

BDProbeTec™ ET CT/GC Amplified DNA Assay Wet Swab Transport for use with Endocervical and Urethral Swab

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ABSTRACT (revised)

Chlamydia and gonorrhea are the most common sexually transmitted bacterial diseases in the United States. Stabilization of the organisms during specimen collection and transport are essential for successful detection. Currently, swab samples to be tested with the BDProbeTec™ ET CT/GC Amplified DNA Assays are shipped in dry plastic sheaths from the collection site to the test site where the swab is removed from the sheath and expressed in BDProbeTec™ ET sample diluent. Here we report the development of a new swab transport kit, which allows transport of swab specimens in the sample diluent, thereby eliminating the need for expression at the test site. This significantly reduces hands-on time for high-volume diagnostic laboratories. The purpose of this study was to examine reagent and sample stability with the new wet swab transport system. Tubes containing 2 mL of sample diluent were stressed at the extremes of the existing reagent stability claims of 2–33°C. At intervals, male and female swabs inoculated with 4000 *Chlamydia trachomatis* (CT) elementary bodies and 4000 *Neisseria gonorrhoeae* (GC) particles (equivalent to 200 organisms per reaction) were introduced into individual tubes. The tubes containing the swabs were then stored at either 2–8°C or 27°C for 6 days to mimic the specified sample storage conditions. To date, baseline, 3, 4, 6, 12, and 13 month time points have been evaluated. At each time point, 42 male and 42 female swabs were tested consuming a total of 1008 male and female swabs. Of these co-seeded swabs, 1008 tested positive for GC and 1006 tested positive for CT. The data demonstrate reagent stability for a minimum of 13 months at 2–33°C and stability of expressed samples for 6 days at 2–27°C. Therefore, the new BDProbeTec™ ET CT/GC Amplified DNA Assay Wet Swab Transport system provides sample storage stability equivalent to the existing dry swab transport method. The Wet Swab Transport System will significantly reduce hands-on time associated with swab specimen processing by eliminating the need for manual swab expression at the testing facility.

INTRODUCTION

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) infections are the most common sexually transmitted bacterial diseases in the United States. The incidences of genital CT and GC infections in the US in 2000 were 257.5 and 131.6 cases per 100,000 respectively. A total of 702,093 chlamydial infections and 358,995 gonorrhea cases were reported to the Centers for Disease Control and Prevention in the US in the year 2000.

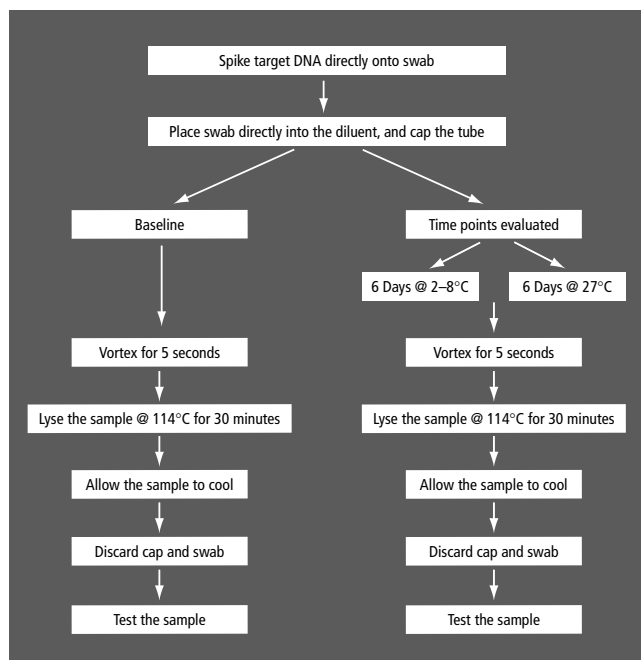
The BDProbeTec™ ET System is an easy-to-use, high throughput, amplification system for detection of nucleic acid from CT and GC infections. The system employs Strand Displacement Amplification (SDA) technology coupled with a homogenous fluorescent energy transfer (ET) detection method to test for CT and GC DNA in male and female urine, endocervical swabs, and male urethral swab specimens.

