

③ BD Control Set for the BD ProbeTec™ *Chlamydia* trachomatis/Neisseria gonorrhoeae/ Trichomonas vaginalis (CT/GC/TV) Qx Amplified DNA Assays









8089071(06) 2021-10 English

REF 441925

INTENDED USE

The Control Set for the BD ProbeTec™ Chlamydia trachomatis / Neisseria gonorrhoeae / Trichomonas vaginalis (CT/GC/TV) QX 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) Qx 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 Qx Positive Control will monitor for substantial reagent failure only. The CT/GC/TV Qx Negative Control monitors for reagent and/or environmental contamination.

The CT/GC/TV Qx 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. 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 Qx 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 Qx 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) Qx 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.
- The Control Set for the BD ProbeTec™ Chlamvdia 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) Qx Amplified DNA Assays and should not be used with other
- 3. For additional specific warnings, cautions, and notes specific to the BD Viper™, consult the BD Viper™ Instrument User's
- 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

 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.

 ${\tt US\ Customers\ only: For\ symbol\ glossary,\ refer\ to\ {\tt bd.com/symbols-glossary}}$

Manufacture Ec REP Authorized representative in the European Community	Symbol	Meaning	Symbol	Meaning
Authorized representative in the European Community Call large Authorized representative in Web European Community Live By date Do not stock Single state borre system Containing a runber Containing a runber Containing a runber Containing a runber Settled using a respective processing stechniques Final Settled using a respective stechniques Final Settled using a respective processing stechniques Final Settled using a respective stechniques Final Settled using a res		•	•	-
Authorized representative in Switzerland Districture			#	Patient number
Lice by date Lice by date Lice by date Single deale barrie system Contains or previous of phylodiate combination of biol 2 ethylhogic size of the product of the pr			† †	This way up
Use by date Discrete Single seemed before system		Date of manufacture	<u> </u>	
Contains or presence of phthidate combination of bit2 ethythogy (Oct-P) and bereal policy inhabition (BRP) Self Coalologue number Contains or presence of phthidate (BRP) (Oct-P) and bereal policy inhabition (BRP) (Oct-P) and bereal po		Use-by date		Do not stack
Set	LOT	Batch code		Single sterile barrier system
Sterile during signifies European techniques	REF	Catalogue number	PHT DEHP BBP	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
Secretary Secr	SN	Serial number		Collect separately
Device for near-patient testing	STERILE	Sterile		Indicates separate collection for waste of electrical and electronic equipment required.
Device for near-patient testing	STERILE A	Sterilized using aseptic processing techniques	CE	CE marking; Signifies European technical conformity
Device for self-testing Device for self-testing		Sterilized using ethylene oxide	40	Davise for page patient tecting
Do not resterilize Non-sterile Non-steril			<u>"</u> "	Device for near-patient testing
Non-sterile Non-sterile Non-sterile Do not use if package is damaged and consult instructions for use Control of manufacture Cord shall be replaced by either the two letter or the three letter co. Coffection time Peed here Sterile fluid path (ethylene axide) Sterile fluid path (irradiation) Finglie, handle with care Keep away from sunlight Keep away from sunlight Keep away from sunlight Lower limit of temperature I Upper limit of temperature I Temperature limit Temperature limit Modical device Ultrainian conformity mark Contains hazardous substances Ultrainian conformity mark Countrol Meets FCC requirements per 21 CFR Part 15 Commodil Negative control Negative control Contains sufficient for <n> tests Port VVD performance evaluation only</n>			į,	Device for self-testing
Country of manufacture Country of manufacture in the two letter or the three letter country Peel here Peel here Reep away from light Hydrogen gas is generated Hydrogen gas is generated For your limit of temperature Country of manufacture in the two letter or the three letter country Collection date Country Reep away from light Hydrogen gas is generated For your limit of temperature Country Contains of temperature End panel sequence number Internal sequence number Modecal device For your feel fluid path Country of manufacture Country of manufacture Country of manufacture Country of manufacture in the two letter or the three letter country Coultry of manufacture Coultry of manufacture in the country of the place of the	(1178/22)	Do not resterilize	R _x Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on
Do not use if package is damaged and consult instructions for use Collection time	NON	Non-sterile		Country of manufacture
Sterile fluid path Sterile fluid path (ethylene oode) Peel here Collection date Fragile, handle with care Keep away from light Keep away from sunlight Keep away from sunlight Lower limit of temperature Upper limit of temperature I temperature limit I temperature limit Biological risks Do not re use Consult instructions for use or consult electronic instructions for use Contains no presence of natural rubber latex I vitro diagnostic medical device Controls Negative control Controls Sequence ontrol Controls Sequence ontrol Controls Sequence of natural rubber latex Upper limit of temperature I in ternal sequence number Will product certification for US and Canada Upper limit of temperature limit I control of temperature I limit of temperature limit I loternal sequence number Minute limit of temperature Will product certification for US and Canada Upper limit of temperature I limit of temperature Will product certification for US and Canada Upper limit of temperature Controls Peat to Sequence number Will product certification for US and Canada Upper limit of temperature Controls or presence of natural rubber latex Upper limit of temperature Unique device identifier		Do not use if package is damaged and consult instructions for use		<u> </u>
