FDA-approved tests for Roche instruments, 9/17

September 2017—Roche received FDA approval for the Cobas CMV test for use on its Cobas 6800 and Cobas 8800 Systems. The test is standardized to the 1st WHO International Standard for improving harmonization in cytomegalovirus testing results across hospital institutions.

Cobas CMV is a real-time polymerase chain reaction test designed to offer an expanded linear range from 34.5 IU/mL to 1E+07 IU/mL with robust coverage across genotypes. The test aims to minimize variability and complexity in testing, offering an alternative to laboratory-developed tests.

The fully automated test can be run simultaneously with HIV-1 or HCV assays on the Cobas 6800/8800 Systems.

Roche also received FDA 510(k) clearance and CLIA waiver for the Cobas Influenza A/B & RSV test for use on the Cobas Liat System. The real-time PCR test differentiates flu and respiratory syncytial virus in 20 minutes. RSV is a cause of more than 80 percent of acute lower respiratory tract infections in infants under one year of age.

Roche launched the MagNA Pure 24 System, a fully automated clinical sample extractor capable of extracting nucleic acids from a wide range of human sample types with a single universal reagent kit. The system offers an extraction solution with onboard primary sample handling for low- to medium-throughput customers and delivers walkaway automation while minimizing hands-on time and purification variability. The system is IVD/CE-IVD labeled and available in most countries, including the U.S. and countries accepting the CE mark.

***Roche**, 317-521-2000*