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Rapid and accurate detection of *Mycoplasmataceae* in clinical samples

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Background

M. genitalium (MG), *M. hominis* (MH), *U. parvum* (UP) or *U. urealyticum* (UU) are bacteria without a cell wall. They are either considered as pathogenic or commensal living organisms in the urogenital tract. They belong to the category of sexually transmitted infections in men and women. Especially MG is associated with urethritis (esp. in men) and bacterial vaginosis in women. In addition, the presence of MG has a higher risk of preterm birth or spontaneous abortion (OR 1,8) or female infertility (OR 2,4)¹. Therefore, rapid and accurate diagnostic tools are necessary for their detection in clinical specimen. The Vivalytic instrument is a new PCR platform using either multiplex RT PCR or microarray for detection of nucleic acids from microbes. The easy-to-use cartridge system can be used in the micro lab or as a point-of-care test (POCT).

Methods

239 urogenital samples (132 urine and 107 swabs) were tested in our hospital. The swabs were a mixture from 26 vaginal, 37 cervical, 19 urethral and 25 rectal swabs. As transport medium, eNAT® 608C medium (COPAN Italia) was used. The Vivalytic MG, MH, UP/UU test (Bosch Healthcare Solutions, Waiblingen, Germany) is an automated qualitative in vitro diagnostic test based on real-time polymerase chain reaction (PCR; Fig. 1) for the detection of nucleic acids from *Mycoplasma genitalium*, *Mycoplasma hominis* and *Ureaplasma parvum/urealyticum* from human urine samples or human swab (cervical, vaginal, urethral, rectal) samples to aid in diagnosis of sexually transmitted infections of symptomatic and asymptomatic individuals. All samples were compared to the Allplex STI Essential Assay (Seegene, Seoul, South Korea) as reference test. To achieve comparable results both tests were performed within 48 hours.