Currently, urethral and endocervical swab specimens can be stored in a dry BD swab transport tube, at 2–27°C for up to 4–6 days following collection. At the collection site a sample is obtained from a patient, the dry swab is placed in a BD swab transport tube, and shipped to a diagnostic laboratory for testing. The testing site receives and processes the swab according to the BDProbeTec™ ET product insert. The processed sample is then loaded into the BDProbeTec™ ET instrument for analysis.

The BDProbeTec™ ET Wet Swab Transport System is utilized for both male urethral and female endocervical swabs. At the collection site a sample is obtained from the patient. The swab is placed in the wet swab transport tube and the shaft is broken at a specific score line. The swab is then captured within the tube by the cap. The tube is shipped to the diagnostic laboratory. By shipping the swab specimen in the diluent tube expression of the swab, capping, and uncapping of the diluent tube is eliminated. The BDProbeTec™ ET Wet Swab Transport System offers greater convenience and a significant labor reduction for the high volume diagnostic laboratories.

METHODS

Wet Swab Transport System Sample Stability Method Flow Chart



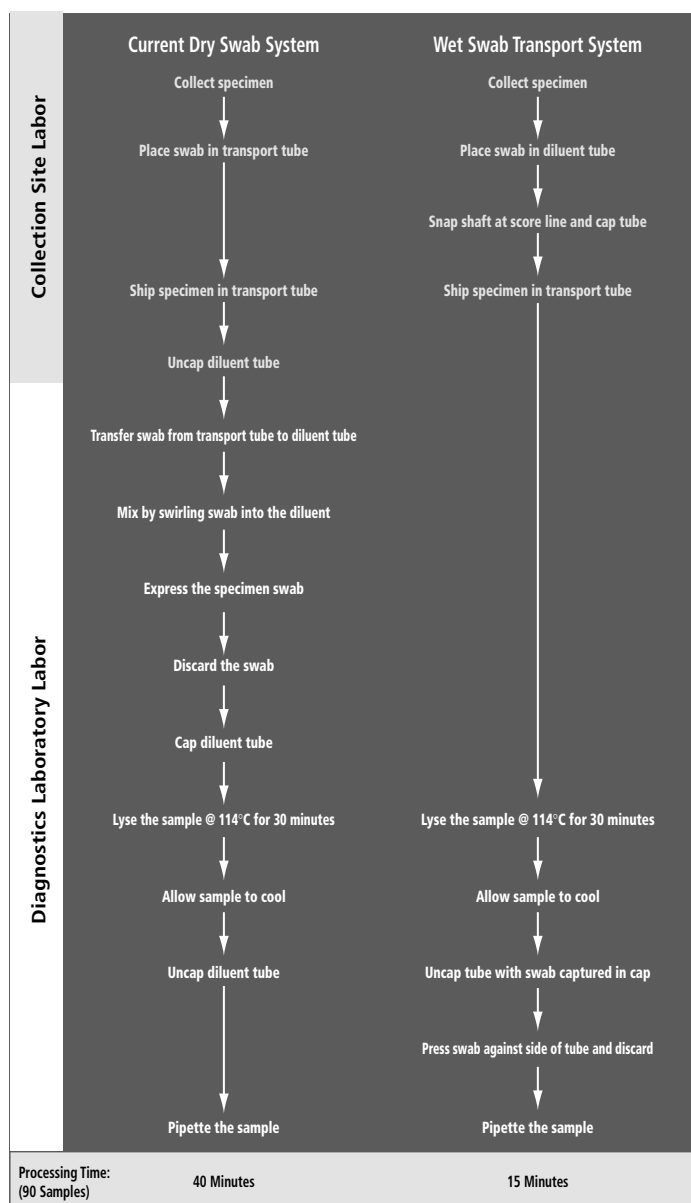
Reagent Stability

- Three lots of the wet swab transport tubes were inverted to maximize contact with the newly designed cap and subjected to the extremes of the current sample diluent reagent storage temperatures of either 2°C or 33°C.
- A total of 180 2 mL wet swab transport tubes from all 3 lots were removed from the storage condition at each specific time point and consumed in the sample stability study.

