A BRIGHT FUTURE FOR ANA - HELIOS, AUTOMATED INDIRECT IMMUNOFLUORESCENCE (IIF) ASSAY

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AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS

INTRODUCTION:

The American College of Rheumatology has reaffirmed IIF as the gold standard method for ANA testing over other methods including solid phase immunoassay. Solid phase ANA testing was gaining popularity because, through automation, it allowed higher throughput testing at a lower cost than IIF, which required manual preparation and interpretation. Solutions must therefore be developed to automate IIF testing.

OBJECTIVE:

To evaluate the **HELIOS®**, the first fully-automated, stand-alone IIF processor and reader system with positive/negative sample discrimination.

METHODS:

Two hundred samples (47 ANA negative, 70 ANA negative & ENA positive, and 83 ANA positive by ELISA) were reevaluated for ANA utilizing the **HELIOS®** system as well as manual microscopic evaluation by two different expert observers.

RESULTS:

Overall agreement between the **HELIOS®** system and the expert observers was 92%, of which a concurrence of 97.6% was observed in the ANA negative group and 90% in the ANA positive group. Notably, all discordant positive samples were characterized by very low fluorescent signal and unidentified patterns. Also of note, the **HELIOS®** system recognized a broad range of fluorescence patterns, including one esoteric pattern.
The correlation between IIF performed by the automated system or manually and ELISA test was 91%.

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.

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

BUILT-IN LED MICROSCOPE
TThe integrated microscope (incorporating Nikon-based optics) is complemented by the **AESKU®** engineered motor which ensures both accuracy and speed.
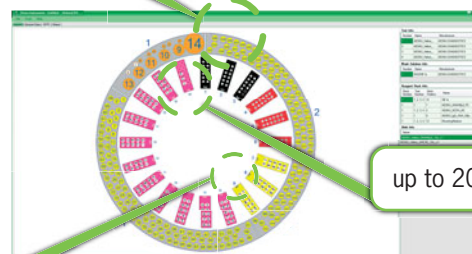
IFA PROCESSING
Based on the **HELMED®** platform, the **HELIOS®** analyzer is capable of performing all IFA processing steps automatically, uniquely including mounting medium dispensation, enabling complete IFA processing without human intervention.

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

up to 190 samples with Barcode

up to 20 slides

up to 4 different assays

BENEFITS:

- Full traceability
- No darkroom needed
- Integrated slide processing and reading
- Automated sample discrimination
- Digital results archive
- Processes up to 720 wells in a normal working day
- Simple to implement in lab routine
- Compact Footprint

CONCLUSIONS:

The **HELIOS®** system is able to correctly discriminate between ANA positive/negative samples, determined by comparison to manual IIF microscopy performed by two independent experts. This novel approach to IIF determination may reduce inter-laboratory variability and time required to perform this test, especially in high throughput laboratories.