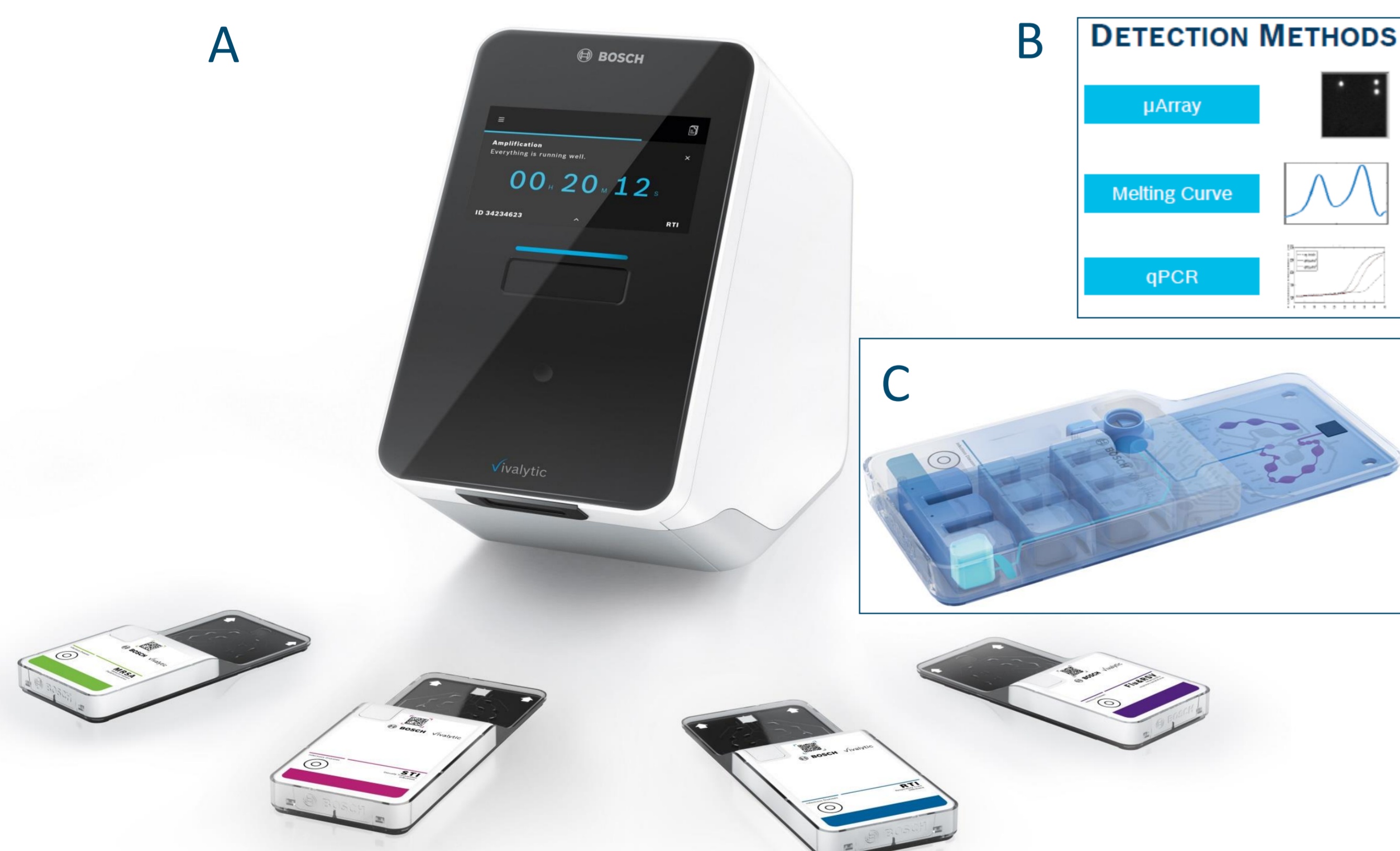
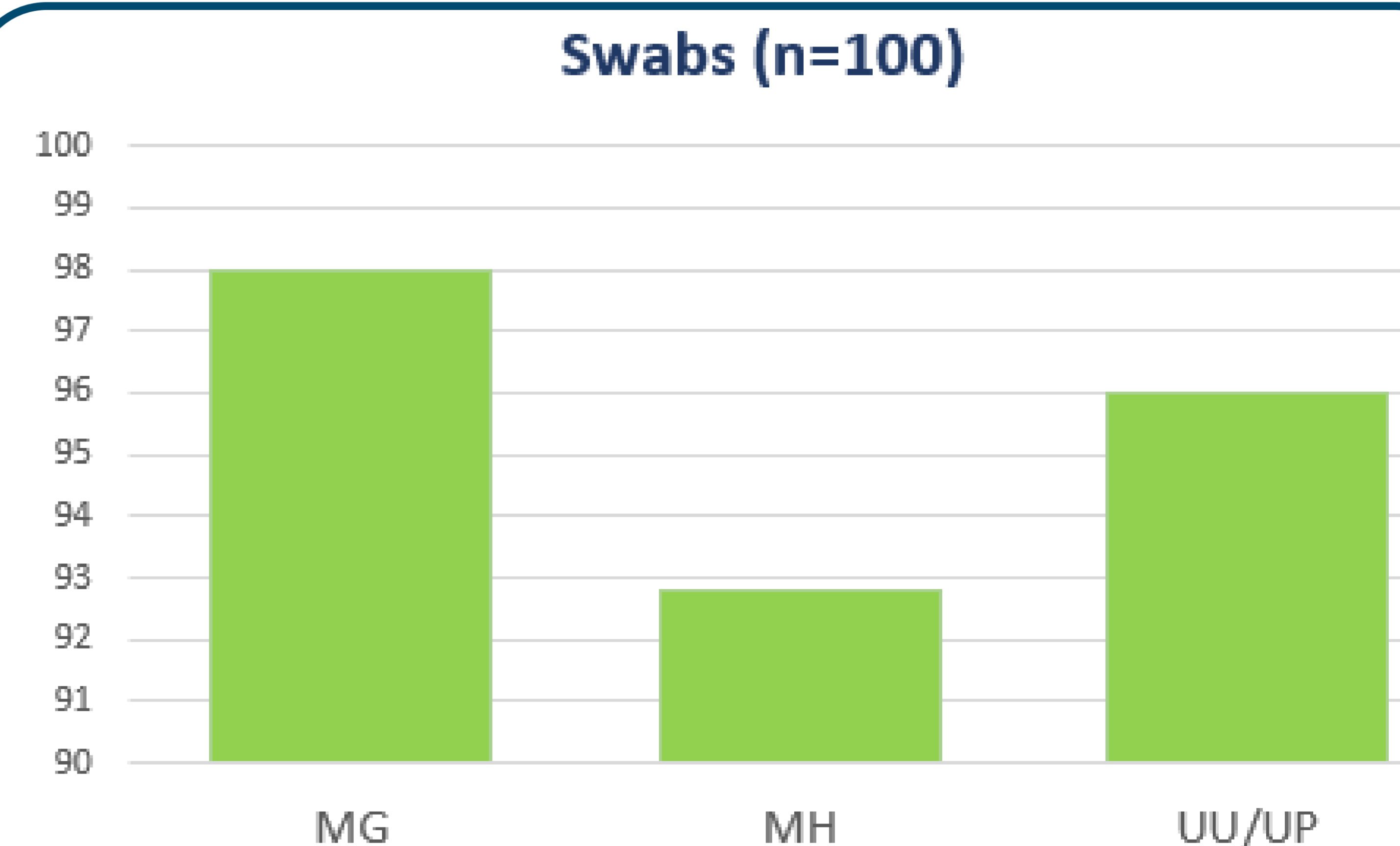
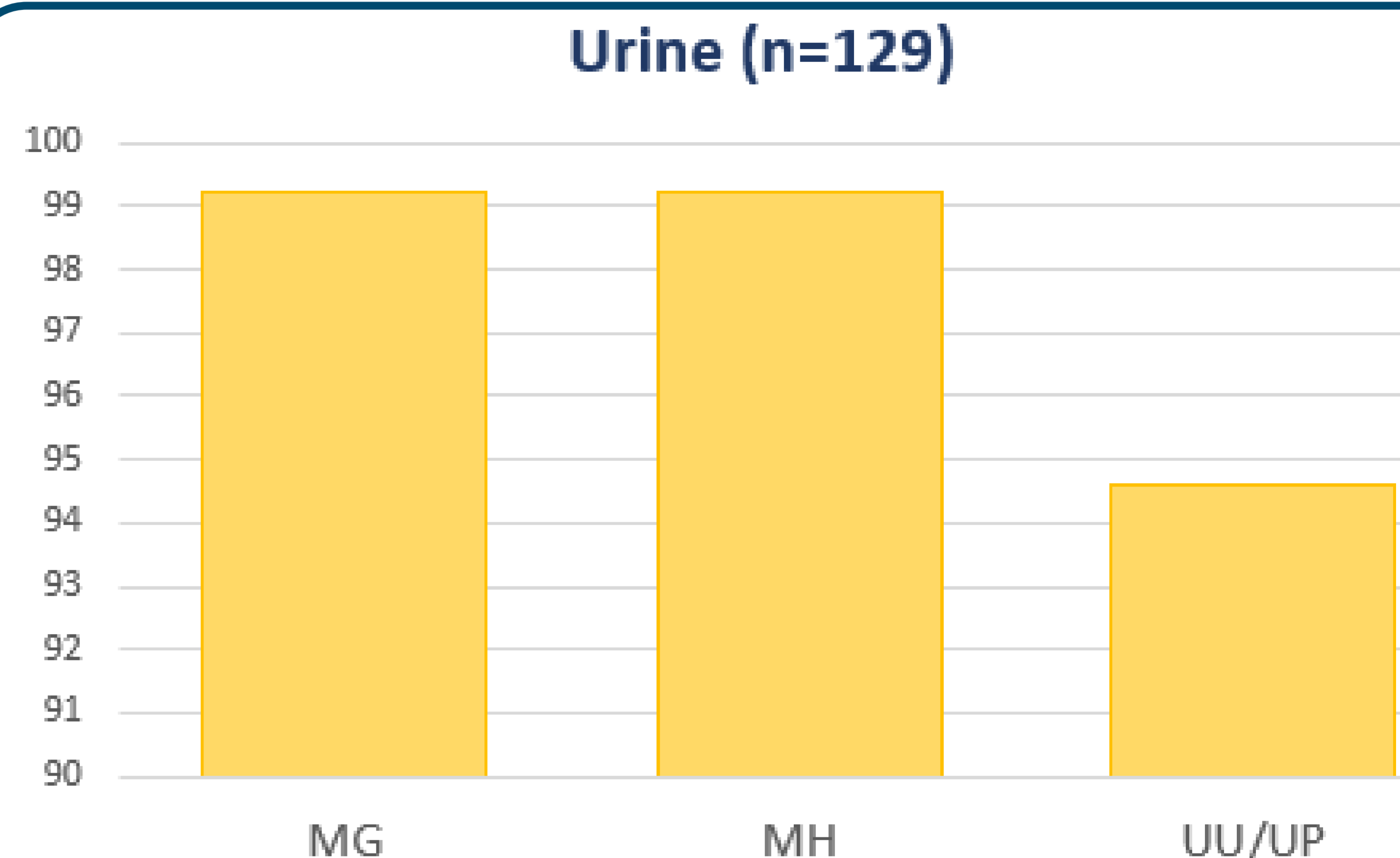


