FDA clearance for BioMérieux products, 9/15

At the AACC show 2015

BioMérieux announced the FDA 510(k) clearance and commercial availability of Vidas 3, the new generation of Vidas. Vidas 3 features enhanced automation, in particular the preanalytical section from the barcoded primary tube including dilution, improved traceability, and new software capabilities, as well as a quality control program in compliance with laboratory certification standards. Vidas 3 is CE marked and registered at the Chinese Food and Drug Administration.

Before the meeting, BioMérieux announced FDA clearance of its Vidas Lyme IgG II and Vidas Lyme IgM II assays to detect Lyme disease in 27 minutes. These tests provide rapid and differential detection of Borrelia burgdorferi infection and allow classification of the infection in early or late stages. Use of recombinant proteins provides the sensitivity and specificity to detect the main disease-causing Borrelia strains, reducing cross-reactivity to other infectious diseases. Because they detect IgM and IgG antibodies separately, the new assays reduce the number of confirmatory tests needed.

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