

# Performance of PreservCyt® Solution Specimens on the BD Viper™ System with XTR™ Technology with the BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay

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## ABSTRACT

The BD Viper™ System with XTR™ Technology (BD Viper System with XTR) in extracted mode has successfully detected *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) DNA in vaginal and endocervical swabs, male urethral swabs, and in female and male urine. The BD Viper System with XTR utilizes the newly developed BD ProbeTec™ CT/GC Q<sup>x</sup> Amplified DNA Assays (CTQ and GCQ).

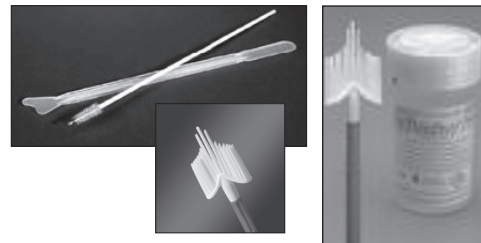
This study examines the performance of the PreservCyt® cytology medium on the BD Viper System with XTR combined with the GCQ assay results vs. the patient infected status (PIS).

Eleven geographically diverse Clinical Centers (family planning, OB/GYN, or STD) enrolled 2074 patients from April through September 2008. The family planning and OB/GYN clinics carried a low GC prevalence (0.7% and 3.0%) while the STD clinics had a high GC prevalence (4.6%). Of the compliant subjects, 75% came from low prevalence clinics, and 25% from high prevalence clinics.

Three endocervical swabs (BD ProbeTec ET, Gen-Probe, BD ProbeTec Q<sup>x</sup>) and a PreservCyt specimen were obtained from symptomatic and asymptomatic females. The BD ProbeTec ET swab was processed with the BD ProbeTec ET CT/GC/AC assays (PT); the Gen-Probe swab with the APTIMA® Combo 2 assay (AC2), and the BD ProbeTec Q<sup>x</sup> swab was tested with the GCQ assay. These three endocervical swabs served as the references for the PIS. The PIS was positive when at least two positive results came from the nucleic acid amplification tests from AC2, PT, or GCQ.

The PreservCyt specimen was tested on the BD Viper System with XTR with the GCQ assay and compared to the PIS.

For PreservCyt specimens the GCQ assay displayed 92.3% sensitivity/100% specificity in asymptomatic subjects (n = 1349) and 100% sensitivity/99.9% specificity in symptomatic subjects (n = 725). When grouped by low and high prevalence clinics, the GCQ assay performance was similar in both populations, 94.7% sensitivity/100% specificity and 95.8% sensitivity/99.8% specificity, respectively. The GCQ assay shows high sensitivity and specificity in both low and high GC prevalence populations supporting the use of this specimen type on the BD Viper System with XTR.



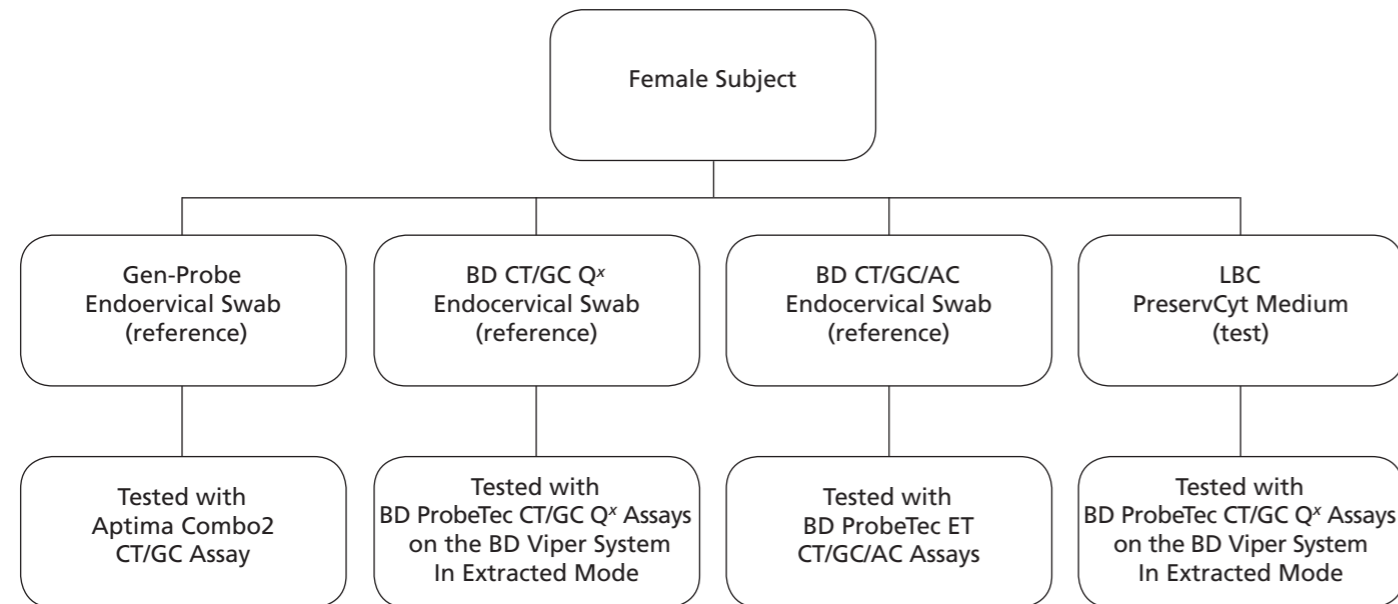
**STUDY SUMMARY**

This study examined the performance of the PreservCyt® Solution (Hologic, Inc.) liquid based cytology medium on the BD Viper™ System with XTR™ Technology (BD Viper System with XTR) combined with the BD ProbeTec *Chlamydia trachomatis* (CT) Q<sup>x</sup> Amplified DNA Assay (CTQ) and the BD ProbeTec *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay (GCQ). The specimens were collected from April 2, 2008 through September 3, 2008. The objective of the study was to examine the performance of the PreservCyt® medium on the BD Viper System with XTR combined with the CTQ/GCQ assays vs. the patient infected status.

