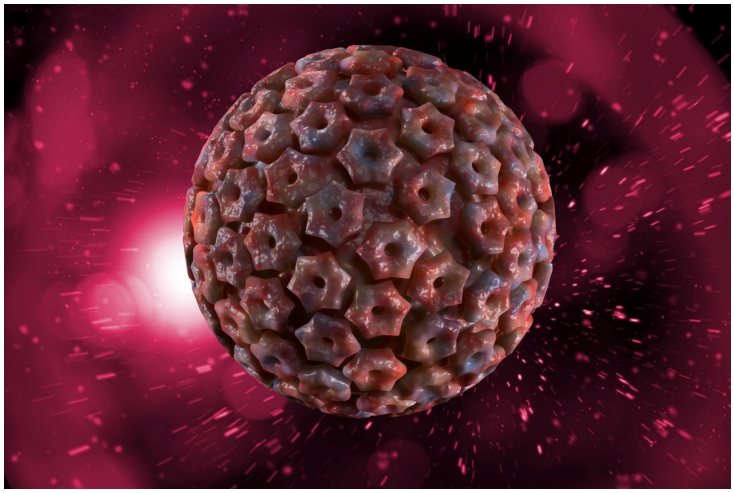
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Korea's Seegene receives US FDA Emergency Use Authorisation for Multiplex PCR Assay

July 22, 2026 | News

Advancing differential diagnosis of HSV-1&2, VZV, and Monkeypox Virus for ulcerative skin lesions



South Korea-based Seegene, Inc., a global leader in molecular diagnostics, has announced that its US subsidiary, Seegene USA, Inc, has received an Emergency Use Authorisation (EUA) from the US Food and Drug Administration (FDA) for the Allplex™ HSV-1&2/VZV/MPXV Assay, a multiplex real-time PCR assay designed to simultaneously detect multiple viral pathogens associated with clinically overlapping lesion presentations.

Unlike molecular tests currently available that target a single pathogen or a limited pathogen group, the assay is designed to enable the concurrent detection of herpes simplex virus type 1 and type 2 (HSV-1, HSV-2), varicella-zoster virus (VZV), and monkeypox virus (MPXV) in a single test. The Allplex™ HSV-1&2/VZV/MPXV Assay is the first multiplex PCR test designed to simultaneously and differentially detect viral pathogens of ulcerative skin lesions in the US market.

The Allplex™ HSV-1&2/VZV/MPXV Assay was developed end-to-end at Seegene USA using Seegene's proprietary high-multiplex PCR technologies, including Dual Priming Oligonucleotide (DPO™), Tagging Oligonucleotide Cleavage and Extension (TOCE™), and Multiple Detection Temperatures (MuDT™), and its automated product development platform (Seegene Digitalised Development System).

With this authorisation, Seegene USA is positioned to expand its portfolio of locally developed multiplex PCR assays for the US market.