FDA-cleared automated microscope, 9/16

September 2016—Immuno Concepts announced that its Image Navigator automated microscope received 510(k) clearance. Image Navigator is a software program that controls a high-quality LED fluorescent microscope with a motorized stage to simplify and organize indirect fluorescent antibody testing. It automatically captures images of each specimen, sorts the images into "possible negative" and "possible positive" categories with a precision greater than 97 percent, and displays them for final review and confirmation by the medical laboratory scientist. Comprehensive separate review screens allow users to assign multiple patterns, order and read titers, and order additional testing within the software. The system is scalable and communicates with pipetting systems and with LIS hosts.

Immuno Concepts, 800-527-2320