

PRODUCT INFORMATION

Product SKU	MRSAP200
Product Name	MRSA Verification Panel
Kit Lot Number	21102510
Source Material 1	Inactivated Methicillin-resistant <i>Staphylococcus aureus</i>
Source Material 2	Inactivated Methicillin-susceptible <i>Staphylococcus aureus</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® MRSA/SA 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.

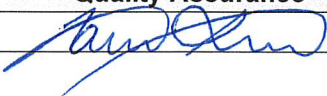
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation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

TESTING DATA

Lot Number	Product Description	Target Concentrations	Testing Results (≥ 95% detection rate)
21102504	MSSA 3x LOD	3,000 cp/mL	Pass
21102505	MSSA 5x LOD	5,000 cp/mL	Pass
21102506	MSSA 10x LOD	10,000 cp/mL	Pass
21102507	MRSA 3x LOD	1,484 cp/mL	Pass
21102508	MRSA 5x LOD	2,474 cp/mL	Pass
21102509	MRSA 10x LOD	4,948 cp/mL	Pass

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

APPROVAL

Quality Assurance	Date
	16 Nov 21