FDA approves Cobas Babesia

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Sept. 20, 2019–Roche received FDA approval for the Cobas Babesia test for use on the Cobas 6800 and Cobas 8800 systems. It is a qualitative in vitro nucleic acid screening test for the direct detection of babesia (*B. microti, B. duncani, B. divergens,* and *B. venatorum*) DNA and RNA in whole blood samples from individual human donors, including donors of whole blood and blood components, and other living donors.

"We are dedicated to helping save patients' lives by providing advanced solutions to enable the protection of the global blood supply from infectious diseases. With the approval of Roche's first whole blood test used in blood screening we can help health care professionals further diminish potential risks of infection from transfused blood products," Thomas Schinecker, head of Roche Diagnostics, said in a company press release. "In addition, we hope to help customers improve their lab efficiency by simplifying sample prep while ensuring maximum detection of infectious pathogens in the blood and the safety of the blood supply for the patients we serve."

The FDA published in May a final guidance on recommendations for reducing the risk of transfusion-transmitted babesiosis.