Sterile fluid path (irradiation) Fragile, handle with care Keep away from light Keep away from light Keep dry Hydrogen gas is generated Perforation Start panel sequence number Lower limit of temperature Upper limit of temperature Internal sequence number Humidity limitation MD Medical device Biological risks Do not re-use Consult instructions for use or consult electronic instructions for use Consult instructions for use or consult electronic instructions for use In vitro diagnostic medical device Cournal: Negative control Cournal: Negative control Contains sufficient for <n> tests For IVD performance evaluation only</n>	STERILE	Sterile fluid path		
Fragile, handle with care Keep away from sunlight Keep dry Lower limit of temperature Upper limit of temperature Internal sequence number Internal sequence number Min Medical device Biological risks Do not re-use Contains paraerous errors for use or consult electronic instructions for use Contains or presence of natural rubber latex In vitro diagnostic medical device In vitro diagnostic medical device Control Negative control	STERILE EO	Sterile fluid path (ethylene oxide)		Peel here
Keep dry	STERILE R	Sterile fluid path (irradiation)	12	Collection date
Reep dry	Ţ	Fragile, handle with care	$ \\ $	Keep away from light
Lower limit of temperature Upper limit of temperature		Keep away from sunlight	H ₂	Hydrogen gas is generated
Upper limit of temperature Image: Temperature limit Internal sequence number Internal sequen	*	Keep dry	((C)	Perforation
Temperature limit MD Medical device		Lower limit of temperature		Start panel sequence number
Temperature limit MD Medical device		Upper limit of temperature		End panel sequence number
Biological risks Do not re-use Ukrainian conformity mark Consult instructions for use or consult electronic instructions for use Caution Caution UATEX Contains or presence of natural rubber latex UDI Unique device identifier UDI Unique device identifier For IVD performance evaluation only		Temperature limit		Internal sequence number
Do not re-use Consult instructions for use or consult electronic instructions for use Caution Carex Contains or presence of natural rubber latex IVD In vitro diagnostic medical device CONTROL-1 Positive control Contains sufficient for <n> tests For IVD performance evaluation only Ukrainian conformity mark Meets FCC requirements per 21 CFR Part 15 Culture ULl product certification for US and Canada Unique device identifier</n>	Ø	Humidity limitation	MD	Medical device
Consult instructions for use or consult electronic instructions for use Caution Cartin Contains or presence of natural rubber latex IVD In vitro diagnostic medical device CONTROL! Negative control Contains sufficient for <n> tests For IVD performance evaluation only Meets FCC requirements per 21 CFR Part 15 CUL us UL product certification for US and Canada Unique device identifier</n>	₩	Biological risks		Contains hazardous substances
Caution Carex Contains or presence of natural rubber latex IVD In vitro diagnostic medical device CONTROL! Positive control Contains sufficient for <n> tests For IVD performance evaluation only Meets FCC requirements per 21 CFR Part 15 LUDI UL product certification for US and Canada ULDI Unique device identifier Void in vitro diagnostic medical device CONTROL! Positive control For IVD performance evaluation only</n>	2	Do not re-use	**	Ukrainian conformity mark
Caution Contains or presence of natural rubber latex UDI Unique device identifier UVD In vitro diagnostic medical device CONTROL! Negative control CONTROL! Positive control Contains sufficient for <n> tests For IVD performance evaluation only</n>	Ţ <u>i</u>	Consult instructions for use or consult electronic instructions for use		Meets FCC requirements per 21 CFR Part 15
Contains or presence of natural rubber latex IVD In vitro diagnostic medical device CONTROL! Negative control CONTROL! Positive control Contains sufficient for <n> tests For IVD performance evaluation only</n>	\triangle	Caution		UL product certification for US and Canada
Negative control	LATEX	Contains or presence of natural rubber latex		Unique device identifier
CONTROL* Positive control Contains sufficient for <n> tests For IVD performance evaluation only</n>	IVD	In vitro diagnostic medical device		
Contains sufficient for <n> tests For IVD performance evaluation only</n>		Negative control		
For IVD performance evaluation only		Positive control		
	Σ	Contains sufficient for <n> tests</n>		
	Ţ,	For IVD performance evaluation only		
Non-pyrogenic Non-pyrogenic	×	Non-pyrogenic		



Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA EC REP Becton Dickinson Ireland Ltd.
Donore Road, Drogheda
Co. Louth, A92 YW26, Ireland

CH REP BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland

Australian and New Zealand Sponsors: Becton Dickinson Pty Ltd. 66 Waterloo Road Macquarie Park NSW 2113, Australia Becton Dickinson Limited 14B George Bourke Drive Mt. Wellington Auckland 1060, New Zealand

BD, the BD Logo, ProbeTec, and Viper are trademarks of Becton, Dickinson and company or its affiliates. All other trademarks are the property of their respective owners. © 2021 BD. All rights reserved.