Exact Diagnostics CT/NG Verification Panel

Catalog Number: CTNGP200

EDX CT/NG Verification Panel Summary	
Catalog Number	CTNGP200
Analyte 1	*Chlamydia trachomatis* (LGV)
Analyte 2	*Neisseria gonorrhoeae*
Matrix	Synthetic Matrix
Preservative	Sodium Azide
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	9 Vials
Number of Uses	Single Use
Shelf Life	18 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

EDX CT/NG Verification Panel Components
EDX CT 3x LOD
EDX CT 5x LOD
EDX CT 10x LOD
EDX NG 3x LOD
EDX NG 5x LOD
EDX NG 10x LOD
EDX CT/NG 3x LOD
EDX CT/NG 5x LOD
EDX CT/NG 10x LOD

INTENDED USE:

The EDX CT/NG Verification Panel is intended to be used with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* assays to monitor the performance of that given assay. EDX CT/NG Verification Panel is used to monitor the presence of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) DNA. EDX CT/NG Verification Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX CT/NG Verification Panel contains whole, intact bacterium. EDX CT/NG Verification Panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX CT/NG Verification Panel is value assigned using digital droplet PCR. EDX CT/NG Verification Panel is formulated in Synthetic Matrix, which contains preservatives.

PROCEDURE:

The EDX CT/NG Verification Panel requires an extraction step. The product must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX CT/NG Verification Panel is unassayed and does not have assigned values. The product is not a substitute for the manufacturer's kit controls provided with the assay. EDX CT/NG Verification Panel is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX CT/NG Verification Panel must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX CT/NG Verification Panel should be stored at -20°C or below.

Thaw EDX CT/NG Verification Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX CT/NG Verification Panel is stable for 24 hours when stored at 2-8°C. Any remaining materials must be disposed of after one use. Do not reuse. Do not dilute.

Do not use EDX CT/NG Verification Panel beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

Manufactured By: Exact Diagnostics LLC, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107
For assistance and reordering, contact customerservice@exactdiagnostics.com or **817.989.9262**
www.exactdiagnostics.com

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WARNINGS AND PRECAUTIONS:

The EDX CT/NG Verification Panel should be considered biohazardous. Universal precautions and proper disposal should be practiced[1]. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

REFERENCES:

[1] Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

SYMBOL REFERENCES:

Catalog Number

Lot Number

For In Vitro Diagnostic Use


Biological Risks


Expiration Date


Do Not Re-Use


Upper Limit of Temperature


Manufacturer


Caution


Consult Instructions for Use

Positive Control

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