FDA clears QuidelOrtho Savanna platform, HSV 1+2/VZV assay

Dec. 21, 2023—QuidelOrtho has received FDA 510(k) clearance for its Savanna PCR platform and Savanna HSV 1+2/VZV in vitro diagnostic test for the detection and differentiation of herpes simplex virus types 1 and 2 and varicella zoster virus nucleic acids isolated and purified from swabs obtained from cutaneous or mucocutaneous lesion specimens from symptomatic patients.

“The Savanna platform’s small footprint hides a powerful set of features, such as integrated sample prep combined with rapid real-time PCR amplification and detection technologies, making it a perfect fit for syndromic testing in hospitals and moderate-complexity labs, with the goal of eventually accessing physician offices, urgent care clinics, and other point-of-care locations,” Douglas Bryant, president and chief executive officer of QuidelOrtho, said in a press release.

The platform enables users to analyze up to 12 pathogens or targets, plus up to four controls, from a single test run in about 25 minutes, depending on the assay. Once the test panel cartridge is inserted into the platform, the instrument performs sample and reagent preparation, nucleic acid extraction and amplification, real-time detection of RNA or DNA target sequence, and qualitative or quantitative result interpretation from a variety of sample types.