processing and reading

Automated sample discrimination

Digital results archive

Processes up to 720 wells in a normal workday

Simple to implement in lab routine

Small footprint (4.6 ft² / 0.42 m²)

Light weight (only 68 lbs / 31 kg)

Compact Footprint

Width 1.87 ft / 57 cm Depth 2.46 ft / 75 cm
Height 2.03 ft / 62 cm Weight 68 lbs / 31 Kg

