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A multicenter prospective trial to asses a new real-time polymerase chain reaction for detection of *Treponema pallidum*, Herpes simplex-1/2 and *Haemophilus ducreyi* in genital, anal and oropharyngeal ulcers

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Running title: PCR for genital, anal or oral ulcer disease

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Abstract

Treponema pallidum, herpes simplex virus types 1 or 2 (HSV-1/2) and Haemophilus ducreyi are sexually transmitted pathogens that can cause genital, anal and oropharyngeal ulcers.

Laboratory evaluation of these pathogens in ulcers requires different types of specimens and tests, increasing the risk for improper specimen handling and time lapse until analysis. We sought to develop a new real-time PCR to facilitate the detection of *T. pallidum*, HSV-1/2 and *H. ducreyi* in ulcers. The new real-time PCR was tested (1) in a retrospective study on 193 specimens of various clinical origin; (2) in a prospective study on 36 patients with genital, anal or oropharyngeal ulcers (ClinicalTrials.gov # NCT01688258). The results of the new real-time PCR were compared with standard diagnostic methods (*T. pallidum*: serology, dark field microscopy; HSV-1/2: PCR; *H. ducreyi*: cultivation). Sensitivity and specificity of the new real-

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