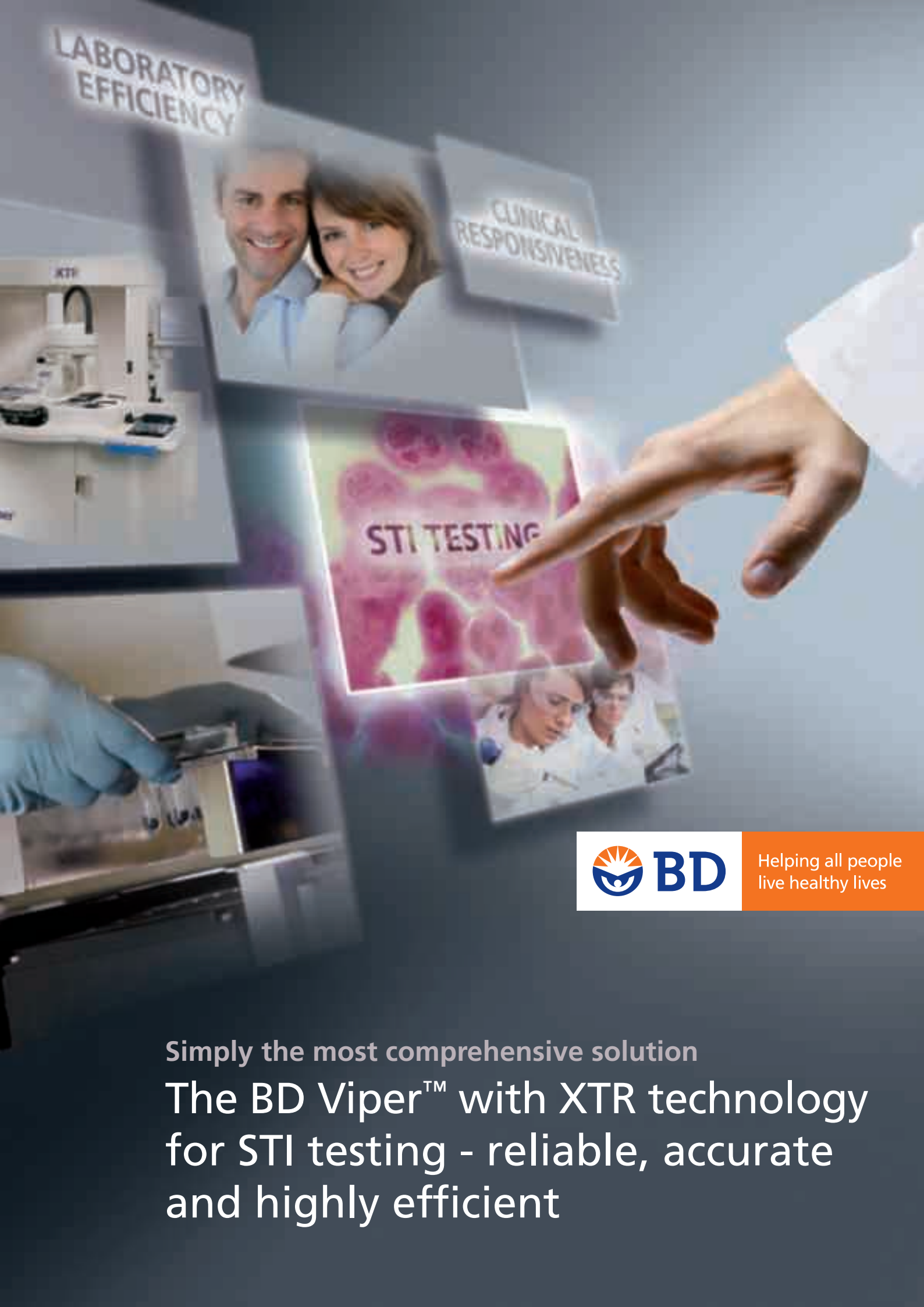


BD

Helping all people live healthy lives

Simply the most comprehensive solution

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


XTR
BD
BD Viper

Summary

Sexually transmitted infections (STI) have been known since antiquity. Gonorrhoea was decribed 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 340000 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.

