

INSTRUCTIONS FOR USE

IVD

■ Assayed SA Nasal Complete Control Panel

INTENDED USE

The Assayed SA Nasal Complete Control Panel is intended for use as an external assayed positive and negative quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA) performed with the Cepheid Xpert® SA Nasal Complete Assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated Methicillin-Resistant *Staphylococcus aureus* as the positive control 1; *Staphylococcus aureus* as the positive control 2; *Staphylococcus epidermidis* as the negative control.

The Assayed SA Nasal Complete Control Panel is not intended to replace manufacturer controls provided with the Cepheid Xpert® SA Nasal Complete Assay.

SUMMARY AND EXPLANATION

The Assayed SA Nasal Complete Control Panel is a ready-to-use external quality control that can be used to monitor the extraction, amplification and detection of the Cepheid Xpert® SA Nasal Complete Assay. Routine use of quality controls helps in identifying problems with the test system due to instrument or reagent failure. At a minimum, controls should be run at the frequency recommended by the assay system manufacturer.

COMPOSITION

The Assayed SA Nasal Complete Control Panel is comprised of cultured microorganisms which have been inactivated by heat treatments. The positive control 1 contains an isolate of Methicillin-Resistant *Staphylococcus aureus* (MRSA) which is detected by the Cepheid Xpert® SA Nasal Complete Assay. Positive control 2 contains an isolate of Methicillin-Susceptible *Staphylococcus aureus* (SA/MSSA) which is detected by the assay. The negative control contains an isolate of Methicillin-Susceptible *Staphylococcus epidermidis* (MSSE) that is commonly present on human skin and mucosal surfaces but not detected by the assay. Each Assayed SA Nasal Complete Control Panel consists of 6 individually packaged MRSA positive control swabs, 6 individually packaged MSSA positive control swabs and 6 individually packaged MSSE negative control swabs. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives and stabilizers. The solution is lyophilized into a ready-to-use swab.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Do not open foil pouch until ready to use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines. The material has been inactivated. However, no known test or inactivation method can assure that this product will not transmit infection.
- Wear proper personal protective equipment.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at www.microbiologics.com or by contacting Technical Support at +1.320.229.7045 or U.S. Toll Free +1.866.286.6691.
- These products are not made with natural rubber latex.

STORAGE AND EXPIRATION

Store the Assayed SA Nasal Complete Control Panel at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately.

The Assayed SA Nasal Complete Control Panel should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The packaging is damaged or shows evidence of tampering
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

- GeneXpert® Dx System
- Cepheid Xpert® SA Nasal Complete kit
- Disposable sterile transfer pipettes
- Package Insert of the Cepheid Xpert® SA Nasal Complete Assay
- Sterile gauze

INSTRUCTIONS FOR USE

1. Read the package insert specific to the Cepheid Xpert® SA Nasal Complete Assay.
2. Tear open the foil pouch containing the quality control swab at the notch.
3. Remove the swab from the pouch.
4. Insert the swab into the Elution Reagent vial provided in the Cepheid Xpert® SA Nasal Complete kit. Wrap sterile gauze (not provided) around both the stem of the swab and the mouth of the Elution Reagent vial when breaking the swab to minimize risk of contamination. Break the swab by lifting the swab a few millimeters from the bottom of the tube and pushing against the rim to break it.
5. Cap the Elution Reagent and vortex at high speed for 10 seconds.
6. Open the lid of the Cepheid Xpert® SA Nasal Complete cartridge. Use a sterile transfer pipette (not provided) to transfer the entire contents of the Elution Reagent tube to the Cepheid Xpert® SA Nasal Complete Cartridge.
7. Close the cartridge lid and start the test. Test must be started within 15 minutes of adding the sample to the cartridge.

LIMITATIONS

- Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.
- Each positive and negative control swab is only intended to be used once.

EXPECTED VALUES

The following results are expected when running the 8196 controls with the Cepheid Xpert® SA Nasal Complete Assay:

8196 Control	Expected Assay Result	Interpretation
6027 – Positive Control 1	MRSA POSITIVE; SA POSITIVE	MRSA target DNA detected; SA target DNA detected All MRSA targets (spa, mecA and SCCmec) have a Ct within the valid range and endpoint above the threshold setting.
6028 – Positive Control 2	MRSA NEGATIVE; SA POSITIVE	MRSA target DNA not detected; SA target DNA detected SA target (spa) has a Ct within the valid range and endpoint above the threshold setting. Target DNA for SCCmec and/or mecA is not detected.
6029 – Negative Control	MRSA NEGATIVE; SA NEGATIVE	SA target DNA not detected SA target (spa) DNA is not detected. Target DNA for mecA and/or SCCmec may or may not be detected.

A positive control that yields a negative result may be indicative of a specimen handling/preparation problem. Repeat the test using a new swab.

If a negative control yields a positive result, clean the GeneXpert® instrument per the user manual and clean the work area. Repeat the test using a new swab.

