

# Assay Training: Xpert<sup>®</sup> SA Nasal Complete

For US-IVD and CE-IVD product only

*Cepheid Training Center*



# Training Agenda

- Xpert® SA Nasal Complete Training
  - Reagents
  - Sample collection
  - Kit storage and handling
  - Precautions
  - Preparing cartridge
  - Quality control
  - Results analysis
- Discussion Q&A



# Training Objectives

At the end of the training, users will be able to:

- Store and handle the Xpert<sup>®</sup> SA Nasal Complete kit.
- Follow proper laboratory safety precautions.
- Collect appropriate specimen and transport specimens appropriately.
- Perform the cartridge set up and run the assay.
- Report the various software-generated results.
- Understand the assay control strategy.

# The Cepheid Solution



- Detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus*
- On-board internal controls for each sample
  - Sample Processing Control (SPC)
  - Probe Check Control (PCC)
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

# Intended Use

The Cepheid Xpert® SA Nasal Complete Assay performed in the GeneXpert® Dx System is a qualitative in vitro diagnostic test designed for rapid and simultaneous detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) from nasal swabs in patients at risk for nasal colonization, including pre-surgical patients. The test utilizes automated real-time polymerase chain reaction (PCR) to detect MRSA/SA DNA.

The Xpert® SA Nasal Complete Assay is intended to aid in the prevention and control of MRSA/SA infections in healthcare settings. The Xpert® SA Nasal Complete Assay is not intended to guide or monitor treatment for MRSA/SA infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.

# System and Reagent Requirements

## GeneXpert Systems

- GeneXpert software v4.3 or higher

## Test Kits:

- US-IVD: GXSACOMP-10, GXSACOMP-120
- CE-IVD: GXSACOMP-CE-10, GXSACOMP-120

## Materials Required but not Provided

- Cepheid sample collection device (900-0370)
- Disposable, sterile transfer pipettes
- Vortex mixer
- Sterile gauze

## Optional

- Uninterruptible Power Supply/ Surge Protector
- Printer

# Good Laboratory Practice

## Personnel Protective Equipment (PPE)

- Wear clean lab coats and gloves
- Change gloves between processing samples

## Lab Bench area

- Clean work surfaces routinely with:
  - ✓ 1:10 dilution of household bleach
  - ✓ 70% Ethanol Solution

*\* Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration in your country*
- After cleaning, ensure that the work surfaces are dry

## Specimens, Samples, and Kits Storage

- Store specimens and sample away from kit to prevent contamination

## Equipment

- Use filtered tips when recommended
- Follow the manufacturer's requirements for calibration and maintenance of equipment

# Kit Handling





# Xpert<sup>®</sup> SA Nasal Complete Kit Components

	Xpert <sup>®</sup> SA Nasal Complete
Catalog Number	GXSACOMP-10, GXSACOMP-CE-10, GXSACOMP-120
Tests per kit	10 or 120
Contents per test cartridge	Reagent beads
	Reagent 1
	Reagent 2
Elution Reagent	1 Elution Vial per Pouch
Kit CD	Assay Definition File (ADF)
	Instructions to import ADF
	Package insert
Storage	2-28 °C



# Xpert<sup>®</sup> SA Nasal Complete Kit Storage and Handling

- Store test kits at 2-28°C. Do not use expired cartridges.
- Each single-use cartridge is used to process one test. Do not reuse processed cartridges.
- Use the cartridge within 2 weeks after opening the foil package.
- Do not open a cartridge until ready to use.
  - Start the test within 15 minutes of adding the sample to the cartridge.
- Avoid cross contamination during sample handling steps.
  - Change gloves between samples.
- Do not use a cartridge that has been dropped or shaken. Shaking or dropping the cartridge after opening the lid may yield invalid results.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use a cartridge that has leaked.
- Do not use any cartridge that has contents that have become cloudy or discolored

# Specimen Collection



# Cepheid Sample Collection



**Cepheid Part Number 900-0370**

SCORE MARK

- **Cepheid Sample Collection Device 900-0370 (Dual Swab in Liquid Stuart Media)**

# Specimen Collection and Storage

## Nasal Specimen Collection Protocol for use with Xpert® assays:

- Xpert MRSA
- Xpert SA Nasal Complete

1

A Copan Venturi Transystem double-swab (Cepheid Collection Device #900-0370) must be used to collect the specimen.

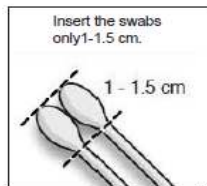
**Note:** The double-swab is not packaged in the transport tube.



2

Insert the dry swabs 1-1.5 cm into the nostril.

**Note:** The swabs must stay attached to the red cap throughout the procedure.



3

Rotate swabs against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.

Do not insert the swabs more than 1-1.5 cm.



4

Repeat Step 3 on the other nostril with the same swabs, using external pressure on the outside of the other nostril.

To avoid specimen contamination, do not touch the swab tips to anything other than the inside of the nostril.



5

Remove and discard the cap on the transport tube and place the swabs into the tube, pushing the red cap down completely.