* ECDC Annual Epidemiological Report 2012

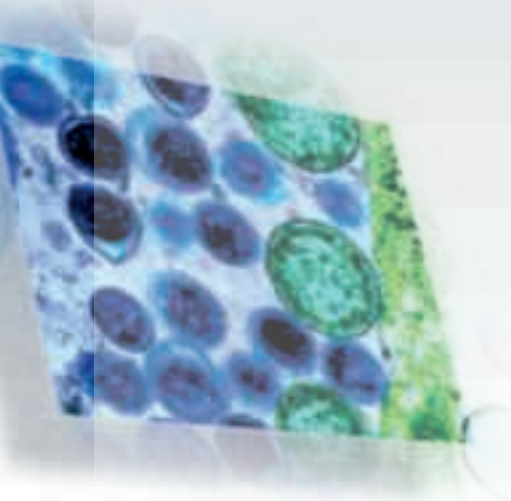
** ECDC STI surveillance report 1990-2009

The BD ProbeTec™ Qˣ Amplified STI DNA Assays: Accurate and

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

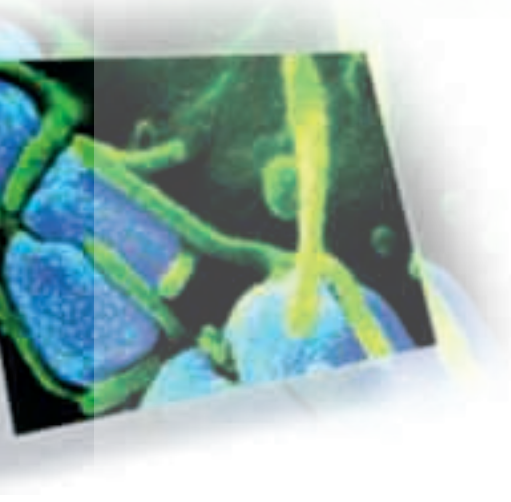


BD ProbeTec™ CT Qˣ Amplified DNA Assay

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

Gonorrheae 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 inthe 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.

Relevant Clinical Answers For Your Patients

CT Q^x and GC Q^x assay specifications

The **BD ProbeTec™** CT Q^x Amplified DNA and GC Q^x 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 Q^x Amplified DNA Assay		GC Q^x Amplified DNA Assay	
	Sensitivity	Specificity	Sensitivity	Specificity
Urine and Swabs	94.5%	98.9%	99.3%	99.4%
LBC	94.1%	99.8%	95.3%	99.95%

Swab specimen type to be processed	Female endocervical swab specimen / Male urethral swab specimen		Vaginal swab specimen			
			Dry vaginal swab specimen (Collection site)		Expressed vaginal swab specimen (Test site)	
Temperature Condition for Transport to Test Site and Storage	2 - 30°C	-20°C	2 - 30°C	-20°C	2 - 30°C	-20°C
Process Specimen According to Instructions	Within 30 days of collection	Within 180 days of collection	Express and process within 14 days of collection	Express and process within 180 days of collection	Within 30 days of expression	Within 180 days of expression
Urine Specimen Type to be Processed	Q^x UPT			NEAT		
Urine Handling Options Prior To Transfer To Q^x UPT	Store urine specimen at 2 - 30°C and transfer to Q^x UPT within 8 h of collection or Store urine specimen at 2- 8°C and transfer to Q^x UPT within 24 h of collection or Transfer to Q^x UPT immediately					
Temperature Condition for Storage and Transport to Test Site	2 - 8°C	2 - 30°C	-20°C	2 - 8°C	2 - 30°C	-20°C
Process Specimen According to Instructions	Within 30 days after transfer to Q^x UPT		Within 180 days after transfer to Q^x UPT	Within 7 days of collection	Within 30 h of collection	Within 180 days of collection

