Simply the most comprehensive solution

The BD Viper™ with XTR technology for STI testing - reliable, accurate and highly efficient
Summary

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Accurate and Relevant Clinical Answers For Your Patients

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Sexually transmitted infections (STI) have been known since antiquity. Gonorrhoea was described by the ancient Egyptians, and was recognized by Greek and Roman medical writers.

STI incidence rates remain high in most of the world, despite diagnostic and therapeutic advances that can cure most patients.

According to the 2012 Annual Epidemiology Report of the European Center for Disease Control, *Chlamydia trachomatis* (CT) is the most frequently reported sexually transmitted infection in EU/EEA countries, with over 340,000 cases reported in 2009.*

Chlamydia infections appear to have reached a plateau in 2010 in Europe while gonorrhoea shows a slight decrease over the past decade.

The real number of infections might be even higher since many are not diagnosed due to absence of symptoms, lack of appropriate methods or because of the diversity in the healthcare and reporting systems across Europe. Yet increasing levels of infection across Europe pose a significant public health challenge.

In this brochure, BD presents a range of solutions to accurately screen for and to diagnose sexually transmitted infections to support the fight against these diseases.

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* ECDC Annual Epidemiological Report 2012

** ECDC STI surveillance report 1990-2009
Trust in results
BD has implemented a broad range of measures to provide you with the most reliable test results to serve your patients’ needs:
• Extraction control included in each sample ensures proper functionality of the reagents
• Positive and negative controls included in each run confirm successful operation
• Ready-to-use reagents exclude any errors during reagent preparation
• Clear yes/no results avoid patient recalls and retesting
• All assays are CE marked according to the IVD Directive and FDA cleared

BD ProbeTec™ CT Qx Amplified DNA Assay
Chlamydia has a rate of 186 per 100,000 population in Europe. 75 % of all cases are reported in young people between 15 and 24 years of age even with a notification rate of 821 per 100,000.*

The BD ProbeTec™ CT Qx Amplified DNA Assay:
• Is suitable for all screening and diagnosis approaches in Europe through its very broad range of approved sample types including patient-collected samples
• Provides excellent sensitivity and specificity resulting in a high PPV even in populations with low infection prevalence
• Reliably detects the Swedish variant of Chlamydia trachomatis

BD ProbeTec™ GC Qx Amplified DNA Assay
Gonorrhea is the second most commonly reported STI in Europe after CT with a rate of 10.4 per 100,000. More than 25 % of all infections are among men who have sex with men and more than 40 % of cases are in young people below 25 years of age.*

The BD ProbeTec™ GC Qx Amplified DNA Assay:
• Is suitable for all screening and diagnosis approaches in Europe through its very broad range of approved sample types including patient-collected samples
• Reliably detects Neisseria gonorrhoeae strains which lack or have significant deletions in the porA pseudogene.
• Gonococcal antimicrobial resistance shows a significant increase. BD offers plated media and the respective discs for resistance testing.

* ECDC Annual Epidemiological Report 2012.
CT Qx and GC Qx assay specifications

The BD ProbeTec™ CT Qx Amplified DNA and GC Qx Amplified DNA Assays, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens.

The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath™ or ThinPrep™ Pap test.

The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.

### CT Qx Amplified DNA Assay

<table>
<thead>
<tr>
<th>Swab specimen type to be processed</th>
<th>Female endocervical swab specimen / Male urethral swab specimen</th>
<th>Vaginal swab specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine and Swabs</td>
<td>2 - 30°C / -20°C</td>
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</tr>
<tr>
<td>LBC</td>
<td>2 - 30°C / -20°C</td>
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### GC Qx Amplified DNA Assay

<table>
<thead>
<tr>
<th>Swab specimen type to be processed</th>
<th>Female endocervical swab specimen / Male urethral swab specimen</th>
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</table>

### Table: Swab specimen type to be processed

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### Table: Temperature Condition for Transport to Test Site and Storage

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### Table: Process Specimen According to Instructions

<table>
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<tr>
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</tr>
</tbody>
</table>

