FDA-cleared automated IFA system, 9/16

September 2016—Aesku Group has received FDA 510(k) clearance for its Helios Automated IFA System with Aeskuslides ANA HEp-2-Gamma Assay. The Helios is an automated system for immunofluorescence processing with image capturing with an integrated fluorescence microscope and software. Results must be confirmed by a trained user. The Helios was designed to overcome the known limitations of IFA, enabling the user to adopt it as the autoimmunity reference screening method. The next assays to be cleared are ANCAs, *Crithidia luciliae*, and tissue sections.

Grifols is the exclusive U.S. distributor of the platform.

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