**STUDY DESIGN**

- 11 geographically diverse Clinical Centers were requested to enroll a total of 2074 patients.
- Clinics were identified as Family Planning clinics, STD clinics, or OB/Gyn clinics. The GC prevalence ranged from 0-13.3%.
- As illustrated in Figure 1 below, three reference endocervical swabs (BD ProbeTec ET, Gen-Probe, BD ProbeTec Q<sup>x</sup>) and a PreservCyt® specimen were obtained for both symptomatic & asymptomatic subjects.
- PreservCyt® specimens were collected by either broom or brush spatula device.
- For all but one clinic, the endocervical swabs were collected randomly before the PreservCyt®.
- Processing of collected reference samples:  
BD ProbeTec ET with ProbeTec CT/GC/AC Assays (PT)  
Gen-Probe with Aptima Combo 2 Assay (AC2)  
BD ProbeTec Q<sup>x</sup> Swab with the GCQ Assay (GCQ)
- The three endocervical swabs served as the references for the PIS.
- PIS was positive when at least two positive results came from the three nucleic acid amplification tests (PT, AC2, or GCQ). (See Table 1)
- An 0.5 mL pre-quot was removed from the PreservCyt® specimen and was tested on the BD Viper™ System with XTR™ with the GCQ assay and compared to PIS.

**Figure 1. Illustrates the swabs collected and testing mechanisms**



**STUDY DESIGN CONTINUED**

**Table 1. Patient Infected Status Definition**

Patient Infected Status	Reference Endocervical Swabs		
	BD ProbeTec Q <sup>x</sup>	Aptima Combo 2	BD ProbeTec ET System
+	+	+	+
	+	+	-
	+	-	+
	-	+	+
-	+	-	-
	-	+	-
	-	-	+
	-	-	-

**Table 2. Percent Enrollment for Compliant Subjects with PIS GC Results by Clinic Type**

Clinic Type		Number of Compliant Subjects with PIS GC Results	
Family Planning	Low Prevalence	1187 (57.2%)	1554 (74.9%)
		367 (17.7%)	
STD	High Prevalence	520 (25.1%)	520 (25.1%)
<b>Total</b>		<b>2074</b>	<b>2074</b>

**Table 3. GCQ Performance with PreservCyt® vs. PIS – By Symptomatic Status and Overall**

Symptomatic	N	Sensitivity		Specificity	
N	1349	92.3% (24/26)	(74.9% - 99.1%)	100.0% (1323/1323)	(99.7% - 100.0%)
Y	725	100.0% (17/17)	(80.5% - 100.0%)	99.9% (708/709)	(99.2% - 100.0%)
<b>Total</b>	<b>2074</b>	<b>95.3% (41/43)</b>	<b>(84.2% - 99.4%)</b>	<b>99.95% (2030/2031)</b>	<b>(99.7% - 100.0%)</b>

**Table 4. GCQ Performance with PreservCyt® vs. PIS – By Collection Clinic Type – Combined Family Planning – OB/GYN and STD**

Clinic Type	Prevalence	N	Sensitivity	95% C.I.	Specificity	95% C.I.	PPV%	NPV%
Family Planning OB/GYN (Low Prevalence)	1.2%	1554	94.7% (18/19)	(74.0% - 99.9%)	100% (1535/1535)	(99.8% - 100.0%)	100.0%	99.9%
STD (High Prevalence)	4.6%	520	95.8% (23/24)	(78.9% - 99.9%)	99.8% (495/496)	(98.9% - 100.0%)	95.9%	99.8%

## RESULTS

### GC Prevalence in Study Population (Table 2)

Low Prevalence:	Ob/Gyn Clinics (3.0% GC) Family Planning Clinics (0.7% GC)
High Prevalence:	STD Clinics (4.6% for GC)

- 75% of compliant enrollment came from low prevalence clinics
- 25% of the enrollment came from high prevalence clinics

### Performance of the GCQ assay with PreservCyt® Solution in low and high prevalence populations (Table 4)

In Low Prevalence Population:	94.7% sensitivity 100% specificity
In High Prevalence Population:	95.8 % sensitivity 99.8% specificity

- The GCQ Assay performed similarly in both high and low prevalence populations

### Performance of GCQ assay with PreservCyt® specimens by symptomatic status (Table 3)

- 92.3% sensitivity and 100% specificity in asymptomatic subjects
- 100% sensitivity and 99.9% specificity in symptomatic subjects

## CONCLUSIONS

The BD ProbeTec *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA assay demonstrated high sensitivity and high specificity on the BD Viper™ System with XTR™ Technology when tested using specimens collected in the PreservCyt® Solution in both low and high GC prevalence populations as well as in asymptomatic and symptomatic subjects.