BD Vaginal Specimen Transport for the BD ProbeTec™ Q^x Amplified DNA Assays

CE 2797 IVD R_x Only STERILE R

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English

REF 441122

INTENDED USE

The Vaginal Specimen Transport for the BD ProbeTec™ Qx Amplified DNA Assays offers a convenient way to collect and transport specimens from the patient to the laboratory. It is intended to be used for patient collection of vaginal swab specimens in a clinical setting according to the instructions provided. This transport system is for use with the BD ProbeTec™ Qx Amplified DNA Assays on the BD Viper™ System in Extracted Mode and the BD Viper™ LT System. Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Vaginal Specimen Transport for the BD ProbeTec™ Qx Amplified DNA Assays is not for home use.

SUMMARY AND EXPLANATION

The Vaginal Specimen Transport for the BD ProbeTec™ Q^x Amplified DNA Assays is a sterile, self-contained system. The polyester-tipped swab on a plastic purple shaft facilitates obtaining the specimen and maintaining the organisms for nucleic acid extraction and amplification on the BD Viper™ System in Extracted Mode.

REAGENTS

Materials Provided

The Vaginal Specimen Transport for the BD ProbeTec™ Q^x Amplified DNA Assays contains 100 units with one copy of patient collection instructions. Each unit contains one polyester-tipped swab in a transport sheath.

Storage Instructions

Store swabs at 5–25 °C. Do not use beyond the expiration date. Swab sterility is guaranteed if primary swab container is intact.

Warnings and Precautions

For in vitro diagnostic use. For Use by Trained Laboratory Personnel.

1. Pathogenic microorganisms including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. “Standard Precautions”[1-4] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
2. Optimal performance of the BD ProbeTec™ Q^x Amplified DNA Assays requires proper specimen collection, handling and transport. Time and temperature conditions for storage must be maintained during transport.
3. Proper labeling should accompany each specimen to the laboratory.
4. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain high levels of organisms. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
5. Specimens must be collected and processed before the expiration date of the Vaginal Specimen Transport.
6. Vaginal Specimen Transport for the BD ProbeTec™ Q^x Amplified DNA Assays is for single use only; reuse may cause a risk of infection and/or inaccurate results.
7. Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

SPECIMEN COLLECTION AND TRANSPORT

NOTE: Ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

1. Wash hands with soap and water. Rinse and dry.
2. It is important to maintain a comfortable balance during the collection procedure.
3. Twist the cap to break the seal. Pull the cap with attached swab from the tube. Do not touch the soft tip or lay the swab down. If you touch or drop the swab tip or the swab is laid down, discard the swab and request a new vaginal swab.
4. Hold the swab by the cap with one hand so that the swab tip is pointing toward you.
5. With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vaginal opening. Point the tip toward your lower back and relax your muscles.
6. Gently slide the swab no more than two inches into the vagina. If the swab does not slide easily, gently rotate the swab as you push. **If it is still difficult, do not attempt to continue.** Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.

7. Rotate the swab for 10–15 seconds.
8. Withdraw the swab without touching the skin. Place the swab in the tube and cap securely.
9. After collection, wash hands with soap and water, rinse, and dry.
10. Return tube with swab as instructed.

Specimen Storage and Transport

Specimens for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing:

Specimens collected with the Vaginal Specimen Transport must be stored and transported to the laboratory and/or test site at 2–30 °C within 14 days of collection. Alternatively, specimens may be stored and transported to the laboratory frozen (-20 °C) within 180 days of collection. Vaginal swab specimens must be transported to the laboratory in the swab tube provided.

Swab Specimen Type to be Processed	Expressed Vaginal Swab Specimens		Dry Vaginal Swab Specimens	
Temperature Condition for Storage and Transport to Test Site	2–30 °C	-20 °C	2–30 °C	-20 °C
Process and Test Specimen According to Instructions	Within 30 days of collection	Within 180 days of collection	Within 14 days of collection	Within 180 days of collection

Specimens for *Trichomonas vaginalis* testing

Specimens collected with the Vaginal Specimen Transport must be stored and transported from the collection site to the test site at 2–30 °C and pre-warmed within 3 days of collection. Specimens stored and transported to the test site at 2–8 °C may be stored at 2–8 °C for up to 14 days prior to pre-warming. Specimens may also be transported and stored frozen at -20 °C for up to 180 days prior to pre-warming. Vaginal swab specimens must be transported to the laboratory in the swab tube provided.

Swab Specimen Type to be Processed	Expressed Vaginal Swab Specimens		Dry Vaginal Swab Specimens		
Temperature Condition for Storage and Transport to Test Site	2–30 °C	-20 °C	2–8 °C	30 °C	-20 °C
Process and Test Specimen According to Instructions	Within 30 days of collection	Within 180 days of collection	Within 14 days of collection	Within 3 days of collection	Within 180 days of collection

For domestic and international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and etiologic agents/infectious substances. Time and temperature conditions for storage must be maintained during transport.

AVAILABILITY

Catalog Number	Description
441122	Vaginal Specimen Transport for the BD ProbeTec™ Qx Amplified DNA Assays

REFERENCES

1. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pa.
2. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guide for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. *17*:53-80.
3. U.S. Department of Health and Human Services. 2007. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 5th ed. U.S. Government Printing Office, Washington, D.C.
4. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/31/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Change History

Revision	Date	Change Summary
(03)	2018-08	Updated BD branding
(04)	2021-10	Added CE Notified Body 2797 for IVDR 2017/746. Added Intended User - For Use by Trained Laboratory Personnel, Serious Incident statement and Safe Disposal statement. Added IVD, Sterile R, Do not Reuse, Do not Use if Package is Damaged and eIFU with URL. Added Availability Section Updated Australian and New Zealand Sponsor addresses. Updated EC REP address. Updated Symbols Glossary. Added CH REP symbol with address.

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for *<n>* tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
	Patient number
	This way up
	Do not stack
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier

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