6

Specimens that are tested within 24 hours can be kept at room temperature. For longer storage, refrigerate the specimen at 2-8° C. Specimens stored at 2-8° C are stable for up to 5 days.



# Xpert<sup>®</sup> SA Nasal Complete Specimen Transport and Storage

Specimen	Transport and Storage Temperature (°C)	Storage Time
Nasal swabs	2-8 °C	5 days
	15-28 °C	24 hours

# Cartridge Preparation



# SA Nasal Complete Cartridge Preparation

## Xpert Cartridge Preparation

- Xpert MRSA
- Xpert MRSA/SA SSTI
- Xpert vanA
- Xpert C. difficile
- Xpert C. difficile/Epi
- Xpert SA Nasal Complete
- Xpert Norovirus

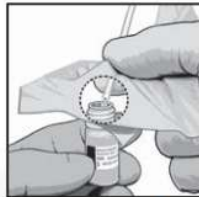
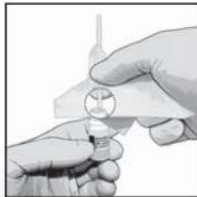
Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com)

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- 1 Obtain one Xpert cartridge and one Sample Reagent vial for each sample.
- 2 Insert the swab into the Sample Reagent vial.
- 3 Break the swab at the score mark near the mouth of the vial.
- 4 Recap the Sample Reagent vial and vortex for 10 seconds.
- 5 Open the Xpert cartridge lid.
- 6 Aspirate all of the Sample Reagent vial contents with a disposable transfer pipette.
- 7 Empty the pipette into the sample chamber.
- 8 Close the Xpert cartridge lid.
- 9 Start the test within the timeframe specified in the package insert.



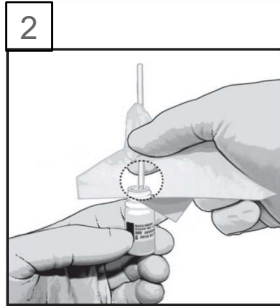
Note: Do not hold the swab below the score mark. Use gauze or its equivalent to minimize the risk of contamination.



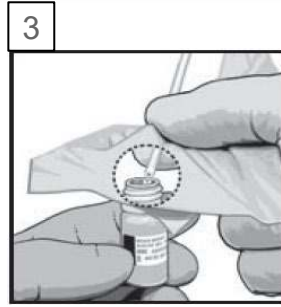
# SA Nasal Complete Cartridge Preparation



Obtain one Xpert cartridge and one Sample Reagent vial for each sample.



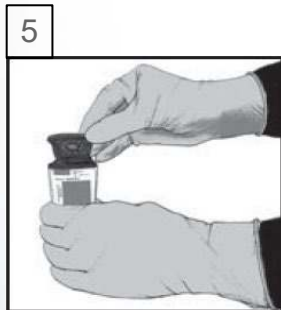
Insert the swab into the Sample Reagent vial.



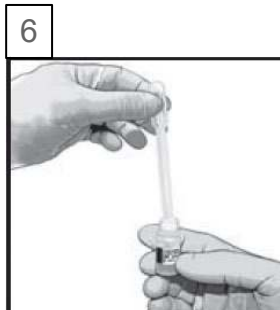
Break the swab at the score mark near the mouth of the vial.



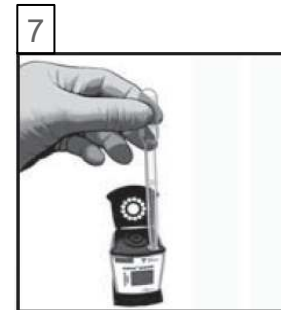
Recap the Sample Reagent vial and vortex for 10 seconds.



Open the Xpert cartridge lid.



Aspirate all of the Sample Reagent vial contents with a disposable transfer pipette.



Empty the pipette into the sample chamber.



Close the Xpert cartridge lid.

9  
Start the test within the timeframe specified in the package insert.

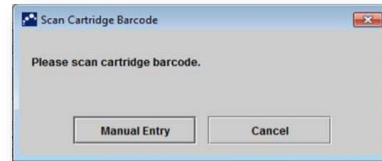
# Run a Test

## 1 Create Test



Start the test within **15 minutes** after adding the sample to the cartridge

## 2 Scan barcodes: Cartridge/ Patient and/or Sample ID



*By default, do not click on  
**Manual Entry** or **Cancel***

## 3 Scan the cartridge



*"For complete details on how to run a test, refer to the Package Insert and the GeneXpert Dx.*

# Create a Test on GeneXpert Dx Software

4 Complete the fields as required

5 The Assay Protocol is selected automatically

6 The module is selected automatically

7 Click on Start Test

8 A green light will flash on the module  
Load the cartridge into module and close the door

The screenshot shows the 'Create Test' software interface. The form contains the following fields and controls:

- Patient ID: [Text input field]
- Sample ID: [Text input field]
- Patient ID 2: [Text input field]
- Last Name: [Text input field]
- Select Assay: [Dropdown menu with 'Xpert Assay name' selected]
- Select Module: [Dropdown menu with 'A3' selected]
- Reagent Lot ID\*: [Text input field with '16119']
- Expiration Date\*: [Text input field with '2016/1/17']
- Test Type: [Dropdown menu with 'Specimen' selected]
- Sample Type: [Dropdown menu with 'Other' selected]
- Other S: [Text input field]
- Notes: [Text area]
- Start Test: [Button]
- Scan Cartridge Barco: [Button]

Orange boxes highlight the Patient ID, Sample ID, Patient ID 2, Last Name, Select Assay, Select Module, Reagent Lot ID, Expiration Date, Test Type, Sample Type, and Start Test button. Orange arrows point from the numbered instructions to these elements.



