

PRODUCT INFORMATION

Product SKU	CTNGP200
Product Name	CT/NG Verification Panel
Kit Lot Number	19120924
Source Material 1	<i>Chlamydia trachomatis</i>
Source Material 2	<i>Neisseria gonorrhoeae</i>
Date of Expiration	2021-05-31
Matrix	Multiprep Specimen Diluent
Preservative	Sodium Azide
Fill Volume	1.0 mL
Storage Temperature	-20°C or Below
Regulatory Status	For In Vitro Diagnostic Use
Testing Platform	cobas® 4800 CT/NG 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	Results
19120915	CT 3x LOD	Pass
19120916	CT 5x LOD	Pass
19120917	CT 10x LOD	Pass
19120918	NG 3x LOD	Pass
19120919	NG 5x LOD	Pass
19120920	NG 10x LOD	Pass
19120921	CT/NG 3x LOD	Pass
19120922	CT/NG 5x LOD	Pass
19120923	CT/NG 10x LOD	Pass

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

APPROVAL

Quality Assurance	Date
	15 Jan 20