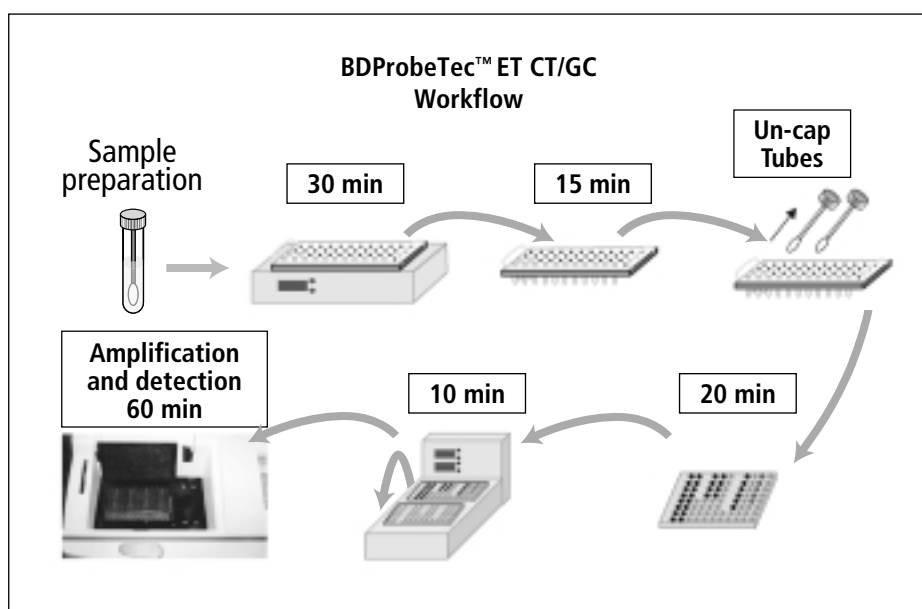
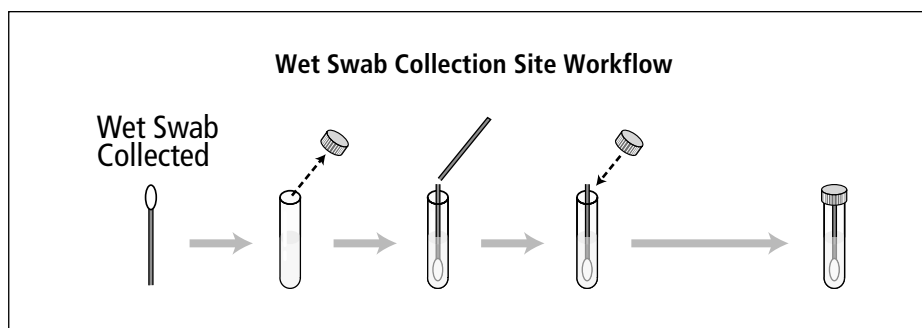
Sample Stability

- 84 wet swab transport tubes were exposed to either a male or female swab inoculated with a suspension of 4000 CT EBs and 4000 GC particles. This spike level results in 2000 CT EBs/ 2000 GC particles per mL of diluent, and 200 CT EBs/ 200 GC particles per reaction.
- 6 wet swab transport tubes were also exposed to male or female swabs inoculated with sodium phosphate buffered saline/bovine serum albumin (PBS/BSA) to serve as negative samples.
- Wet swab transport tubes previously stored at 2–8°C were inoculated and placed at 2–8°C for 6 days.
- Wet swab transport tubes previously stored at 33°C were inoculated and placed at 27°C for 6 days.
- At baseline and each test point/temperature condition, 42 positive and 3 negative male and female swabs were lysed and assayed according to the BDProbeTec™ ET CT/GC/AC product insert.

Labor Release Flow Chart



RESULTS



Results Algorithm

CT or GC MOTA Score	AC MOTA	Results
≥ 2000	Any	Positive
< 2000	≥ 1000	Negative
< 2000	< 1000	Indeterminate

- * Reportable observations were either positive or negative results.
- * The reportable results from all three wet swab transport tube lots were used to calculate proportion positive results.