### LBC Specimen Type to be processed

<table>
<thead>
<tr>
<th>LBC Specimen Type to be processed</th>
<th>Storage and Transport of Specimens Transferred to the LBC Specimen Dilution Tube</th>
<th>Process Specimen According to the instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine and Swabs</td>
<td>2 - 30°C / -20°C</td>
<td>2 - 30°C / -20°C</td>
</tr>
<tr>
<td>LBC</td>
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</tr>
</tbody>
</table>

### Table: Urine Specimen Type to be Processed

<table>
<thead>
<tr>
<th>Urine Specimen Type to be Processed</th>
<th>Qx UPT / NEAT</th>
<th>Qx UPT / NEAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qx UPT / NEAT</td>
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</tr>
</tbody>
</table>

### Table: Temperature Condition for Storage and Transport to Test Site

<table>
<thead>
<tr>
<th>Temperature Condition for Storage and Transport to Test Site</th>
<th>2 - 30°C / -20°C</th>
<th>2 - 30°C / -20°C</th>
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</thead>
<tbody>
<tr>
<td>Process Specimen According to Instructions</td>
<td>Within 30 days after transfer to Qx UPT</td>
<td>Within 180 days of collection</td>
</tr>
</tbody>
</table>

### Table: Urine Handling Options Prior To Transfer To Qx UPT

<table>
<thead>
<tr>
<th>Urine Handling Options Prior To Transfer To Qx UPT</th>
<th>Store urine specimen at 2-30°C and transfer to Qx UPT within 8 h of collection or Transfer to Qx UPT immediately</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qx UPT / NEAT</td>
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</tr>
</tbody>
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### Table: Relevant Clinical Answers For Your Patients

Relevant Clinical Answers For Your Patients

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<tr>
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<tr>
<th>Temperature Condition for Storage and Transport to Test Site</th>
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<tr>
<td>Process Specimen According to Instructions</td>
<td>Within 30 days after transfer to Qx UPT</td>
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</table>

### Table: LBC Specimen Type to be processed

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<thead>
<tr>
<th>LBC Specimen Type to be processed</th>
<th>Storage and Transport of Specimens Transferred to the LBC Specimen Dilution Tube</th>
<th>Process Specimen According to the instructions</th>
</tr>
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<tbody>
<tr>
<td>Urine and Swabs</td>
<td>2 - 30°C / -20°C</td>
<td>2 - 30°C / -20°C</td>
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<tr>
<td>LBC</td>
<td>2 - 30°C / -20°C</td>
<td>2 - 30°C / -20°C</td>
</tr>
</tbody>
</table>
BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Qx Amplified DNA Assay

Genital herpes is caused by either herpes simplex virus type 1 (HSV-1) or type 2 (HSV-2) but, globally, the large majority of cases are caused by HSV-2. Although many infections are asymptomatic, genital lesions can be very painful. The virus can also be passed from mother to child during birth. 80% of infants with disseminated disease die, and those who do survive are often brain damaged.*

The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Qx Amplified DNA Assay

• Is a NAAT test which is the method of choice for diagnosis of genital HSV infection as recommended by the European Guidelines from 2010.**
• Accurately diagnoses HSV 1 and/or 2 infection even at late stages of presentation.
• Detects HSV 1 and HSV 2 in a single test to guide counselling and management.

** Int J STD AIDS, 2011 Jan; 22 (1): 1-10
**Herpes Simplex Viruses (HSV 1 & 2) Qx assay specifications**

The **BD ProbeTec™** Herpes Simplex Viruses (HSV 1 & 2) Qx Amplified DNA Assays (HSV Qx Assays), when tested with the **BD Viper™** System in Extracted Mode, use Strand Displacement Amplification technology for the direct, qualitative detection and differentiation of Herpes Simplex virus type 1 (HSV1) and Herpes Simplex virus type 2 (HSV2) DNA in clinician-collected external anogenital lesion specimens. The assays are indicated for use with symptomatic individuals to aid in the diagnosis of anogenital HSV1 and HSV2 infections.

The assay is intended for use with the **BD ProbeTec™** Qx Collection Kit for Endocervical or Lesion Specimens, **BD Universal Viral Transport Medium (UVT) (3 mL)** with polyester-fiber-tip swab collection kit or identical Copan Universal Transport Medium and polyester-fiber-tip swab collection kit.