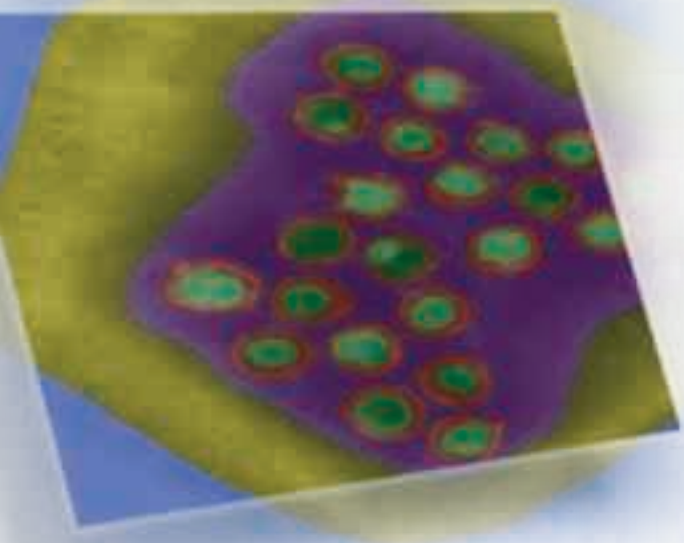
LBC Specimen Type to be processed		
Storage and Transport of Specimens Transferred to the LBC Specimen Dilution Tube	2 - 30°C	-20°C
Process Specimen According to the instructions	30 days	30 days

BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x 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) Q^x Amplified DNA

- 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.



* Bulletin of the World Health Organization 2008;86:805–812.

** 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.

	HSV 1 Qˣ Amplified DNA Assay		HSV 2 Qˣ Amplified DNA Assay	
	Sensitivity	Specificity	Sensitivity	Specificity
UVT in Qˣ Swab Diluent	96.8%	97.6%	98.4%	83.7%
Qˣ Swab Diluent	96.7%	95.1%	98.4%	80.6%

BD ProbeTec™ Qˣ Collection Kit for Endocervical or Lesion Specimens		
Temperature Condition for Transport to Test Site and Storage	2 - 30°C	-20°C
Process Specimen According to Instructions	≤14 days of collection	≤120 days of collection

UVT Specimen			
Temperature Condition for Transport to Test Site and Storage	20 - 25°C	2 - 8°C	-70°C
Process Specimen According to Instructions	Aliquot and prewarm within 48 h of collection	Aliquot and prewarm within 14 days of collection	Aliquot and prewarm within 120 days of collection

UVT Specimen Transferred into Qˣ Swab Diluent			
Temperature Condition for Transport to Test Site and Storage	15 - 30°C	2 - 8°C	-20°C
Process Specimen According to Instructions	Pre-warm within 24 h after aliquottlng	Pre-warm within 14 days of collection	Pre-warm within 120 days of collection

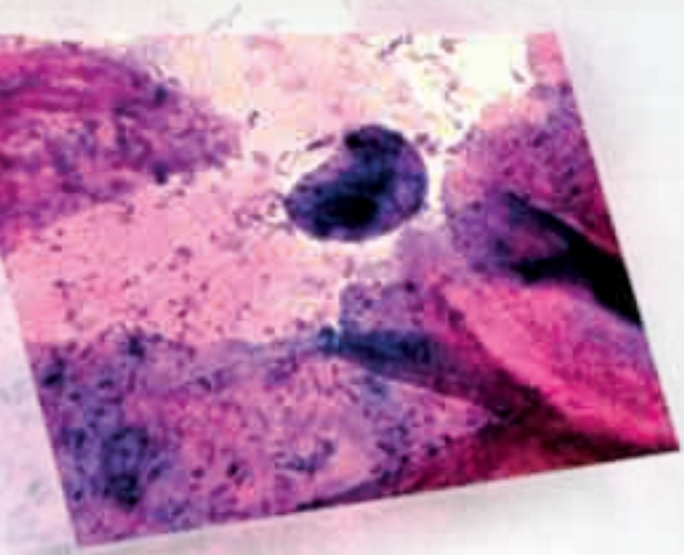
The BD ProbeTec™ Q^x Amplified STI DNA Assays: Accurate and