Positive Samples

Time Point	Reagent Storage	Sample Storage	CT		GC		AC	
	Temperature	Temperature	Male	Female	Male	Female	Male	Female
Baseline	NA	NA	42/42	42/42	42/42	42/42	42/42	42/42
Baseline + 6 Days	2–8°C	2–8°C	42/42	42/42	42/42	42/42	42/42	42/42
Baseline + 6 Days	33°C	27°C	42/42	41/42	42/42	42/42	42/42	42/42
3 Month + 6 Days	2–8°C	2–8°C	42/42	42/42	42/42	42/42	42/42	42/42
3 Month + 6 Days	33°C	27°C	41/42	42/42	42/42	42/42	42/42	42/42
4 Month + 6 Days	2–8°C	2–8°C	42/42	42/42	42/42	42/42	42/42	42/42
4 Month + 6 Days	33°C	27°C	42/42	42/42	42/42	42/42	42/42	42/42
6 Month + 6 Days	2–8°C	2–8°C	42/42	42/42	42/42	42/42	42/42	42/42
6 Month + 6 Days	33°C	27°C	42/42	42/42	42/42	42/42	42/42	42/42
12 Month + 6 Days	2–8°C	2–8°C	42/42	42/42	42/42	42/42	42/42	42/42
12 Month + 6 Days	33°C	27°C	42/42	42/42	42/42	42/42	42/42	42/42
13 Month + 6 Days	2–8°C	2–8°C	42/42	42/42	42/42	42/42	42/42	42/42
13 Month + 6 Days	33°C	27°C	42/42	42/42	42/42	42/42	42/42	42/42

* Baseline assayed at ambient temperature.

* 12 and 13 month data points collected after ASM abstract approval.

Negative Samples

Time Point	Reagent Storage	Sample Storage	CT		GC		AC	
	Temperature	Temperature	Male	Female	Male	Female	Male	Female
Baseline	NA	NA	3/3	3/3	3/3	3/3	3/3	3/3
Baseline + 6 Days	2–8°C	2–8°C	3/3	3/3	3/3	3/3	3/3	3/3
Baseline + 6 Days	33°C	27°C	3/3	3/3	3/3	3/3	3/3	3/3
3 Month + 6 Days	2–8°C	2–8°C	3/3	3/3	3/3	3/3	3/3	3/3
3 Month + 6 Days	33°C	27°C	3/3	3/3	3/3	3/3	3/3	3/3
4 Month + 6 Days	2–8°C	2–8°C	3/3	3/3	3/3	3/3	3/3	3/3
4 Month + 6 Days	33°C	27°C	3/3	3/3	3/3	3/3	3/3	3/3
6 Month + 6 Days	2–8°C	2–8°C	3/3	3/3	3/3	3/3	3/3	3/3
6 Month + 6 Days	33°C	27°C	3/3	3/3	3/3	3/3	3/3	3/3
12 Month + 6 Days	2–8°C	2–8°C	3/3	3/3	3/3	3/3	3/3	3/3
12 Month + 6 Days	33°C	27°C	3/3	3/3	3/3	3/3	3/3	3/3
13 Month + 6 Days	2–8°C	2–8°C	3/3	3/3	3/3	3/3	3/3	3/3
13 Month + 6 Days	33°C	27°C	3/3	3/3	3/3	3/3	3/3	3/3

* Baseline assayed at ambient temperature.

* 12 and 13 month data points collected after ASM abstract approval.

CONCLUSIONS

- The BDProbeTec™ ET Wet Swab Transport System maintained reagent stability for 13 months at both 2–8°C and 33°C.
- The stability of expressed CT/GC organisms with the Wet Swab Transport System was for 6 days at both 2–8°C and 27°C.
- The BDProbeTec™ ET Wet Swab Transport System provides sample storage stability equivalent to the existing dry swab transport method.
- The new BDProbeTec™ ET CT/GC Amplified DNA Assay Wet Swab Transport System offers a streamlined approach for sample collection that will significantly reduce hands-on time associated with swab specimen processing by eliminating the need for manual swab expression at the testing facility.