<table>
<thead>
<tr>
<th></th>
<th>HSV 1 Qx Amplified DNA Assay</th>
<th>HSV 2 Qx Amplified DNA Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td><strong>UVT in Qx Swab Diluent</strong></td>
<td>96.8%</td>
<td>97.6%</td>
</tr>
<tr>
<td><strong>Qx Swab Diluent</strong></td>
<td>96.7%</td>
<td>95.1%</td>
</tr>
</tbody>
</table>

**BD ProbeTec™ Qx Collection Kit for Endocervical or Lesion Specimens**

- **Temperature Condition for Transport to Test Site and Storage**  
  - HSV 1: 2 - 30°C  
  - HSV 2: -20°C

- **Process Specimen According to Instructions**  
  - HSV 1: ≤14 days of collection  
  - HSV 2: ≤120 days of collection

**UVT Specimen**

- **Temperature Condition for Transport to Test Site and Storage**  
  - HSV 1: 20 - 25°C  
  - HSV 2: 2 - 8°C  
  - HSV 2: -70°C

- **Process Specimen According to Instructions**  
  - HSV 1: Aliquot and prewarm within 48 h of collection  
  - HSV 2: Aliquot and prewarm within 14 days of collection  
  - HSV 2: Aliquot and prewarm within 120 days of collection

**UVT Specimen Transferred into Qx Swab Diluent**

- **Temperature Condition for Transport to Test Site and Storage**  
  - HSV 1: 15 - 30°C  
  - HSV 2: 2 - 8°C  
  - HSV 2: -20°C

- **Process Specimen According to Instructions**  
  - HSV 1: Pre-warm within 24 h after aliquotting  
  - HSV 2: Pre-warm within 14 days of collection  
  - HSV 2: Pre-warm within 120 days of collection
Vaginal trichomoniasis in women has been associated with adverse pregnancy outcomes, particularly premature rupture of membranes, preterm delivery, and low birth weight. It can increase a woman’s susceptibility to HIV infection, and may also increase the likelihood of HIV transmission to sex partners. However, further research is needed to confirm these associations and to prove them to be causal.*

The BD ProbeTec™ Trichomonas vaginalis Qx Assay:

- Is a NAAT test which provides superior sensitivity and specificity over the existing detection methods, i.e. microscopy or culture.
- Allows you to run studies with an approved and highly accurate diagnostic test

TV Qx assay specifications

The BD ProbeTec™ Trichomonas vaginalis (TV) Qx Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Trichomonas vaginalis* DNA in clinician-collected female endocervical swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and female urine specimens. The assay is indicated for use with asymptomatic and symptomatic females to aid in the diagnosis of trichomoniasis.

<table>
<thead>
<tr>
<th>TV Qx Amplified DNA Assay</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neat Urine</td>
<td>95.5%</td>
<td>98.7%</td>
</tr>
<tr>
<td>Vaginal Swab Specimen</td>
<td>98.3%</td>
<td>90.0%</td>
</tr>
<tr>
<td>Endocervical Swab Specimen</td>
<td>96.5%</td>
<td>99.7%</td>
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</table>

<table>
<thead>
<tr>
<th>Neat urine stability</th>
<th>2 - 8°C</th>
<th>2-30°C</th>
<th>-20°C</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>7 days</td>
<td>24 hours</td>
<td>14 days</td>
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<table>
<thead>
<tr>
<th>Vaginal Swab Specimens stability</th>
<th>Dry vaginal swab specimens (collection site)</th>
<th>Expressed vaginal swab specimens (Test site)</th>
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<tbody>
<tr>
<td></td>
<td>2 – 8°C</td>
<td>30°C</td>
</tr>
<tr>
<td>Express and process within</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 days of collection</td>
<td></td>
<td></td>
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<tr>
<td>Express and process within</td>
<td></td>
<td></td>
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<tr>
<td>3 days of collection</td>
<td></td>
<td></td>
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<tr>
<td>Within 180 days of collection</td>
<td></td>
<td></td>
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<tr>
<td>Within 30 days of expression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 180 days of expression</td>
<td></td>
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<table>
<thead>
<tr>
<th>Endocervical swab specimens stability</th>
<th>2 – 30°C</th>
<th>-20°C</th>
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<td></td>
<td>Within 30 days of collection</td>
<td>Within 180 days of collection</td>
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</table>
Most efficient use of the system