Fig. 1:
Vivalytic® instrument (A)
Detection methods: μ Array, Melting curve analysis and qPCR (B)
Cartridge with reservoirs and microfluidic system (C)
[The study was supported by Bosch Healthcare Solutions GmbH by providing Vivalytic® cartridges]

Concordance in %



Results and Conclusion

The Vivalytic MH/MG/UP&UU cartridge demonstrated an excellent concordance with a sensitive reference test and delivered accurate and rapid results (<1hr).

The overall concordance rate for urine samples was 97,7%, the positive percent agreement (PPA) was 96% and the negative percent agreement (NPA) 98,7%. For swabs overall concordance was 95,6% and PPA/NPA were 94,6/ 98,0% respectively.

The assay is suitable for hospital labs as well as for outpatients' settings due to its short time-to result and the ease-of-use of the Vivalytic cartridge. Mycoplasmataceae infections are not mild and neglectable infections. Especially *Mycoplasma genitalium* is an important cause of urethritis in men and cervicitis and pelvic inflammatory disease in women, putting them at risk of infertility.

Raj and colleagues recently called them a "new superbug"², as drug resistance to macrolides and fluoroquinolones in MG is rising globally.

References:

- 1) Lis et al., *Mycopl. genitalium* infection...: a meta-analysis; CID 2015:61
- 2) 2) Raj et al., *Mycopl. genitalium*: A new superbug; Indian J Sex Transm Dis. 2022; 43: 1-12.

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