# COMPARISON OF THE AESKU HELIOS® IFA SYSTEM WITH ANOTHER ANA SCREENING METHOD

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## Introduction:

ANA screening is widely used in routine laboratory testing within various autoimmune diseases. Achieving the highest sensitivity as well as specificity will yield more diagnostically significant and clinically relevant results and it is therefore of high interest to find the most robust system.

## Objective:

To compare the ***AESKUSLIDES®*** HEp-2 cell line processed on the first fully-automated **HELIOS®** IFA processor and reader (AESKU.SYSTEMS) to NOVA Lite® HEp-2 cell line (INOVA) processed on the PhD system (Bio-Rad Laboratories).

## Methods:

82 de-identified samples were tested on the **HELIOS®** at AESKU.INC in Oakland and processed on the PhD system at University of Pittsburgh Medical Center (UPMC). Discrepant positive samples were sub-sequently run in the BioPlex® 2200 system using the BioPlex 2200 ANA screen (Bio-Rad Laboratories). Two independent scientists evaluated the results at both locations.

## Results:

Qualitatively, 80/82 (97.6%) **HELIOS®** results were concordant with the PhD system. Titration results also correlated well. 5 out of 7 samples within two titers of the NOVA Lite® HEp-2/PhD results had higher **HELIOS®** end-point titrations (range 1:320-1:1280). 3 out of 4 samples with a distance of 3 titers had higher **HELIOS®** end-point titrations. Clinical data and BioPlex results of these 3 samples indicated autoimmune hepatitis or Sjögrens syndrome and an SS-A or Centromere result >8 (BioPlex cut-off <1.0). The clinical and diagnostic accuracy of the ***AESKUSLIDES®*/HELIOS®** reagent system is favorable based on higher end-point titrations and confirmatory data.

## Conclusions:

Many laboratories allow a comparative titer discrepancy of 1 dilution as a diagnostic convention when determining precision. Therefore, the combination of ***AESKUSLIDES®*** and **HELIOS®** analyzer has a higher sensitivity and specificity than the NOVA Lite® HEp-2/PhD system. AESKU® ANA IFA reagent systems are designed to be more clinically relevant to disease state individuals and are therefore more diagnostically significant.

### *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*

The 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.

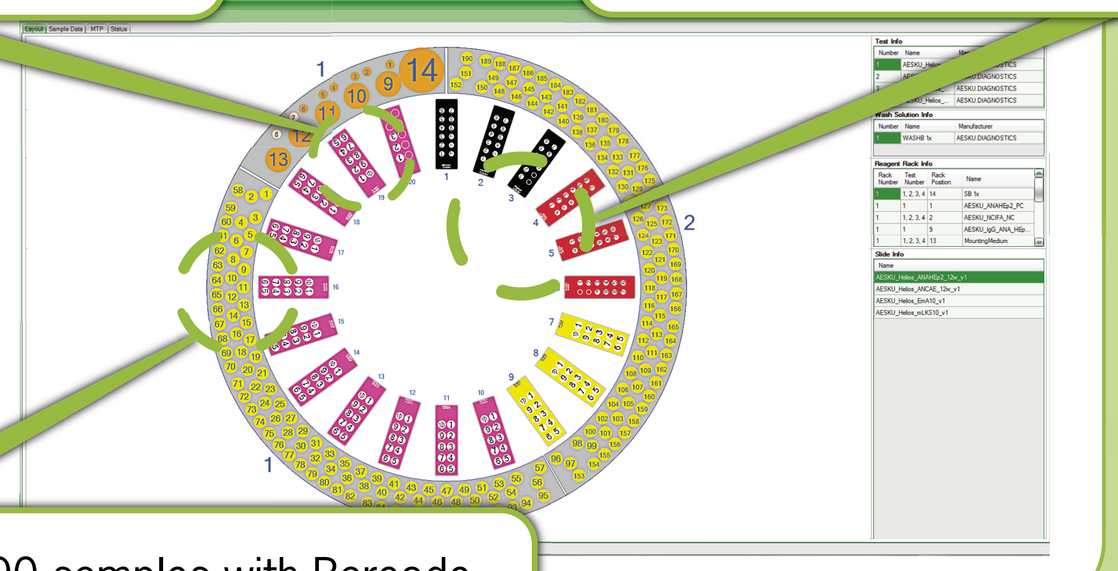
### *Compact Footprint*

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

- 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 $ft^2$ / 0.42 $m^2$)
- Light weight (only 68 lbs / 31 kg)

up to 20 slides

up to 4 different assays



up to 190 samples with Barcode