- Single unit dose reagents - just as many as you need
- Free combination of sample types
- Flexible combination of all parameters
  - all in one run:
    - CT
    - GC
    - TV
    - HSV 1 & 2
    - CT/GC
    - CT/GC, HSV 1 & 2
    - CT/GC/TV
    - CT/TV
  - GC/TV
  - TV, CT
  - TV, GC
  - TV, CT/GC
  - TV, CT/GC, HSV 1 & 2
  - TV, CT/GC/TV
  - TV, HSV 1 & 2
  - TV, CT, HSV 1 & 2
  - TV, GC, HSV 1 & 2

Fast, actionable results

- 10 min set-up time only
- 2 hrs 40 min for the first 184 CT/GC results
- 1 hrs 40 for the following 184 CT/GC results
- 736 CT/GC results within 9.5 hrs
- Clear yes/no results – no equivocal zone

Minimum reagent storage and space requirements

- Few ready-to-use reagents
- Reagent storage at room temperature

BD FOX™ Extractor Module:
Holds 96 single-dose BD FOX extraction tubes and permanent magnet assembly for on-board DNA extraction.

Sample Processing Station:
Up to 96 specimens, including controls, can be loaded for walk-away capability.
**Safe waste management**
- Liquid waste is automatically neutralised and collected in waste bottle
- Pipette tips are automatically discarded and collected in waste box

**Worry-free and most efficient operation**
- No reagent preparation required
- Fully integrated workflow covering sample extraction, amplification and detection
- Full walk-away operation
- Pierceable caps avoid manual opening of sample tubes
- Patient Sample Identification Location: a membrane switch pad records the location of each sample tube.

**Maximize your efficiency**
- Use BD’S LEAN expertise to optimize your workflow and to compare to existing solution
- Lowest maintenance required
- LIS compatibility

**Amplification/Detection Staging Station:**
Up to two amplification microwell plates can be incubated for real-time amplification and detection.

**Priming Station:**
Two heaters incubate up to two priming microwell plates for hybridization of primers.

**Pipettor Head:**
For consumable check, fluid volume transfer, and microwell plate sealing.
All in one run
Comprehensive STI testing with proven DNA amplification technology
System Overview

High Throughput System
Continuous batching, batch size 96 specimens
2 hours and 40 minutes for the first 184 CT/GC results
184 CT/GC results every 1 hour 40 minutes following
the first results

Amplification and Detection Technology
Strand displacement amplification with real-time
amplification and detection

Contamination Prevention
Closed solid barrier amplification system

Waste Management
Solid (disposable tips) and neutralized liquid waste

Specimen Handling

Specimen Collection Type
Vaginal & endocervical swabs, urethral swabs, urine,
liquid-base cytology (LBC). All collection devices utilize
pierceable caps during processing

On-Board Sample Capacity
96 samples including controls per run

Patient Sample Identification Location
A membrane switch pad records the location of the
tube.
Capacity to read multiple barcode configurations: 2 of
5, code 39, code 128, codabar

Sample Dispensing System
6-station pipettor with liquid-level sensing

Sample Volume
800 μL

Reagent Handling

Reagent Format
Up to 96 microwells, ready-to-use reagents

BD ProbeTec™ Q* Reagent Stability
18 months, 6 weeks after opening at 2 – 33°C

Physical Dimensions

Height
80 in. (203cm)

Width
75 in. (191cm)

Depth
42 in. (107cm)

Weight
1,535 lb (698kg)

Optical Readers
2 optical fluorescence readers

Data Management

Operating Computer
VNS-786 running VxWorks 5.5.1

Host Interface
LIS-RS-232 Serial ASTM 1381/1394

Data Storage
Stores up to 30 runs, capacity to log up to 29
runs in advance

Environmental Requirements

System Operating Temperature Range
64.4° – 91.4°F (18° – 33°C)

Ambient Humidity
20% – 85% RH non-condensing

Noise Specification
Less than 65 dbA

Heat Dissipation
2048 BTU/hr. (600 watt hour)

Location
Level surface, no direct heat

Electrical Requirements

Input Voltage
208 – 240 VAC (single phase line NEMA L6-20P
twist lock plug)

Input Current
20 Amp

Line Frequency
50 – 60 Hz (±3 Hz)

