RESISTANCEPLUS MG FLEXIBLE FOR THE GENEXPERT ENABLES NEAR PATIENT TESTING OF MYCOPLASMA GENITALIUM AND MACROLIDE RESISTANCE MARKERS

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Aim: Molecular assays that detect *Mycoplasma genitalium* (Mgen) and presence of macrolide resistance markers such as *ResistancePlus*® MG, have enabled clinicians to implement resistance-guided therapy for Mgen infections. This is a crucial strategy in the management of STIs, with the challenge of increasing antimicrobial resistance and limited treatment options, where syndromic management may no longer be adequate. The *ResistancePlus* MG test is intended for testing in centralised laboratories, however there is also a demand for clinics with onsite STI testing and to improve workflow for small to medium laboratories. Therefore, the *ResistancePlus* MG FleXible was developed to run on the GeneXpert. Here, we evaluated the clinical performance of *ResistancePlus* MG FleXible.

Method: Clinical performance of *ResistancePlus* MG FleXible was evaluated on 68 Mgen positive and 116 Mgen negative samples (performed at the University of Queensland). Mgen detection was compared to a MgPa real time PCR assay and detection of the 23S rRNA mutations was compared to *ResistancePlus* MG (performed on the ABI 7500 Fast Dx).

Results: Compared to the reference methods, *ResistancePlus* MG FleXible was shown to have 97.1% sensitivity and 99.1% specificity for detection of Mgen, and 100% sensitivity and 100% specificity for the detection of 23S rRNA mutants.

Conclusion: With the availability of *ResistancePlus* MG FleXible for use on the GeneXpert instrument, clinicians can have faster access to patient results for both Mgen infection and macrolide resistance, allowing wider implementation of resistance-guided therapy.

Conflicts of interest: Non-SpeeDx employees received funding from SpeeDx supporting this work. Corey Oostendorp, Tina Lonergan, Rachel Wee, Akanksha Arvind and Litty Tan are employees of SpeeDx and have shares in the company.

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