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Clinical evaluation of two commercial assays for the detection of fluoroquinolone resistance in *Mycoplasma genitalium*

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Background

The increasing frequency of fluoroquinolone resistance is an emerging issue in the treatment of *Mycoplasma genitalium* infection. We aimed to evaluated the performance and handling characteristics of two Research Use Only commercial kits for the detection of fluoroquinolone resistance-associated mutations:

- the **MGMO qPCR (NYtor)**, a multiplex real-time Taqman-based PCR kit, which detects four *parC* mutations associated with fluoroquinolone resistance (Ser83Ile, Ser83Arg, Asp87Asn, Asp87Tyr)
- the LightMix Modular parC (TIBMOLBIOL) kit, which is a FRET-based real-time PCR kit detecting *parC* alterations.

Materials

A total of 374 remnants of *M. genitalium*-positive specimens collected between 2018 and 2020 at the French National Reference Center for Bacterial Sexually Transmitted Infections in Bordeaux University Hospital, France, were assessed according to the manufacturer's instructions. Results were compared to those of *parC* Sanger sequencing used as the reference method. Mutations Ser83Ile, Ser83Arg, Asp87Asn, Asp87Tyr, and Gly81Cys were considered as associated with fluoroquinolone resistance based on the literature.

Results

The percentage of invalid and uninterpretable results was 2.1% (8/374) and 4.8% (18/374) for the NYtor and the TIBMOLBIOL kits, respectively.
The clinical sensitivity for fluoroquinolone resistance detection was 93.2% (95% confidence interval (CI), 85.1-97.1) and 98.6% (95%CI, 92.4-99.8%) for the NYtor and the TIBMOLBIOL kits, respectively, with no significant difference between both kits. The NYtor kit missed three samples harboring the Gly81Cys mutation because the NYtor kit was not designed to detect this substitution.
The clinical specificity for resistance detection was 100% (95%CI, 98.7-100%) for the NYtor kit, significantly higher that of the TIBMOLBIOL kit (95.4%; 95%CI: 92.3-97.3%). Among the 13 false resistant results obtained with the TIBMOLBIOL kit, 11 specimens harbored ParC substitutions not likely to be associated with fluoroquinolone resistance.
Regarding data analysis, results from the NYtor kit were easy to interpret whereas analysis of the amplification curves from the TIBMOLBIOL kit was more subjective and required comparison with curves from wild-type and mutated controls.

Conclusion

Kits detecting fluoroquinolone resistance in *M. genitalium* will be helpful for the resistance-guided therapy of *M. genitalium* infection. The NYtor kit showed higher specificity and easier data interpretation than the TIBMOLBIOL kit.