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Verification of the COR™ MX/PX instrument in STI diagnostics

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

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

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

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

References

- BD (2023) BD COR™ System. Accessed on 4/09/2023 at https://www.bd.com/en-us/products-and-solutions/products/product-brands/cor#products
- Newman L., Rowley J., Vander Hoorn S., Saman Wijesooriya N., Unemo M., Low N., Stevens G., Gottlieb S., Kiarie J., Temmerman M (2015) Global Estimates of the Prevalence and Incidence of Four Curable Sexually Transmitted Infections in 2012 Based on Systematic Review and Global Reporting. *PLoS One*. **10** (12)
- Justice A (2023) Verification of BD COR MX/PX instrument with the BD CTGCTV2 assay for the molecular detection of Chlamydia trachomatis, Neisseria gonorrhoea and Trichomonas vaginalis. Oxford University Hospitals NHS Foundation Trust, Department of Microbiology

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].

CT	BD Viper™/Micropathology	
	POS	NEG
BD COR™ POS	17	0
BD COR™ NEG	0	412

GC	BD Viper™/Micropathology	
	POS	NEG
BD COR™ POS	31	2
BD COR™ NEG	1	393

TV	BD Viper™/Micropathology	
	POS	NEG
BD COR™ POS	3	1
BD COR™ NEG	0	150

Figure 2 – Clinical sample results for specimens tested on BD COR ™ and BD Viper ™/Micropathology Ltd.

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

Chlamydia trachomatis	Manufacturer (Lowest, highest)	Oxford Microbiology
Specificity	98.9%, 99.4%	100%
Sensitivity	94.5%, 98.4%	100%
PPV	80.9%, 89.3%	100%
NPV	99.7%, 99.9%	100%

Neisseria gonorrhoea	Manufacturer (Lowest, highest)	Oxford Microbiology
Specificity	99.8%, 100%	99.49%
Sensitivity	95.3%, 100%	96.88%
PPV	97.3%, 98.2%	93.94%
NPV	99.8%, 100%	99.75%

Trichomonas vaginalis	Manufacturer (Lowest, highest)	Oxford Microbiology
Specificity	98.7%, 99.7%	99.34%
Sensitivity	93.8%, 100%	100%
PPV	82.4%, 94.9%	75%
NPV	99.7%, 100%	99.35%

Figure 3 – BD COR ™ Performance statistics for Chlamydia trachomatis (CT), Neisseria gonorrhoea (GC), and Trichomonas vaginalis (TV) infection against manufacturers standards (Justice, 2023)

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.

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