BD ProbeTec™ Trichomonas vaginalis Q^x Assay

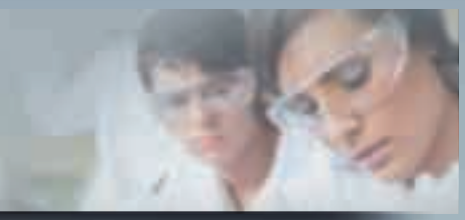
Vaginal trichomoniasis in women has been associated with adverse pregnancy outcomes, particularly premature rupture of membranes, preterm delivery, and low birth weight. It can increase a woman's susceptibility to HIV infection, and may also increase the likelihood of HIV transmission to sex partners. However, further research is needed to confirm these associations and to prove them to be causal.*

The BD ProbeTec™ Trichomonas vaginalis Q^x 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



* Sherrard et al., Int J STD AIDS August 2011 22:421–429.



TV Q^x assay specifications

The **BD ProbeTec™** *Trichomonas vaginalis* (TV) Q^x 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.

	TV Q^x Amplified DNA Assay	
	Sensitivity	Specificity
Neat Urine	95.5%	98.7%
Vaginal Swab Specimen	98.3%	90.0%
Endocervical Swab Specimen	96.5%	99.7%

Neat urine stability		
2 - 8°C	2-30°C	-20°C
7 days	24 hours	14 days

Vaginal Swab Specimens stability				
Dry vaginal swab specimens (collection site)			Expressed vaginal swab specimens (Test site)	
2 – 8°C	30°C	-20°C	2 – 30°C	-20°C
Express and process within 14 days of collection	Express and process within 3 days of collection	Within 180 days of collection	Within 30 days of expression	Within 180 days of expression

Endocervical swab specimens stability	
2 – 30 °C	-20°C
Within 30 days of collection	Within 180 days of collection

The BD Viper™ System with XTR Technology: Your Solution for

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:

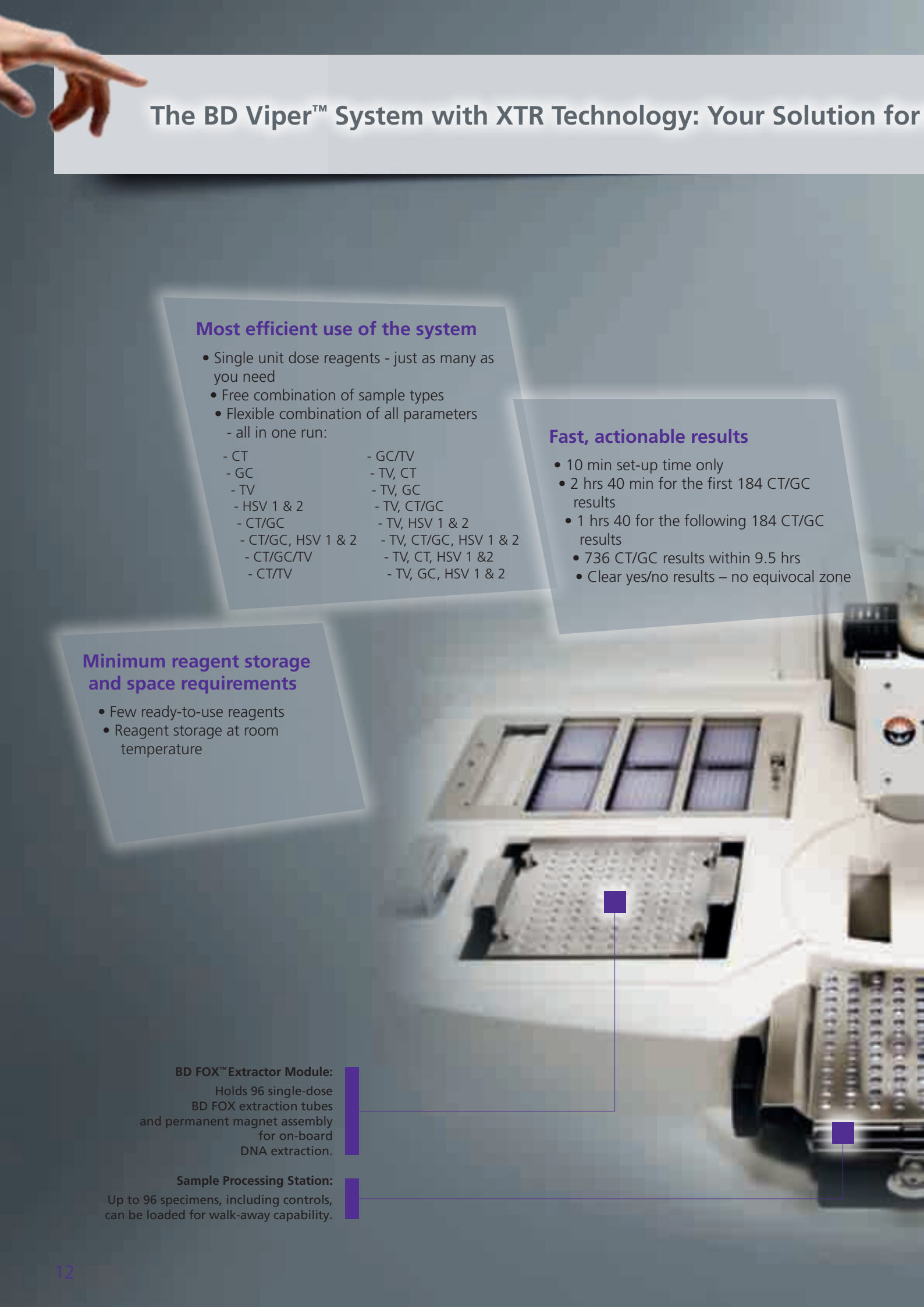
- CT
- GC
- TV
- HSV 1 & 2
- CT/GC
- CT/GC, HSV 1 & 2
- CT/GC/TV
- CT/TV
- GC/TV
- TV, CT
- TV, GC
- TV, CT/GC
- TV, HSV 1 & 2
- TV, CT/GC, HSV 1 & 2
- TV, CT, HSV 1 &2
- TV, GC, HSV 1 & 2

