

# Endocervical Swab Performance from STD Clinics with the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q<sup>x</sup> Amplified DNA Assay and the BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay on the BD Viper™ System with XTR™ Technology (BD Viper System with XTR)

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## ABSTRACT

**BACKGROUND:** This study examined overall performance at sexually transmitted disease (STD) clinics of endocervical swabs versus the patient infected status (PIS) on the BD Viper™ System with XTR™ Technology in extracted mode which utilizes the BD ProbeTec™ CT/GC Q<sup>x</sup> Amplified DNA Assays (CTQ and GCQ).

**OBJECTIVE:** To examine the performance of the endocervical swab specimens in the BD Viper™ System with XTR™ combined with the CTQ/GCQ assays vs. the patient infected status.

**METHODS:** A total of 359 symptomatic and 167 asymptomatic female subjects were enrolled from 5 geographically diverse STD clinical centers with prevalence ranging from 10.0%-18.1% for CT and 1.4%-19.0% for GC. A urine specimen, 4 endocervical swabs and a self-collected vaginal swab were obtained from each subject. The urine was transferred to a UPT, (Urine Preservative Transport) for testing with the BD ProbeTec™ ET CT/GC/AC assay, and to a UTT, (urine transport tube) for testing on the APTIMA Combo 2 (AC2) CT/GC assay. These were both used for reference testing. The first-collected endocervical swab was used for a GC culture or as a standard of care swab. The remaining 3 endocervical swabs were collected in randomized order and consisted of the Gen-Probe unisex swab for testing with the AC2 CT/GC assays as a reference, the BD ProbeTec ET dry swab for testing with the BD ProbeTec ET CT/GC/AC assays as a reference, and the BD ProbeTec CT/GC Q<sup>x</sup> endocervical swab, which was tested with the CTQ/GCQ assays on the BD Viper System with XTR Technology.

**RESULTS:** The BD ProbeTec CT/GC Q<sup>x</sup> swab results were then compared to the PIS, which was defined as at least one positive result from both the BD ProbeTec ET assays and the AC2 assays, regardless of specimen type, urine or swab. Overall endocervical swab performance vs. PIS for CTQ had a sensitivity of 91.8%, with a specificity of 97.8%. GCQ had 98.1% sensitivity with 99.6% specificity.

**CONCLUSIONS:** Testing for the presence of CT and GC DNA in endocervical swab specimens utilizing the BD ProbeTec CT/GC Q<sup>x</sup> Assays on the BD Viper System with XTR was highly sensitive and specific when compared to PIS.

## BACKGROUND

This study examined the performance of endocervical swabs collected in an STD clinical setting on the BD Viper™ System in extracted mode combined with the CTQ/GCQ Amplified DNA assays. The specimens were collected from November 2007 to March 2008 at various STD clinics.

## OBJECTIVE

To examine the performance of the endocervical swab specimens in the BD Viper™ System with XTR™ combined with the CTQ/GCQ assays vs. the patient infected status.

## METHODS

A total of 359 symptomatic and 167 asymptomatic female subjects were enrolled from 5 clinics located in Alabama, Indiana, Louisiana, Maryland, and Mississippi. Prevalences ranging from 10.0%-18.1% for CT and 1.4%-19.0% for GC. A urine specimen, 4 endocervical swabs and a self-collected vaginal swab were obtained from each subject. Urine specimens were transferred to a UPT, (Urine Preservative Tube) for testing with the BD ProbeTec ET CT/GC/AC assay, and to a UTT, (urine transport tube) for testing on the AC2 CT/GC assay. These were both used for reference testing. The first-collected endocervical swab was used for a GC culture or as a standard of care swab. The subsequent 3 endocervical swabs were collected in randomized order and included a Gen-Probe unisex swab for testing with the AC2 CT/GC assay, a BD ProbeTec ET dry swab for testing with the BD ProbeTec ET CT/GC/AC assay, and the BD ProbeTec CT/GC Q<sup>x</sup> endocervical swab, which was tested with the CTQ/GCQ assays on the BD Viper System with XTR Technology.

METHODS CONTINUED

**Patient Infected Status Definitions**

The BD ProbeTec CT/GC Q<sup>x</sup> swab test results were then compared to the patient Infected Status (PIS), which was defined as at least one positive result from both BD ProbeTec ET assay and AC2 assay, regardless of specimen type, urine or swab.

