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

January 2024—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 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.

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