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.

Efficient and Worry Free STI Testing

Safe waste management

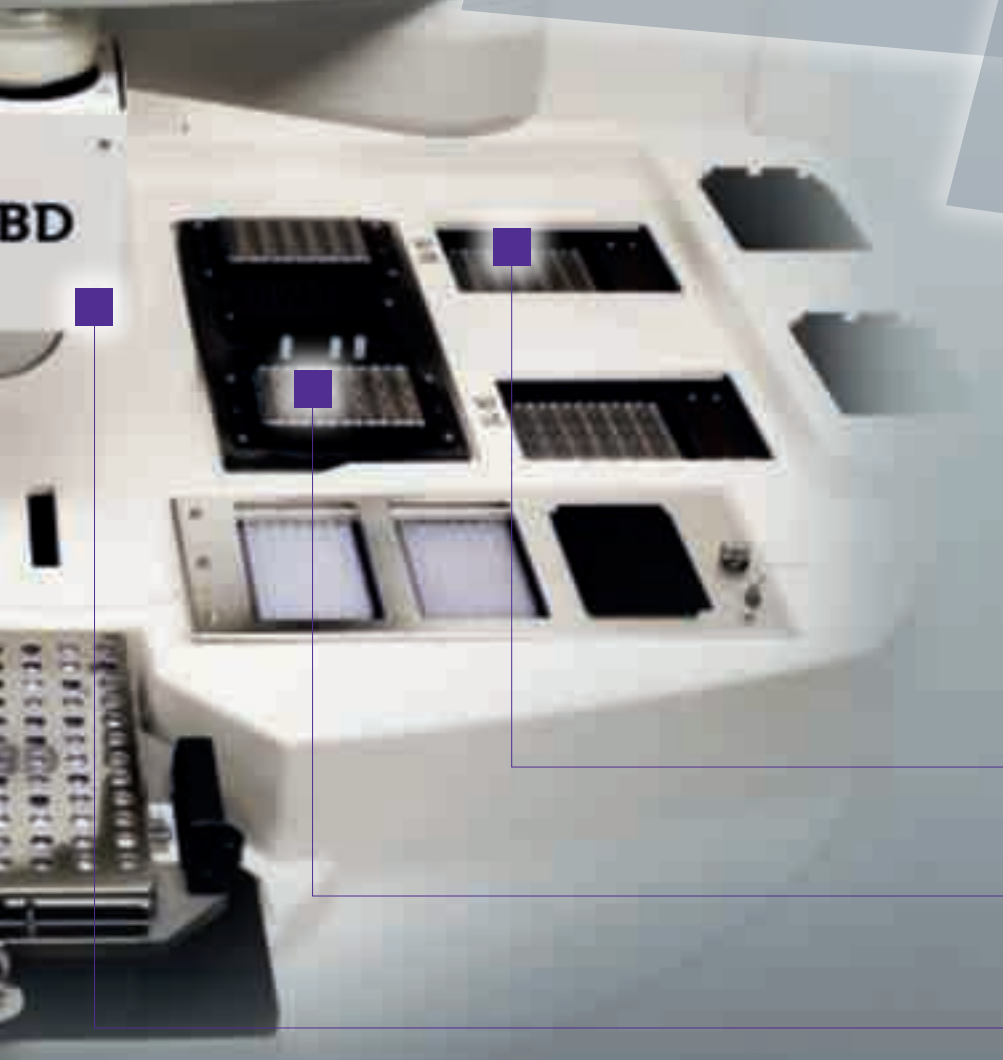
- Liquid waste is automatically neutralised and collected in waste bottle
- Pipette tips are automatically discarded and collected in waste box

