EV0528
ePoster Viewing
Diagnostic bacteriology – non-culture based, including molecular and MALDI-TOF

Confirmatory testing of Neisseria gonorrhoeae with LightMix modular kits detecting gyrA and opaD

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Background: Globally, over 1 million people acquire sexually transmitted infections each day. Many could have a serious impact on the patient beyond the initial infection, which warrants sensitive and specific diagnostic methods. Modular kits allow flexibility to build multiplex PCR tests to meet laboratory requirements or respective legal regulations. The TIB MOLBIOL STI panel extends testing beyond *Chlamyida trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) to detect other pathogens of interest. These kits may also be used for confirmatory testing of NG in low prevalence settings where postives are rare. Two modular kits, one targeting gyrA, the other opaD, were evaluated for detection of NG with a comparative clinical study. These two kits use different dye channels and can be used also for dual target testing.

Material/methods: A total of 792 clinical specimens were taken from the microbiological routine diagnostic workup of which 15% (119/792) were urogenital swabs and 85% (673/792) were urine samples. Nucleic acids were extracted from each sample with the MagNAPure 96 instrument (Roche) using the Pathogen Universal protocol of the MagNA Pure 96 DNA and Viral NA Small Volume Kit. Eluates were tested on a LightCycler 480 II instrument with a 5-plex real-time PCR application using LightMix Modular kits for the detection of *Treponema pallidum, Mycoplasma genitalium, Trichomonas vaginalis* and a fourth pathogen, with NG gyrA combined with *Ureaplasma urealyticum*, and NG opaD combined with *Mycoplasma hominis*.

Results: Of the 440 samples evaluated for opaD, 7% (31/440) were positive; from 352 samples tested for gyrA, 6.5% (23/352) were positive. All positive results were confirmed by retesting the sample with the alternative assay. In total, 6.8% of the samples (54/792) were positive for NG. These results were found to be 100% concordant with an accredited in-house assay that was used to evaluate all 792 specimens, providing a clinical sensitivity and specificity of 100%.

Conclusions: The LightMix Modular STI panel is a flexible solution for diagnostic testing and provides the opportunity for clinical labs to confirm positive results for NG, targeting either the opaD or the gyrA gene.