

Autoimmunity

Helios[®] Automated IFA System

All-in-one IFA solution to aid in the diagnosis of autoimmune diseases

Expand the scope of your laboratory's autoimmune diagnostic solutions with fully automated processing and review of results.

Instrument details

Helios systems are scalable to accommodate laboratories of any size.

- Up to 190 samples, 20 slides, and 4 substrates per run
- FDA-cleared Helios systems' software identifies 7 immunofluorescence patterns^{1,2}
- Integrated LED microscope with automated digital image capturing
- Customizable rack configurations to meet lab workflow needs

Optimized workflow

Helios systems enable maximum walkaway time with minimal operator touchpoints required.

- Fully automated process reduces manual interventions and potential transcription errors, including:
 - Processing and imaging on one system
 - Onboard system predilutions
 - Screening, reading, and titration
 - Pipette mounting media onto completed wells to preserve results
- Proprietary software allowing quick call out of negative/positive results to proper next steps (reflexing, titer/pattern, etc.)
- Connects to LIS for seamless reporting, reflexing, and remote confirmation

High quality

Helios systems deliver confidence with accurate, consistent, and high-quality results.

- Integrated humidity and temperature control (HTC) module helps ensure standardization of humidity and temperature regardless of hourly and seasonal changes in testing microenvironment
- Brings the gold standard of ANA screening to the benchtop³
- Controlled liquid management system ensures consistent incubation times and avoids cross-contamination



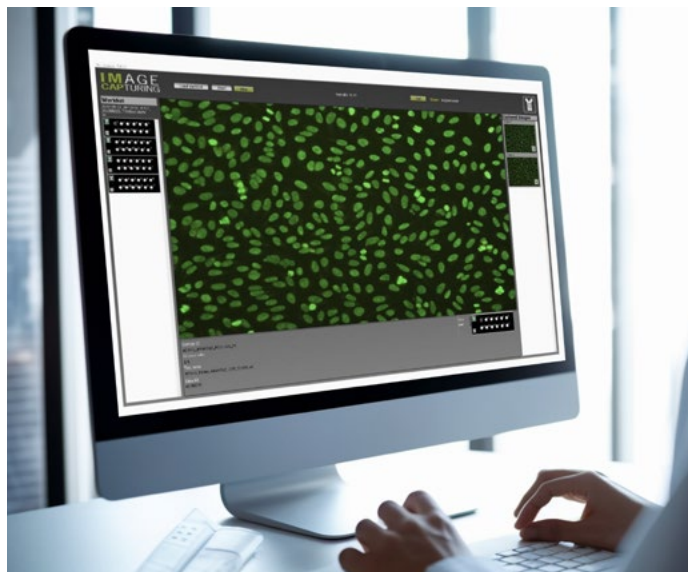
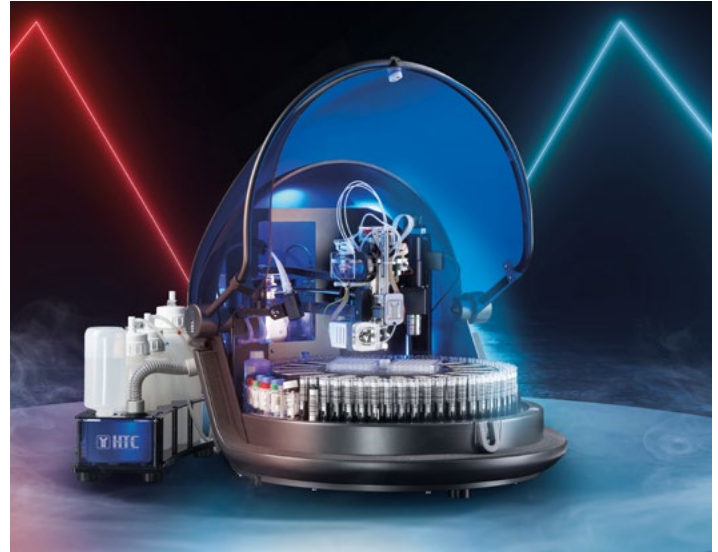
Helios Automated IFA System

Aids in the diagnosis of autoimmune diseases

Menu of automated tests

Helios systems offer FDA-cleared pattern and end-point titer analysis for:

- ANA by HEp-2
- ANCA by ethanol-fixed granulocytes
- ANCA by formalin-fixed granulocytes
- dsDNA by *Crithidia luciliae*



Dynamic software for improved IFA results

Helios systems can help take the uncertainty and tediousness out of IFA testing.

- Digital pattern resolution images that can be archived
- “Patient view” shows all results on one screen, offering ease of interpretation
- Software-suggested estimated endpoint titer
- Large digital library, reference images and pattern atlases assist with classification
- Computer-aided interpretation reduces overall imprecision over manual interpretation
- Intuitive software organizes samples by fluorescent intensity for confirmation of negative results

Interested in adding a Helios system to your lab? **Contact an expert.**

References

1. Evans R. AESKU receives FDA clearance Helios automated IFA system [internet]. Medical Design & Outsourcing; 2016 Aug 1 [cited 2024 June 18]. Available from: <https://www.medicaldesignandoutsourcing.com/fda-clearance-helios-auto-ifa-system/>. 2. 510(k) Substantial Equivalence Determination Decision Memorandum [internet]. US Food and Drug Administration [cited 2024 June 18]. Available from: https://www.accessdata.fda.gov/cdrh_docs/reviews/K153117.pdf. 3. Khalifah MJ, Almansouri O, et al. Comparison of Indirect Immunofluorescence and Enzyme Immunoassay for the Detection of Antinuclear Antibodies. Cureus. 2022 Nov 3;14(11):e31049. doi: 10.7759/cureus.31049. PMID: 36475172; PMCID: PMC9719102.

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