REPRODUCIBILITY STUDY

The performance of the Assayed SA Nasal Complete Control Panel was evaluated in a study that was performed using three different production lots, three test sites using three different GeneXpert® Dx Systems and six different users. The results of the study are summarized below.

Positive Analyte	Agreement (%) by Test Site/GeneXpert® System				
Location	Site 1	Site 2	Site 3 ¹	NO RESULT	Overall Correct Result
Assay Response	Correct Result	Correct Result	Correct Result		
Methicillin-Resistant <i>Staphylococcus aureus</i> (SPA, mec, SCC)	30/30 (100)	30/30 (100)	30/30 (100)	1	90/90 (100)
<i>Staphylococcus aureus</i> (SPA)	30/30 (100)	30/30 (100)	30/30 (100)	2	90/90 (100)

¹ Three NO RESULT responses were observed; new controls were retested and the expected results were obtained.

Negative Analyte	Agreement (%) by Test Site/GeneXpert® System								
Location	Site 1 ¹		Site 2 ^{1,3}			Site 3 ^{1,2}			Overall
Assay Response	Correct Result	INVALID	Correct Result	INVALID	ERROR	Correct Result	INVALID	NO RESULT	
<i>Staphylococcus epidermidis</i>	30/30 (100)	8 ⁴	30/30 (100)	2	1	30/30 (100)	4	1	90/90 (100)

¹ Multiple INVALID responses were observed; new controls were retested and the expected results were obtained.

² One NO RESULT response was observed; a new control was retested and the expected results were obtained.

³ One ERROR response was observed; a new control was retested, and the expected results were obtained.

⁴ Eight INVALID responses from single user.

KEY OF SYMBOLS



Batch code (Lot)



In vitro diagnostic medical device



Catalog number



Manufacturer



Caution



Temperature limit



Consult instructions for use or consult electronic instructions for use



Use-by-date



Contains sufficient for <n> tests

Rx ONLY

Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

- These products are warranted to meet the specifications and performance printed and illustrated in the product inserts, instructions, and supportive literature.
- The warranty, expressed or implied, is limited when:
 - The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
 - The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

NOTICE TO PURCHASERS

- The purchase of this product allows the purchaser to use it for Research and Quality Control. No general patents or other license of any kind other than this specific right of use from purchase is granted hereby. No other rights are conveyed expressly, by implication or by estoppel to any other patents. Furthermore, no rights for resale are conferred with the purchase of this product.
- Issues regarding the performance of the Assayed SA Nasal Complete Control Panel should be addressed to Microbiologics, Inc. directly.
- The Microbiologics logo and Helix Elite™ are registered trademarks of Microbiologics, Inc.

WEBSITE

Visit our website, www.microbiologics.com, for current technical information and product availability.

BIBLIOGRAPHY

1. Cepheid Xpert® SA Nasal Complete Assay [product insert]. Cepheid, Sunnyvale, CA 94089 USA

ASSISTANCE



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Additional copies of this product insert may be obtained at www.microbiologics.com or by emailing info@microbiologics.com.

ILLUSTRATED INSTRUCTIONS

1

Read the package insert specific to the Cepheid Xpert® SA Nasal Complete Assay.

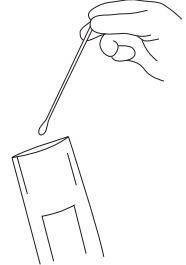
2

Tear open the foil pouch containing the quality control swab at the notch.



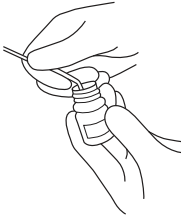
3

Remove the swab from the pouch.



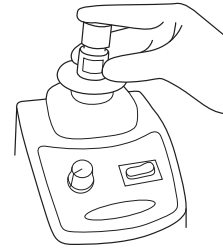
4

Insert the swab into the Elution Reagent vial provided in the Cepheid Xpert® SA Nasal Complete kit. Wrap sterile gauze (not provided) around both the stem of the swab and the mouth of the Elution Reagent vial when breaking the swab to minimize risk of contamination. Break the swab by lifting the swab a few millimeters from the bottom of the tube and pushing against the rim to break it.



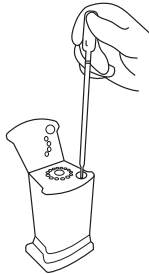
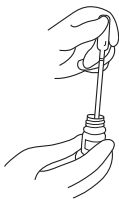
5

Cap the Elution Reagent and vortex at high speed for 10 seconds.



6

Open the lid of the Cepheid Xpert® SA Nasal Complete cartridge. Use a sterile transfer pipette (not provided) to transfer the entire contents of the Sample Reagent tube to the Cepheid Xpert® SA Nasal Complete Cartridge.



7

Close the cartridge lid and start the test. Test must be started within 15 minutes of adding the sample to the cartridge.

