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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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BACKGROUND/AIMS & METHODS:

- *Mycoplasma genitalium* (MG) is an emerging STI
  - ✓ associated with cervicitis, and PID in women
  - ✓ urethritis and persistent NGU in men
- MG is often asymptomatic and because of its sequelae it is important to be able to rapidly diagnose and treat such infections
- The study aims were to evaluate 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.

- We determined the LOD, for the 2 research assays using 11 MG strains w/ 7 serial 10x dilutions from 11 strains
- We evaluated the assays on 325 prospectively self-collected clinical vaginal samples from a cohort of adolescents & young adults
- Inclusivity testing was performed for 11 strains, while exclusivity testing was performed on 14 non-genitalium Mycoplasma species
- Study assessment: 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.
- Statistical analysis: Probit analysis used for LOD and sensitivity and specificity were determined

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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]
- 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 [95% CI: 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/IMPLICATIONS:

- The ResistancePlus MG assay compared very well to the lab developed qPCR assays.
- The ResistancePlus MG assay provides additional useful molecular information for azithromycin resistance, in addition to identification of MG.
- The implications for research establish that the ResistancePlus MG assay will assist future epidemiological research by providing a commercial assay, easily adapted for use by laboratories, for clinicians to have rapid and useful information for diagnosing and treating MG infected patients.
- This work has a positive impact on the community for accurately diagnosing MG infected patients, as well as guide antibiotic therapy.
- Since the ResistancePlus MG assay demonstrated high sensitivity and specificity compared to two highly regarded lab-developed research qPCR assays, this information will provide further evidence for its future use in clinical practice.