

“Near-patient” testing for *Mycoplasma genitalium* and macrolide resistance mutations – how does it compare to standard testing?

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Background

Antibiotic resistance in *Mycoplasma genitalium* (MG) is increasing globally. The ResistancePlus MG FleXible (SpeeDx) is a “near-patient test” capable of detecting MG and four macrolide-resistance mutations (MRM), enabling rapid reporting of results and tailored therapies in clinical settings. In this study we compared the performance of the ResistancePlus MG FleXible assay with the standard of care reference assay, ResistancePlus MG (SpeeDx).

Methods

Samples were collected from patients presenting to Melbourne Sexual Health Centre with indications for MG testing between May and October 2019. A urine or vaginal/rectal swab was provided for standard diagnosis by the reference assay. An additional specimen was collected for testing on the ResistancePlus MG FleXible assay. Test concordance was determined using positive percent agreement (PPA), negative percent agreement (NPA), and kappa statistic. Samples with discordant results for MRM detection underwent sequencing of the 23S rRNA gene.

Results

For 270 valid tests, the ResistancePlus MG FleXible assay yielded a high PPA of 94.1% (96/102; 95%CI: 87.6-97.8%) and NPA of 95.2% (160/168; 95%CI: 90.8-97.9%) for MG detection compared to the reference assay (kappa for test concordance of 0.89; 95%CI: 0.83-0.95). Performance was similar across different sample types. For the detection of MRM, ResistancePlus MG FleXible had a PPA of 97.1% (66/68;

95%CI: 89.8-99.6) and NPA of 78.6% (22/28; 95%CI: 59.0-91.7), with test comparison kappa of 0.79 (95%CI: 0.65-0.93). Of six discordant results (i.e. MRM positive by the FleXible test and wild type by the reference assay), five were positive for MRM by Sanger sequencing.

Conclusion

In comparison to the standard of care test, the ResistancePlus MG FleXible assay demonstrates excellent agreement in performance for MG detection and higher sensitivity for MRM detection. This assay has the potential to improve patient management by delivering rapid results and may be an efficient modality for resistance-guided therapy of MG.

Disclosure of Interest Statement

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