Roche HIV 1/2 qualitative test approved on Cobas 6800/8800

Sept. 1, 2020—Roche announced FDA approval for the Cobas HIV-1/HIV-2 Qualitative test for use on the fully automated Cobas 6800/8800 systems in the United States. The Cobas HIV-1/HIV-2 Qualitative is an in vitro nucleic acid amplification test for the qualitative detection and differentiation of human immunodeficiency virus type 1 and type 2 RNA in human serum and plasma.

"Being able to reliably determine a person's HIV status and accurately diagnose which HIV type they may have is crucial for patients and health care providers in preventing further community transmission and selecting an individual's best treatment options," Thomas Schinecker, CEO Roche Diagnostics, said in a press statement.

The Cobas HIV-1/HIV-2 Qualitative may also be used as an additional test to confirm the presence of HIV-1 or HIV-2 infection in an individual with specimens reactive for HIV-1 or HIV-2 antibodies or antigens.