

PRODUCT INFORMATION

Product SKU	CDFP200
Product Name	<i>C. difficile</i> Verification Panel
Kit Lot Number	21102204
Source Material	Inactivated <i>Clostridium difficile</i>
Date of Expiration	2023-03-31
Base Matrix	Multiprep Specimen Diluent
Preservative	Sodium Azide
Fill Volume	1.0 mL
Storage Temperature	-20°C or Below
Regulatory Status	CE-IVD
Testing Platform	cobas® Cdiff Test

This is an unassayed control and does not have assigned analyte values. The end user is responsible for determining the value of the control. This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.


As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

Lot Number	Product Description	Target Concentration	Results
21102201	<i>C. difficile</i> 3x LOD	150,000 cp/mL	Pass
21102202	<i>C. difficile</i> 5x LOD	250,000 cp/mL	Pass
21102203	<i>C. difficile</i> 10x LOD	500,000 cp/mL	Pass

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

APPROVAL

Quality Assurance	Date
	16 Nov 21