VALIDATION OF THE BD PROBETEC™ Q^X AMPLIFIED DNA ASSAY FOR THE DETECTION OF CHLAMYDIA AND GONORRHEA IN A PUBLIC HEALTH LABORATORY SETTING

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BACKGROUND

- ***Chlamydia trachomatis*** **(CT) and** ***Neisseria gonorrhoeae*** **(GC) infections are the two most commonly reported sexually transmitted diseases.**
- **Rapid diagnoses of CT and GC infections have significant impacts on preventing complications and reducing transmission.**

INTRODUCTION

- **We previously validated the BD Viper System (BD Diagnostics, Sparks, MD) for its performance of the BD ProbeTec™ ET CT and GC Amplified DNA Assays.**
  - **The BD Viper System is a fully automated instrument for the detection of CT and GC in urogenital specimens using the real-time Strand Displacement Amplification technology.**
  - **The system provides for walk-away processing of the extraction, amplification, and detection of target nucleic acids, with a capacity of 184 assay results per run [(92 patient samples extracted /run) x (2 assay results/run) = 184 total results per run].**
- **The BD Viper System in our laboratory was recently upgraded to perform the BD ProbeTec™ CT/GC Q^x Amplified DNA Assay (extracted mode).**
- **Here, we evaluated the clinical agreement of Qx Assay when compared to the ET Assay (non-extracted mode) and their operator advantages.**

MATERIALS & METHODS

- **Urine specimens previously tested for CT and GC DNA by the BD ProbeTec™ ET CT and GC Amplified DNA, as well as spiked swab samples, were tested by the BD ProbeTec™ CT/GC Q^x Amplified DNA Assays using the BD Viper System.**
  - **The Q^x Assay requires the use of new Female Endocervical Specimen Collection Kit and new Male Urethral Specimen Collection Kit.**
  - **Swab diluent spiked with AmpliTrol CT/GC (Bio-Rad Laboratories, Hercules, CA).**

RESULTS

Table 1. Percentage Agreement of 236 Total Samples Tested (47 CT positive, 39 GC positive)

Assay Type	Specimen Type	% Agreeement
CT	Urine (N=186)	100%
	Swab (N=50)	100%
GC	Urine (N=186)	100%
	Swab (N=50)	100%

Sensitivity: 100%; Specificity: 100%

Table 2. Clinical Agreement of 50 Mock Swab Samples

Detection of CT		Intended results/ Spiked or not	
		Positive	Negative
Q^x Assay (Extracted)	Positive	22	0
	Negative	0	28

Sensitivity = 100%; Specificity = 100%

Detection of GC		Intended results/ Spiked or not	
		Positive	Negative
Q^x Assay (Extracted)	Positive	22	0
	Negative	0	28

Sensitivity = 100%; Specificity =100%

Table 3. Clinical Agreement of 186 Urine Samples

Detection of CT		ET Assay (Non-Extracted)	
		Positive	Negative
Q^x Assay (Extracted)	Positive	25	0
	Negative	0	161

Sensitivity = 100%; Specificity = 100%

Detection of GC		ET Assay (Non-Extracted)	
		Positive	Negative
Q^x Assay (Extracted)	Positive	17	0
	Negative	0	169

Sensitivity = 100%; Specificity = 100%

Table 4. Work-flow Analysis (per 48 urine samples) of Q^x Assay in Comparison to the ET Assay

Q^x Assay (Extracted)	ET Assay (Non-Extracted)
Pre-warm: 15min Cool: 15min Instrument set-up: 20min Instrument clean-up: 20min	Pre-warm: 10min Cool: 15min Centrifuge: 30min Decant, Add diluent, and Vortex: 45min Lysing: 30min Cool: 15min Instrument set-up: 15min Instrument clean-up: 15min
Total: 70min	Total: 175min

SUMMARY

- **Least amount of hands-on time: saves 105min of technologist's time that can be re-assigned to other tasks.**
- **Increased sensitivity and specificity according to the package insert data.**
- **Less interference due to interfering substances (eg. leukocytes in swab and urine samples; deodorant sprays, Bilirubin, and seminal fluid in urine samples) according to the package insert.**
- **Higher tolerance for blood in swab samples.**
- **Additional specimen source (vaginal) is FDA approved.**
- **No repeat testing of positives: this may reduce the cost since we repeated about 8% of the total samples tested using the non-extracted method.**

CONCLUSIONS

We concluded that the performance of the BD ProbeTec™ Q^x Assay was equivalent to the performance of the BD ProbeTec™ ET Assay. In addition, the Q^x Assay offer a major advantage in terms of least amount of hands-on-time required to prepare and process specimens by the laboratory scientists. Further investigation is needed to evaluate the work-flow efficiencies and cost-effectiveness of combining the Q^x Assay using the automated BD Viper System with lean management.

REFERENCES

- BD ProbeTec™ *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay Package Insert (BD 8081408 and 8081409).
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DISCLAIMER

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