BD ProbeTec ET CT/GC/AC		Gen-Probe AC2 CT/GC		Patient Infected Status
Endocervical Swab	Urine (UPT)	Endocervical Swab	Urine (UTT)	
	+		+	Positive
	-		+	Negative
	+		-	Negative
	-		-	Negative

RESULTS

**Overall endocervical swab performance vs. PIS for CTQ had a sensitivity of 100%, with a specificity of 97.8%. GCQ had 98.1% sensitivity with 99.6% specificity.**

		CTQ Endocervical Swab Performance Compared to PIS						GCQ Endocervical Swab Performance Compared to PIS			
Collection Site	N	Sensitivity	95% C.I.	Specificity	95% C.I.	Collection Site	N	Sensitivity	95% C.I.	Specificity	95% C.I.
IND	105	89.5% (17/19)	(66.9% - 98.7%)	100.0% (86/86)	(95.8% - 100.0%)	IND	105	100.0% (20/20)	(83.2% - 100.0%)	100.0% (85/85)	(95.8% - 100.0%)
JHU	41	80.0% (4/5)	(28.4% - 99.5%)	97.2% (35/36)	(85.5% - 99.9%)	JHU	41	100.0% (2/2)	(15.8% - 100.0%)	100.0% (39/39)	(91.0% - 100.0%)
LSU	155	96.0% (24/25)	(79.6% - 99.9%)	96.2% (125/130)	(91.3% - 98.7%)	LSU	155	100.0% (13/13)	(75.3% - 100.0%)	99.3% (141/142)	(96.1% - 100.0%)
UAB	155	88.2% (15/17)	(63.6% - 98.5%)	98.6% (136/138)	(94.9% - 99.8%)	UAB	154	93.8% (15/16)	(69.8% - 99.8%)	99.3% (137/138)	(96.0% - 100.0%)
UMMC	70	100.0% (7/7)	(59.0% - 100.0%)	96.8% (61/63)	(89.0% - 99.6%)	UMMC	70	100.0% (1/1)	(2.5% - 100.0%)	100.0% (69/69)	(94.8% - 100.0%)
<b>Total</b>	<b>526</b>	<b>91.8% (67/73)</b>	<b>(83.0% - 96.9%)</b>	<b>97.8% (443/453)</b>	<b>(96.0% - 98.9%)</b>	<b>Total</b>	<b>525</b>	<b>98.1% (51/52)</b>	<b>(89.7% - 100.0%)</b>	<b>99.6% (471/473)</b>	<b>(98.5% - 99.9%)</b>

For female subjects, infection localized to the endocervix or the urethra has been reported in the literature and was also noted by the data in this study. Potentially localized site-specific infections against the overall PIS algorithm for the endocervical specimen type as seen by collection site are listed in the table below. Additional analyses were performed to evaluate removal of the potentially localized site-specific infections from the overall PIS algorithm for the endocervical specimen type. This was expressed as positive and negative percent agreement. As seen in the table below, the positive percent agreement was calculated by removing the subjects where the PIS was positive as determined by the reference urine specimens only. Those subjects were considered negative in the localized endocervical site and were included in the negative percent agreement calculation.

**Overall endocervical swab performance vs. Site Specific PIS for CTQ had a positive percent agreement of 100%, with a negative percent agreement of 97.8%.**

		CTQ Endocervical Swab Performance Compared to Site Specific PIS			
Collection Site	N	Positive Percent Agreement	95% C.I.	Negative Percent Agreement	95% C.I.
IND	105	100.0% (17/17)	(80.5% - 100.0%)	100.0% (88/88)	(95.9% - 100.0%)
JHU	41	100.0% (4/4)	(39.8% - 100.0%)	97.3% (36/37)	(85.8% - 99.9%)
LSU	155	100.0% (24/24)	(85.8% - 100.0%)	96.2% (126/131)	(91.3% - 98.7%)
UAB	155	100.0% (15/15)	(78.2% - 100.0%)	98.6% (138/140)	(94.9% - 99.8%)
UMMC	70	100.0% (7/7)	(59.0% - 100.0%)	96.8% (61/63)	(89.0% - 99.6%)
<b>Total</b>	<b>526</b>	<b>100.0% (67/67)</b>	<b>(94.6% - 100.0%)</b>	<b>97.8% (449/459)</b>	<b>(96.0% - 99.0%)</b>

**CONCLUSION**

Testing for the presence of CT and GC DNA in endocervical swab specimens utilizing the BD ProbeTec CT/GC Q<sup>x</sup> Assays on the BD Viper System with XTR demonstrated high sensitivity and specificity when compared to the patient infected status.