FDA approves Hologic Aptima CMV Quant assay

May 16, 2022—Hologic announced that the FDA approved its Aptima CMV Quant assay for quantifying the viral load of cytomegalovirus in patients who have had solid organ or stem cell transplants. The test runs on the company's fully automated Panther system.

"It is imperative to have highly accurate, reproducible results to monitor viral load trends of CMV infections over time in plasma of transplant patients," Karen Harrington, PhD, head of scientific affairs for diagnostic solutions at Hologic, said in a press statement. "Our assay aligns with the international quantitative standards, offering laboratories and health care providers confidence in the results each and every time, ultimately helping to enhance patient management and outcomes."

The Aptima CMV Quant assay also is CE marked for diagnostic and viral load monitoring use in Europe. The company says it intends to pursue regulatory approvals for other transplant assays that are in development, including BK virus and Epstein-Barr virus.