BD Control Set for the BD ProbeTec™ *Chlamydia trachomatis/Neisseria gonorrhoeae/ Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays

CE 2797 IVD R_x Only bd.com/e-labeling

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INTENDED USE

The Control Set for the BD ProbeTec™ *Chlamydia trachomatis / Neisseria gonorrhoeae / Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays contains Positive and Negative Controls that are intended for the qualitative Quality Control of the automated BD ProbeTec™ *Chlamydia trachomatis* Q^x Amplified DNA Assay, the BD ProbeTec™ *Neisseria gonorrhoeae* Q^x Amplified DNA Assay, and/or the BD ProbeTec™ *Trichomonas vaginalis* Q^x Amplified DNA Assay when tested with the BD Viper™ System in Extracted Mode.

SUMMARY AND EXPLANATION

Quality control must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

The BD ProbeTec™ *Chlamydia trachomatis*/*Neisseria gonorrhoeae*/*Trichomonas vaginalis* (CT/GC/TV) Q^x Positive and Negative Controls must be included with each BD Viper™ run. Controls must be positioned according to the BD Viper™ Instrument User's Manual. The CT/GC/TV Q^x Positive Control will monitor for substantial reagent failure only. The CT/GC/TV Q^x Negative Control monitors for reagent and/or environmental contamination.

The CT/GC/TV Q^x Positive Control contains cloned CT/GC/TV target regions. This control may be used for internal quality control or users may develop their own internal quality control material.[1] Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. Refer to CLSI C24-A3 for additional guidance on appropriate internal quality control testing practices.[1] The Positive Control contains approximately 2,400 copies per mL of each pCTB4 and pGCint3 linearized plasmids, and approximately 4,000 copies per mL of TVAP651 linearized plasmid.

REAGENTS

Materials Provided

Each Control Set for the BD ProbeTec™ *Chlamydia trachomatis*/*Neisseria gonorrhoeae*/*Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays contains: 24 CT/GC/TV Q^x Positive Control Tubes containing approximately 2,400 copies per mL of each pCTB4 and pGCint3 linearized plasmids, and approximately 4,000 copies of TVAP651 linearized plasmid in carrier nucleic acid, and 24 CT/GC/TV Q^x Negative Control Tubes containing carrier nucleic acid alone. The concentration of the pCTB4, pGCint3, and the TVAP651 plasmids are determined by UV spectrophotometry.

Materials Required But Not Provided

BD ProbeTec™ *Chlamydia trachomatis*/*Neisseria gonorrhoeae*/*Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays and accessories, Nitrile gloves.

Storage and Handling Requirements

Reagents may be stored at 2–33 °C. Do not freeze.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use. For Use by Trained Laboratory Personnel.
2. The Control Set for the BD ProbeTec™ *Chlamydia trachomatis/Neisseria gonorrhoeae/Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays is used to evaluate the performance of the BD ProbeTec™ *Chlamydia trachomatis/ Neisseria gonorrhoeae/Trichomonas vaginalis* (CT/GC/TV) Q^x Amplified DNA Assays and should not be used with other methods.
3. For additional specific warnings, cautions, and notes specific to the BD Viper™, consult the BD Viper™ Instrument User's Manual.
4. Do not re-hydrate the controls prior to loading in the BD Viper™ Lysing Rack.
5. Do not eat, drink or smoke in areas where specimens or kit reagents are handled.

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.

QUALITY CONTROL PREPARATION

The CT/GC/TV Q^x Positive and Negative Controls (i.e., assay controls) do not require addition of fluid by the user prior to loading in the BD Viper™ Lysing Rack.

Interpretation of Quality Control Results

The CT/GC/TV Q^x Positive Control and the CT/GC/TV Q^x Negative Control must test as positive and negative, respectively, in order to obtain patient results. If controls do not perform as expected, the run is considered invalid and patient results will not be reported by the instrument. If either of the controls does not provide the expected results, repeat the entire run using a new set of controls, new extraction tubes, new extraction reagent trough, new lysis trough and new microwells. If the repeat QC does not provide the expected results, contact BD Technical Services.

Refer to the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay (BD Catalog Number 441126) / BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (BD Catalog Number 441124) / BD ProbeTec™ *Trichomonas vaginalis* Q^x Amplified DNA Assay (BD Catalog Number 441917) package inserts for further interpretation of the quality control results.

LIMITATIONS OF THE PROCEDURE

The CT/GC/TV Q^x Control Set may not adequately control for specimen processing. To prepare and test specimen processing controls, refer to the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay (BD Catalog Number 441126) / BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (Catalog Number 441124) / BD ProbeTec™ *Trichomonas vaginalis* Q^x Amplified DNA Assay (Catalog Number 441917) package inserts.

REFERENCE

1. Clinical and Laboratory Standards Institute. 2006. Approved Guideline C24-A3. Statistical quality control for quantitative measurement procedures: principles and definitions, 3rd ed. CLSI, Wayne, PA.

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.

Refer to the Eudamed website: https://ec.europa.eu/tools/eudamed for Summary of Safety and Performance.

Change History

Revision	Date	Change Summary
06	2021-10	Added CE Notified Body 2797 for IVDR 2017/746. Added Intended Use, Intended User, Serious Incident statement and Safe Disposal statement. Added IVD, R_X Only, eIFU with URL and Do not Use if Package is Damaged symbol. Updated Australian and New Zealand Sponsor addresses. Updated EC REP address.. Updated Technical Information and Eudamed link. 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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