FDA clears Panther Fusion SARS-CoV-2/Flu A/B/RSV assay

May 24, 2023—Hologic announced the FDA has granted 510(k) clearance for its Panther Fusion SARS-CoV-2/Flu A/B/RSV assay. This molecular diagnostic test, previously under EUA, detects and differentiates SARS-CoV-2, influenza A and B, and respiratory syncytial virus. It runs on the Panther Fusion system, which provides initial results in about three hours and can process more than 1,000 tests in 24 hours. The assay launches with the new RespDirect collection kit, which enables laboratories to load samples directly on the Panther Fusion system without uncapping or performing specimen transfer steps.