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^{x} 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)

Catalog Numbers	Description
441091	**BD Viper™** with XTR™ Technology
441126	**BD ProbeTec™** *Chlamydia trachomatis* Q^x Reagent Pack, 1152 tests
441124	**BD ProbeTec™** *Neisseria gonorrhoeae* Q^x Reagent Pack, 1152 tests
441125	Control Set for the **BD ProbeTec™** *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Q^x Amplified DNA Assays
441917	**BD ProbeTec™** *Trichomonas vaginalis* (TV) Q^x Reagent Pack, 1152 tests
443433	**BD ProbeTec™** *Trichomonas vaginalis* (TV) Q^x Reagent Pack, 384 tests
441925	Control Set for the **BD ProbeTec™** *Chlamydia trachomatis / Neisseria gonorrhoeae / Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays
441749	**BD ProbeTec™** Herpes Simplex Viruses (HSV 1 & 2) Q^x Reagent Pack, 94 tests
441748	Control Set for the **BD ProbeTec™** Herpes Simplex Viruses (HSV1&2) Q^x Amplified DNA Assays
441128	**BD Viper™** Extraction Reagent and Lysis Trough
441129	**BD FOX™** Extraction Tubes
441354	**BD Viper™** Neutralization Pouch
440752	Microwell Package for the **BD Viper™** System
440724	**BD Viper™** Pipette Tips
441391	**BD Viper™** Trash Bags
441392	**BD Viper™** Trash Box
441853	Accessory Kit for use on the **BD Viper™** System (Extracted Mode)
441358	Male Urethral Specimen Collection Kit for the **BD ProbeTec™** Q^x Amplified DNA Assays
441357	**BD ProbeTec™** Q^x Collection Kit for Lesion or Endocervical Specimens
441122	Vaginal Specimen Transport for the **BD ProbeTec™** Q^x Amplified DNA Assays
441361	Swab Diluent for the **BD ProbeTec™** Q^x Amplified DNA Assays
441360	Specimen Tubes and Caps for use on the **BD Viper™** (Extracted Mode)
441359	Caps for the use on the **BD Viper™** (Extracted Mode)
441362	**BD™** Urine Preservative Transport for the **BD ProbeTec™** Q^x Amplified DNA Assays
441444	Liquid Based Cytology Specimen (LBC) Dilution Tubes for the **BD ProbeTec™** Q^x Amplified DNA Assays
441443	Liquid Based Cytology Specimen (LBC) Dilution Tube Caps for the **BD ProbeTec™** Q^x Amplified DNA Assays

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Link to Business.