

## CE mark for herpes virus test, 9/16

**September 2016**—SpeedX received CE-IVD marking for its PlexPCR HSV-1&2, VZV multiplex qPCR kit. The multiplex molecular diagnostic test offers a single-well solution to cover the detection and differentiation of three herpes viruses (HSV-1, HSV-2, VZV) in addition to an internal control. Validated for use on multiple lesion specimen types, the test is designed to streamline herpes testing workflows and support appropriate clinical and therapeutic management for infections that present similarly.

SpeedX also announced that a study, published in PLoS One (Tabrizi SN, et al. 2016;11[6]:e0156740), found using a beta version of PlexPCR *M. genitalium* ResistancePlus shows strong results in the detection of *M. genitalium* and mutations in the 23S rRNA gene of the bacteria that have been shown to confer resistance to commonly prescribed macrolide-based antibiotics. The assay was evaluated in 400 samples from 254 (186 males and 68 females) consecutively infected participants, undergoing tests of cure. Using the MG 23S assay, 83 percent (331/400) of samples were positive, with 56 percent of positives carrying a macrolide resistance mutation. Due to the detection of macrolide resistance, broad-spectrum antibiotics, including azithromycin therapy, would not be an effective treatment for more than half the patient samples included in this study.

In a separate announcement, the company entered into a distribution agreement with Goffin Molecular Technologies, based in Beesd, the Netherlands, which will sell the SpeedX PlexPCR and ResistancePlus multiplex real-time PCR product lines in the Belgium, Netherlands, and Luxembourg markets.

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