

EDX <i>C. difficile</i> Verification Panel Summary	
Catalog Number	CDFP200
Analyte	Inactivated <i>C. difficile</i>
Matrix	Synthetic Matrix
Preservative	Sodium Azide
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	3 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 <i>C. difficile</i> Verification Panel Components
EDX <i>C. difficile</i> 3x LOD
EDX <i>C. difficile</i> 5x LOD
EDX <i>C. difficile</i> 10x LOD

**PROCEDURE:**

The EDX *C. difficile* 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 *C. difficile* 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 *C. difficile* Verification Panel is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX *C. difficile* Verification Panel must be established by the end user for their specific assay.

**STORAGE AND HANDLING:**

The EDX *C. difficile* Verification Panel should be stored at -20°C or below.

Thaw EDX *C. difficile* Verification Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX *C. difficile* 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 *C. difficile* Verification Panel beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

**WARNINGS AND PRECAUTIONS:**

The EDX *C. difficile* Verification Panel contains heat inactivated bacterium but should be considered biohazardous. Universal precautions and proper disposal should be practiced<sup>1</sup>. 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.

**INTENDED USE:**

The EDX *C. difficile* Verification Panel is intended to be used with *Clostridium difficile* assays to monitor the performance of that given assay. EDX *C. difficile* Verification Panel is used to monitor the presence of *Clostridium difficile* DNA. Routine use of EDX *C. difficile* Verification Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

**PRODUCT DESCRIPTION:**

The EDX *C. difficile* Verification Panel contains whole, intact bacterium that has been heat inactivated. EDX *C. difficile* Verification Panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX *C. difficile* Verification Panel is value assigned using digital droplet PCR. EDX *C. difficile* Verification Panel is formulated in Synthetic Matrix, which contains preservatives.

**REFERENCES:**

<sup>1</sup> 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



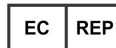
Consult Instructions for Use



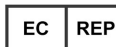
Positive Control



European Mark of Conformity



Authorized Representative



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