Power Consumption
<3500 watts

UPS
2.1 to 3.6 KVA

Lysing Heater

Power Requirements
108 – 132 VAC/50 – 60 HZ (220 – 240 VAC/50
HZ)

Operating Temperature
64.4°F – 91.4°F (18°C – 33°C)

Operating Humidity
20% – 85% RH non-condensing

Operating Altitude
0 – 6,562 ft. (2,000 m)
<table>
<thead>
<tr>
<th>Catalog Numbers</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>441091</td>
<td><strong>BD Viper™</strong> with XTR™ Technology</td>
</tr>
<tr>
<td>441126</td>
<td><strong>BD ProbeTec™</strong> <em>Chlamydia trachomatis</em> Q* Reagent Pack, 1152 tests</td>
</tr>
<tr>
<td>441124</td>
<td><strong>BD ProbeTec™</strong> <em>Neisseria gonorrhoeae</em> Q* Reagent Pack, 1152 tests</td>
</tr>
<tr>
<td>441125</td>
<td>Control Set for the <strong>BD ProbeTec™</strong> <em>Chlamydia trachomatis/Neisseria gonorrhoeae</em> (CT/GC) Q* Amplified DNA Assays</td>
</tr>
<tr>
<td>441917</td>
<td><strong>BD ProbeTec™</strong> <em>Trichomonas vaginalis</em> (TV) Q* Reagent Pack, 1152 tests</td>
</tr>
<tr>
<td>443433</td>
<td><strong>BD ProbeTec™</strong> <em>Trichomonas vaginalis</em> (TV) Q* Reagent Pack, 384 tests</td>
</tr>
<tr>
<td>441925</td>
<td>Control Set for the <strong>BD ProbeTec™</strong> <em>Chlamydia trachomatis / Neisseria gonorrhoeae / Trichomonas vaginalis</em> (CT/GC/TV) Q* Amplified DNA Assays</td>
</tr>
<tr>
<td>441749</td>
<td><strong>BD ProbeTec™</strong> Herpes Simplex Viruses (HSV 1 &amp; 2) Q* Reagent Pack, 94 tests</td>
</tr>
<tr>
<td>441748</td>
<td>Control Set for the <strong>BD ProbeTec™</strong> Herpes Simplex Viruses (HSV1&amp;2) Q* Amplified DNA Assays</td>
</tr>
<tr>
<td>441128</td>
<td><strong>BD Viper™</strong> Extraction Reagent and Lysis Trough</td>
</tr>
<tr>
<td>441129</td>
<td><strong>BD FOX™</strong> Extraction Tubes</td>
</tr>
<tr>
<td>441354</td>
<td><strong>BD Viper™</strong> Neutralization Pouch</td>
</tr>
<tr>
<td>440752</td>
<td>Microwell Package for the <strong>BD Viper™</strong> System</td>
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<td><strong>BD Viper™</strong> Pipette Tips</td>
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<td>Accessory Kit for use on the <strong>BD Viper™</strong> System (Extracted Mode)</td>
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<td>441358</td>
<td>Male Urethral Specimen Collection Kit for the <strong>BD ProbeTec™</strong> Q* Amplified DNA Assays</td>
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<td><strong>BD ProbeTec™</strong> Q* Collection Kit for Lesion or Endocervical Specimens</td>
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<td>Vaginal Specimen Transport for the <strong>BD ProbeTec™</strong> Q* Amplified DNA Assays</td>
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<td>Swab Diluent for the <strong>BD ProbeTec™</strong> Q* Amplified DNA Assays</td>
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<td>Specimen Tubes and Caps for use on the <strong>BD Viper™</strong> (Extracted Mode)</td>
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<td>Caps for the use on the <strong>BD Viper™</strong> (Extracted Mode)</td>
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<td><strong>BD™</strong> Urine Preservative Transport for the <strong>BD ProbeTec™</strong> Q* Amplified DNA Assays</td>
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<td>Liquid Based Cytology Specimen (LBC) Dilution Tubes for the <strong>BD ProbeTec™</strong> Q* Amplified DNA Assays</td>
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<td>Liquid Based Cytology Specimen (LBC) Dilution Tube Caps for the <strong>BD ProbeTec™</strong> Q* Amplified DNA Assays</td>
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