

INSTRUCTIONS FOR USE

IVD

■ Assayed CT/NG Control Panel

INTENDED USE

The Assayed CT/NG Control Panel is intended for use as an external assayed positive and negative quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) performed with the Cepheid Xpert® CT/NG assay on the GeneXpert® Instrument System. The controls comprise cultured and inactivated *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as the positive control and human cells as the negative control.

The Assayed CT/NG Control Panel is not intended to replace manufacturer controls provided with the device.

SUMMARY AND EXPLANATION

The Assayed CT/NG Control Panel is a ready to use external quality control that can be used to monitor the extraction, amplification and detection of the Cepheid Xpert® CT/NG Assay. Routine use of quality controls helps in identifying problems with the test system due to instrument or reagent failure. At a minimum, controls should be run at the frequency recommended by the assay system manufacturer.

COMPOSITION

The Assayed CT/NG Control Panel is comprised of cultured organisms which have been inactivated by radiological or temperature treatments. The positive control contains inactivated *Neisseria gonorrhoeae* cells and inactivated *Chlamydia trachomatis* elementary bodies at target levels designed to provide reproducible performance above the limit of detection of the assay. *Neisseria gonorrhoeae* cells are grown on non-selective agar, collected in suspending buffer, and inactivated prior to processing into swab controls. *Chlamydia trachomatis* elementary bodies are collected from cell culture and cellular debris is removed by centrifugation. The negative control contains human cells that serve as a target for the Sample Adequacy Control test within the assay. Each Assayed CT/NG Control Panel consists of 6 individually packaged positive control swabs and 6 individually packaged negative control swabs. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives and stabilizers. The solution is lyophilized into a ready-to-use swab.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Not to be used by untrained personnel.
- Do not open foil pouch until ready to use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines. The material has been inactivated. However, no known test or inactivation method can assure that this product will not transmit infection.
- Wear proper personal protective equipment.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at www.microbiologics.com or by contacting Technical Support at +1.320.229.7045 or U.S. Toll Free +1.866.286.6691.
- These products are not made with natural rubber latex.

STORAGE AND EXPIRATION

Store the Assayed CT/NG Control Panel at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately.

Assayed CT/NG Control Panel should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The packaging is damaged or shows evidence of tampering
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

- GeneXpert® Instrument System.
- Cepheid Xpert® CT/NG Assay Kit
- Cepheid Xpert® Vaginal/Endocervical Specimen Collection Kit (SWAB/A-50)
- Cepheid Xpert® Urine Collection Kit (URINE/A-50)
- Package Insert of the Cepheid Xpert® CT/NG Assay
- 1mL Transfer Pipettes provided in the Cepheid Xpert® CT/NG Assay Kit
- Nuclease-free water (HPLC minimum grade)
- Vortex

INSTRUCTIONS FOR USE

1. Read the package insert specific to the Cepheid Xpert® CT/NG assay.
2. Tear open the foil pouch containing the quality control swab at the notch.
3. Remove the swab from the pouch.

Endocervical/Vaginal Collection Kit

4. Insert the swab into the Transport Reagent Tube from the dedicated Cepheid Xpert® CT/NG Vaginal/Endocervical Specimen Collection Kit for the Cepheid Xpert® CT/NG assay.
5. Break the swab by snapping the shaft on the rim of the transport reagent tube
6. Cap the transport reagent tube and vortex the vial for 10 seconds.
7. Open the lid of the Cepheid Xpert® CT/NG cartridge. Fill transfer pipette provided in the Cepheid Xpert® CT/NG assay to just above the mark on the pipette shaft and empty the pipettes' contents into the sample chamber of the Cepheid Xpert® CT/NG Cartridge. Test must be started within 30 minutes of adding the sample to the cartridge.
8. Close the cartridge lid and start the test.

Urine Collection Kit

9. Add 1.5mL of nuclease-free water to the Urine Transport Reagent Tube from the dedicated Cepheid Xpert® CT/NG Urine Specimen Collection Kit for the Cepheid Xpert® CT/NG assay.
10. Insert the swab into the Urine Transport Reagent Tube
11. Break the swab by snapping the shaft on the rim of the transport reagent tube
12. Cap the transport reagent tube and vortex vial for 10 seconds.
13. Open the lid of the Cepheid Xpert® CT/NG cartridge. Fill transfer pipette provided in the Cepheid Xpert® CT/NG assay to just above the mark on the pipette shaft and empty the pipettes' contents into the sample chamber of the Cepheid Xpert® CT/NG Cartridge. Test must be started within 30 minutes of adding the sample to the cartridge.
14. Close the cartridge lid and start the test.

LIMITATIONS

- Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.
- Each positive and negative control swab is only intended to be used once.

EXPECTED VALUES

The following results are expected when running the Assayed CT/NG Control Panel with the Cepheid Xpert® CT/NG Assay:

8196 Control	Expected Assay Result	Interpretation
6016 – Positive Control	CT Detected NG Detected	CT target and NG target DNA sequences are detected.
6017 – Negative Control	CT Not Detected NG Not Detected	Neither CT nor NG target DNA sequences are detected.

A positive control that yields a negative result may be indicative of a specimen handling/preparation problem. Repeat the test using a new swab.

If a negative control yields a positive result, clean the GeneXpert® instrument per the user manual and clean the work area. Repeat the test using a new swab.

Each lab should establish its own quality systems.

REPRODUCIBILITY STUDY

The Assayed CT/NG Control Panel was evaluated at three testing sites with two operators at each site (total of six operators). Three lots of the control material were tested with the Cepheid Xpert® CT/NG assay on the Cepheid Xpert® Instrument, over five days. Each positive and negative control was tested in three replicates on each day. There were seven ERROR results (assay aborted due to instrument or reagent problem) and one INVALID result (failure of the internal control/s). Those samples were retested using a new control swab according to the Instructions for Use. All testing utilized the Cepheid Xpert Vaginal/Endocervical Swab Specimen Collection kit.

