

PRODUCT INFORMATION

Product SKU	CTNGP200
Product Name	CT/NG Verification Panel
Kit Lot Number	21041910
Source Material 1	<i>Chlamydia trachomatis</i>
Source Material 2	<i>Neisseria gonorrhoeae</i>
Date of Expiration	2022-09-30
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	Target Concentrations	Results
21041901	CT 3x LOD	CT: 600 cp/mL	Pass
21041902	CT 5x LOD	CT: 1,000 cp/mL	Pass
21041903	CT 10x LOD	CT: 2,000 cp/mL	Pass
21041904	NG 3x LOD	NG: 3,000 cp/mL	Pass
21041905	NG 5x LOD	NG: 5,000 cp/mL	Pass
21041906	NG 10x LOD	NG: 10,000 cp/mL	Pass
21041907	CT/NG 3x LOD	CT: 600 cp/mL NG: 3,000 cp/mL	Pass
21041908	CT/NG 5x LOD	CT: 1,000 cp/mL NG: 5,000 cp/mL	Pass
21041909	CT/NG 10x LOD	CT: 2,000 cp/mL NG: 10,000 cp/mL	Pass

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

APPROVAL

Quality Assurance	Date
	06 Jan 22