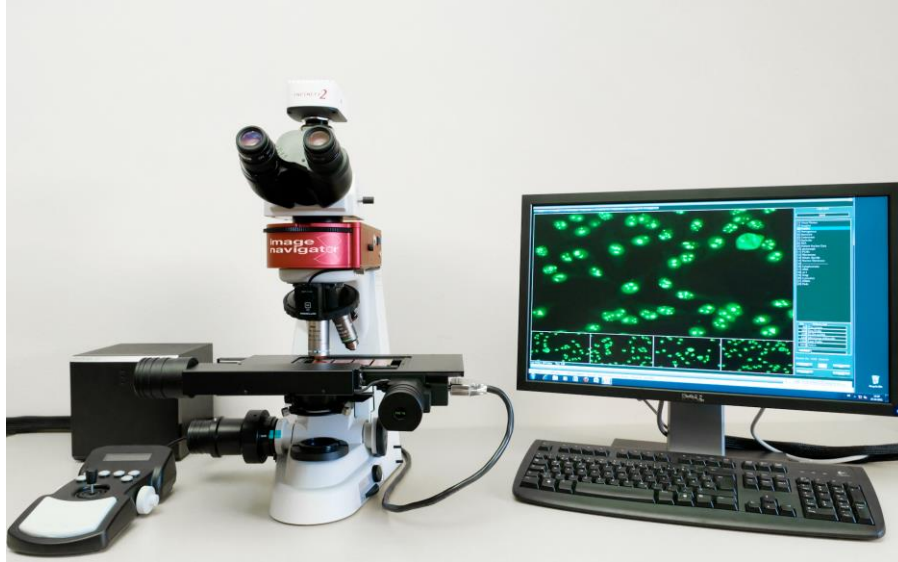


Image Navigator[®] automated microscope receives FDA 510(k) clearance



Sacramento, June 17, 2016 – Immuno Concepts, a recognized leader in innovation of autoimmune diagnostic reagents and instrumentation, is pleased to announce that the United States Food and Drug Administration (FDA) has cleared the Image Navigator[®] automated microscope through the 510(k) process.

The indirect immunofluorescent (IIF) test has long been the gold standard for determination of Anti-Nuclear Antibodies (ANA). The innovative Image Navigator[®] is a solution that eliminates the usual tedious labor of the IIF test, while still allowing the laboratory professional to control the interpretation and reporting of these tests.

Image Navigator[®] is a software program that controls a high quality LED fluorescent microscope with a motorized stage to simplify and organize IFA testing. It automatically captures images of each specimen, sorts the images into “possible negative” and “possible positive” categories with a precision >97%, and displays them for final review and confirmation by the Medical Laboratory Scientist. Comprehensive separate review screens allow the MLS to assign multiple patterns, order and read titers, and order additional testing within the Image Navigator[®] software. The system is scalable and communicates with pipetting systems and with LIS hosts.

“The Image Navigator[®] represents a significant step forward for a well-proven, traditional laboratory test,” commented Eric S. Hoy, Ph.D., SI(ASCP), Chief Scientific Officer of Immuno Concepts. “The ANA test is an outstanding screening test for connective tissue disease, but the labor intensive nature and subjective interpretation of the fluorescent ANA assay have limited its use. Previous attempts to automate the ANA test using other immunoassay techniques have fallen short of the fluorescent ANA. The Image Navigator[®] combines traditional fluorescent microscopy



with modern digital technology to eliminate the repetitive, monotonous tasks of the fluorescent ANA, freeing the laboratory professional to perform other tasks until it is time to use the professional's skills in reading and interpreting the assay. The Image Navigator[®] is based on a standard fluorescent microscope, and the ANA is performed using the same slides and reagents as are used in Immuno Concepts regular ANA kits. There are no "magic ingredients" or special conditions for the ANA test. The slides can be read manually on the Image Navigator[®] microscope, or any other fluorescent microscope using standard techniques. This system truly saves labor, increases accuracy, and helps assure reproducibility of the fluorescent ANA test."

In the USA, schedule a demonstration of our solution for total automation of IFA testing by calling 1.800.527.2320 or emailing demo@immunoconcepts.com. Outside the US, contact your local Immuno Concepts distributor.

About Immuno Concepts

In 1979, Immuno Concepts pioneered the industry conversion from rodent tissue to HEp-2 cells for detection of ANA's. We followed up with HEp-2000[®], the only patented ANA substrate genetically enhanced to improve sensitivity for detection of autoantibodies to the SS-A/Ro antigen. Today, Immuno Concepts has the automated solution for IFA assays, the Image Navigator[®]. Together, the family of AFT pipetting instruments and Image Navigator[®] can process a patient sample from collection tube to final result, with better reproducibility and accuracy than manual methods. Come see what's next at <http://www.immunoconcepts.com>.

Press Contact

Bert R. Williams, III
President of Immuno Concepts
1.800.527.2320
bert@immunoconcepts.com