Positive Target	Agreement (%) with Expected Results, by Test Site			
	Site 1 ^{1,4}	Site 2 ^{2,4}	Site 3	Overall
<i>C. trachomatis</i>	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
<i>N. gonorrhoeae</i> (NG2)	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
<i>N. gonorrhoeae</i> (NG4)	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
SPC ³	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)

¹ Three ERROR results were observed; in all cases a new control was retested and the expected results were obtained.

² Two ERROR results and one INVALID result were obtained; in all cases a new control was retested and the expected results were obtained.

³ SPC: Sample Processing Control

⁴ More than 30 measurements were taken as extra positive controls were ran during re-tests of negative controls.

Negative Target	Agreement (%) with Expected Results, by Test Site			
	Site 1 ^{1,2,3}	Site 2 ^{2,3}	Site 3	Overall
SAC	33/33 (100)	34/34 (100)	30/30 (100)	97/97 (100)
SPC	33/33 (100)	34/34 (100)	30/30 (100)	97/97 (100)

¹ Two ERROR results were observed at Site 1; in all cases a new control was retested and the expected results were obtained.

² One Negative Control at Site 1 and two Negative Controls at Site 2 generated a positive result for NG2 target, however the qualitative results were negative in each case because the Cepheid Xpert® CT/NG Assays requires both NG2 and NG4 targets to be positive in order to return a positive result for NG. In accordance with the assay protocol, the work area was cleaned and the controls were retested.

³ More than 30 measurements were taken as extra negative controls were ran during re-tests of positive controls.











Site	Mean Ct (%CV) Positive Control		
	CT1	NG2	NG4
1	31.3 (1.3)	31.2 (1.4)	30.6 (1.5)
2	31.2 (2.6)	31.8 (2.1)	31.1 (2.6)
3	33.0 (3.9)	33.4 (4.1)	32.5 (4.0)
All Sites	31.8 (3.8)	32.1 (4.0)	31.4 (3.9)

%CV: Percent Coefficient of Variation; SPC: Sample Processing Control

Site	Mean Ct (%CV) Negative Control	
	SAC	SPC
1	27.3 (1.8)	31.6 (0.9)
2	27.7 (1.8)	31.4 (0.7)
3	28.8 (4.1)	31.5 (0.5)
All Sites	27.9 (3.5)	31.5 (0.7)

%CV: Percent Coefficient of Variation; SAC: Sample Adequacy Control; SPC: Sample Processing Control

KEY OF SYMBOLS

	Batch code (Lot)		In vitro diagnostic medical device
	Catalog number		Manufacturer
	Caution		Temperature limit
	Consult instructions for use or consult electronic instructions for use		Use-by-date
	Contains sufficient for <n> tests		Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

- These products are warranted to meet the specifications and performance printed and illustrated in the product inserts, instructions, and supportive literature.
- The warranty, expressed or implied, is limited when:
 - The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
 - The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

NOTICE TO PURCHASERS

- The purchase of this product allows the purchaser to use it for Research and Quality Control. No general patents or other license of any kind other than this specific right of use from purchase is granted hereby. No other rights are conveyed expressly, by implication or by estoppel to any other patents. Furthermore, no rights for resale are conferred with the purchase of this product.
- Issues regarding the performance of the Assayed CT/NG Control Panel should be addressed to Microbiologics, Inc. directly.
- The Microbiologics logo and Helix Elite™ are registered trademarks of Microbiologics, Inc.

WEBSITE

Visit our website, www.microbiologics.com, for current technical information and product availability.

BIBLIOGRAPHY

1. Xpert® CT/NG [product insert]. Cepheid, Sunnyvale, CA 94089 USA

ASSISTANCE



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Additional copies of this product insert may be obtained at www.microbiologics.com or by emailing info@microbiologics.com.

ILLUSTRATED INSTRUCTIONS

1

Read the package insert specific to the Cepheid Xpert® CT/NG assay.

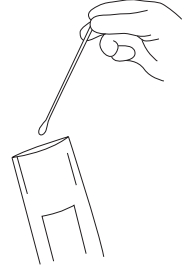
2

Tear open the foil pouch containing the quality control swab at the notch.



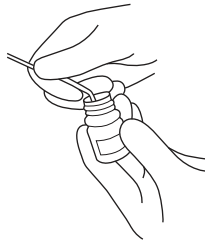
3

Remove the swab from the pouch.



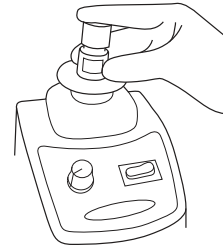
4

Uncap a Transport Reagent tube and carefully transfer the swab to the tube. For a collection device without transport reagent, add appropriate volume of nuclease-free water and transfer the swab to the collection device. Break the swab by snapping the shaft.



5

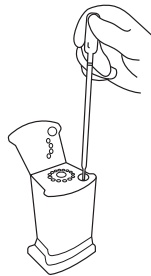
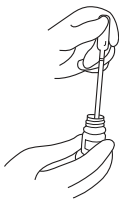
Vortex the vial for 10 seconds.



6

Use transfer pipette provided in the Cepheid Xpert® CT/NG assay to transfer the appropriate volume listed in the assay package insert to transfer the prepared sample to the Cepheid Xpert® CT/NG Cartridge.

Test must be started within 30 minutes of adding the sample to the cartridge.



7

Close the cartridge lid and start the test.

