

PRODUCT DESCRIPTION:

Each aliquot contains 1 µg of DNA extracted from a pure culture of *Clostridioides difficile*. The identification of this organism was confirmed by 16S sequencing. The purity of the culture was monitored by additional culturing and Gram staining to detect any contaminating bacteria. The DNA was extracted from the cells following a custom protocol utilizing a FastPrep[®]-24 and Qiagen[®] QIAamp DNA Mini Kit protocols and reagents. DNA concentration and A_{260/280} ratios are determined using a NanoDrop[®]. The extracted DNA also tested positive on an in-house real time PCR assay.

INTENDED USE:

Purified Genomic DNA is designed for use as an amplification and/or detection control for nucleic acid testing of *Clostridioides difficile*. It can also be used to determine a limit of detection (LOD), in diagnostic assay development, cross-reactivity studies or genomic sequencing. When used as a control for nucleic acid tests, the same protocols as those used to amplify extracted clinical specimens should be employed.

PRECAUTIONS:

- Use Universal Precautions when handling Genomic DNA.
- The material may be re-frozen after thawing. Repetitive freezing and thawing is not recommended (aliquot material if necessary).
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

This control is supplied in TE Buffer and should be frozen at -20°C or below.

NOT FOR USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development or manufacturing use only. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

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PI0801619DNA-1UG Revision: 04 Effective Date: 08/06/2021

REF	Catalog Number	X	Temperature Limitation
LOT	Batch Code		Expiration Date
RUO	For Research Use Only	8	Biological Risk
	Manufacturer		

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