Introduction

Approximately 1,000,000 sexually transmitted infections (STIs) are acquired every day across the world - the majority of cases are attributable to Chlamydia trachomatis (CT), Neisseria gonorrhoea (GC), and Trichomonas vaginalis (TV) infection (Newman et al., 2015)

The high frequency of asymptomatic cases in the population and an increased uptake in users due to the accessibility of online services highlights the need for a high-throughput analyser to perform accurate and rapid diagnostic PCR.

The BD-COR™ PX is being used in conjunction with the MX Instrument for the first time in the UK in a controlled launch stage to support random access, high-throughput testing.

The fully automated multiplex PCR platform integrates extraction, amplification, and detection of three of the most common STIs in the CTGCTV2 assay. The platform aims to reduce manual contact time for technicians, improve workflow and produce faster results.

Aims

• This investigation aims to verify the BD-COR™ analyser [figure 1], and determine whether it is a suitable STI diagnostics platform for use within the OUH clinical diagnostic laboratory

Methods

Three cohorts of specimens were analysed in parallel on the BD-VIPER™/Micropathology Ltd. and on BD-COR™ MX/PX as part of a verification project comprising of:

I. 28 Qnostics and QCMD proficiency panel samples
II. 23 external quality assurance samples
III. 433 clinical samples

Figure 1 – The BD COR™ PX/MX (BD, 2023)

Results

- Cohort I demonstrated 100% concordance for CT, GC, and TV detection.
- Cohort II demonstrated 100% concordance in the CT and TV assays, but samples were insufficient to test 2 known Neisseria gonorrhoea positives.
- Cohort III demonstrated concordance of 100%, 99.30% and 99.35% for CT, GC, and TV respectively, [figure 2].

Performance statistics for the CTGCTV2 assay were > 93% for all specifications except the PPV of the TV assay [figure 3].

Discussion

- No sample types were found to be inhibitory.
- Although no GC EQA samples were tested during verification, the assay performance will continue to be monitored through quality assurance schemes.
- All performance specifications exceed 93% - excluding the Trichomonas vaginalis PPV due to only testing 4 positive samples.
- One sample tested positive for TV infection on BD COR but not on BD Viper which is due to the increased sensitivity of BD COR.

Conclusion

BD COR performs to manufacturers standards and improves turn-around-times, workflow and reduces reagent waste, therefore is suitable to be implemented as an STI diagnostic platform in OUH Microbiology.

Keywords

Chlamydia trachomatis, Neisseria gonorrhoea, Trichomonas vaginalis, diagnostic multiplex PCR platform