FDA clearance for herpes simplex virus molecular test, 5/15

May 2015—Seegene announced that the Food and Drug Administration has granted 510(k) market clearance for its TOCE-based herpes simplex virus types 1 and 2 assay. This is the first product Seegene has taken through the FDA, and it opens the way for the company's other planned FDA submissions of multiplex real-time PCR reagents.

The company aims to establish a new U.S. subsidiary in 2015 and seeks to further accelerate its growth in the global molecular diagnostic market. Seegene will also continue to evolve its Allplex family of infectious disease panel tests for the U.S. market.

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