PERFORMANCE ASSESSMENT OF THREE PCR ASSAYS FOR THE DETECTION OF MULTIPLE STRAINS OF *MYCOPLASMA GENITALIUM* AS WELL AS THEIR *ASSESSMENT* IN CLINICAL STRAINS

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Introduction: *Mycoplasma genitalium* (MG) is an emerging sexually transmitted infection. It is often asymptomatic and has been associated with cervicitis, and PID in women and urethritis and persistent NGU in men.

Methods: We evaluated three PCRs for MG: the SpeeDx RsistancePlus MG assay, based on the *MgPa* gene, and two qPCR research MG assays for the *16S rRNA* and *pdhD* genes. The limit of detection (LOD) for the two research assays was determined 11 MG strains with 7 ten-fold serial dilutions from laboratory stocks of the following strains: G: G37, M2300, M2321, M2341, M30 Early, M6271, M6302, M6303, M6320, M6604, and M6926. Inclusivity testing was performed for the above organisms, while exclusivity testing was performed on 14 non-genitalium Mycoplasma species. The three assays were performed on 325 prospectively self-collected clinical vaginal samples from a cohort of adolescents and young adults. Patient sample test results for the three assays were compared to a “patient infected status”: the reference standard for true positives required at least 2 of 3 positive tests.

Results: By probit analysis, the pdhD assay had an LOD of 1324 copies/reaction, while the 16S PCR had an LOD of 1536 copies/reaction. All inclusivity/exclusivity testing performed as expected. The ResistancePlus MG assay had 96% sensitivity (24/25) and 99% specificity (296/300) Kappa=0.89 [95% CI: 0.81-0.99] while the 16S PCR had 96% sensitivity (24/25) and 100% specificity (300/300) Kappa=0.98 [95% CI: 0.94-1]. The pdhD PCR had 100% sensitivity (25/25) and 100% specificity (300/300) Kappa=1 [1-1]. The ResistancePlus MG assay demonstrated a rate of *23S*-gene mutants of 48% (12/25) in this cohort, where the MG prevalence was 7.7%.

Conclusions: The ResistancePlus MG assay compared very well to the lab developed qPCR assays. The ResistancePlus MG assay provides additional useful information for azithromycin resistance, in addition to identification of MG.