

nDNA (Crithidia luciliae) now FDA cleared with HELIOS System

AESKU Receives FDA 510(k) Clearance for nDNA (Crithidia luciliae) with the HELIOS AUTOMATED IFA SYSTEM

(Wendelsheim, Germany / Oakland, California,) AESKU.GROUP – a science-focused manufacturer of innovative products and services for the early detection, diagnosis, and prognosis of autoimmune, allergy, and infectious disease – received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for AESKUSLIDES nDNA (Crithidia luciliae) with the new HELIOS AUTOMATED IFA SYSTEM. The kit is the second FDA cleared immunofluorescence assay on the HELIOS, after ANA HEp-2 (cleared in 2016), and will be followed by ANCA and tissue section slides.

“Laboratories have continued to return to IFA testing ever since the 2009 ACR position statement, which asserts that IFA is the Gold Standard for systemic autoimmune disease screening. The HELIOS improves traceability and turnaround time and eliminates the subjectivity and labor-intensiveness of immunofluorescence assays, so labs can follow the ACR recommendations and ultimately improve the quality of patient testing.” said Dr. Matthias, founder and CEO of the AESKU.GROUP.

“Laboratories performing IFA will be able to screen for ANA's and then reflex to a very specific assay to detect anti-dsDNA antibodies using the most automated system on the market: the HELIOS. This a great tool to help clinicians diagnose Lupus patients. We look forward to making this kit available on the HELIOS to US clinical laboratories with the help of Grifols, our exclusive distribution partner in the US,” said Bruno Larida, Vice-President AESKU. INC.



The HELIOS is a revolutionary platform that both processes and analyzes patient immunofluorescence (IFA) samples in a single run. It is the first and only clinical platform to offer this level of IFA automation, overcoming the previous limitations of IFA testing and letting users return to the gold-standard method for Autoimmunity screening. Over 300 HELIOS systems are in clinical use worldwide, in over 40 countries.

Kimberly Pacella, Director of Clinical Operations at HNL in Allentown, PA chose the HELIOS to address a surge in IFA orders: *“in order to absorb all that volume without adding staffing, we need to be able to do things more efficiently. This [HELIOS] will absolutely help with that,”* said Pacella.

The HELIOS system and its FDA cleared kits will be displayed at the American Association of Clinical Chemistry meeting and is available in the U.S.

“Our pathology network, SDS Laboratories, has 9 Helios platforms installed in various laboratories throughout Australia. The level of scientific and technical support offered with the systems has been exemplary and unparalleled in my years of experience in diagnostic pathology.” “On this basis, I have no hesitation in offering my avid recommendation of the products and support of Aesku.”

Lucinda Wallman MB BS PhD FRACP FRCPA, Clinical Immunologist and Immunopathologist, Director of Immunology, Laverly Pathology

In addition to the HELIOS, AESKU offers a range of innovative and flexible solutions to meet laboratories' needs in the complex and connected diagnostic testing space.

A powerful software engine and middleware, AESKU.LAB allows centralized management of any LIS connected analytical instrument in the world.

Tailored to each laboratory's unique testing algorithms, AESKU.LAB adds efficiency to any workflow and streamlines the daily routine.

For additional information please visit www.whatishelios.com

About AESKU.GROUP

AESKU.GROUP (www.aesku.com) is headquartered in Wendelsheim, Germany and is made up of the following divisions: AESKU.DIAGNOSTICS, AESKU.THERAPY (Autoimmune Therapies), AESKU.SYSTEMS (Lab Automation), AESKU.INC (North American headquarters based in Oakland, CA), AESKU.NY (IFA Manufacturing and Research).

Besides its own outstanding commitment to research and development, AESKU.GROUP initiated and supports the AESKU.KIPP INSTITUTE, a non-profit organization, primarily active in basic research and interdisciplinary knowledge transfer in autoimmunity.