# Automated Xpert<sup>®</sup> Protocol



# Waste Disposal

- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents and require use of standard precautions.
- Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures.
- If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

# Quality Control

*Refer to the Package Insert for  
complete details*



# Cepheid Assay Control Strategy

## Xpert® SA Nasal Complete Quality Controls

- Each Xpert cartridge is a self-contained test device.
- Cepheid designed specific molecular methods that include internal controls that enable the system to detect specific failure modes within each cartridge.
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)

# Internal Quality Controls

## Probe Check Controls (PCC)

- Before the PCR step, fluorescence signal is measured on all probes and compared with default factory settings to monitor
  - bead rehydration
  - reaction tube filling
  - probe integrity
  - dye stability

## Sample Processing Controls (SPC)

- Verifies that conditions for adequate sample processing were met
- Detects PCR inhibition
- Should be positive in a negative sample
- Can be positive or negative in a positive sample



# Commercially Available External Controls

Company	Description	Catalog Number
MicroBioLogics KWIK-STIKs™	External positive control (ATCC 700699)	0158MRSA
	External positive control (ATCC 25923)	0360MSSA
	External negative control (ATCC 1228)	0371MSSE

[www.microbiologics.com](http://www.microbiologics.com)

External controls should be used in accordance with local, state, and federal accrediting organizations, as applicable.

# MicroBioLogics External Control Procedure

1. Tear open the pouch at notch and remove the KWIK-STIK<sup>®</sup>.
2. Pinch the bottom of the ampoule in the cap to release the hydrating fluid.
3. Hold vertically and tap to facilitate flow of fluid through the shaft and into the bottom of unit containing pellet.
4. To facilitate dissolution of the lyophilized cell pellet, crush the pellet and gently pinch the bottom chamber.
5. Pull apart the KWIK-STIK<sup>®</sup> to release the swab, and insert the swab into the tube containing the Elution Reagent (black cap).
6. The KWIK-STIK<sup>®</sup> swab is now ready for SA Nasal Complete Assay testing.

# Results Analysis

*Refer to the Package Insert for  
complete details*



# Results Summary

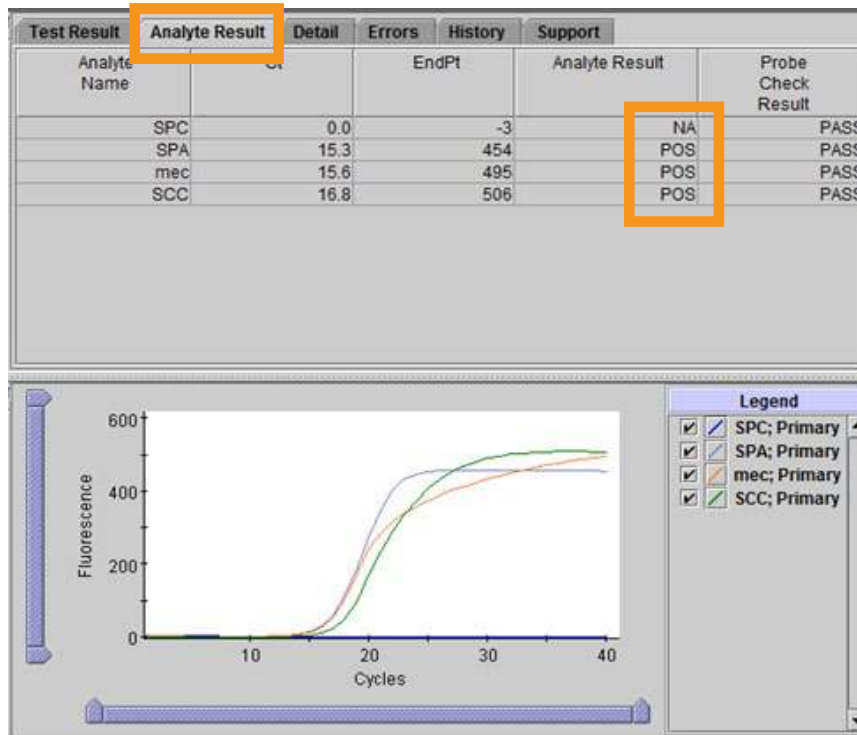
Result displayed	SPA	mec	SCC	SPC
<b>MRSA POSITIVE</b>	+	+	+	+/-
<b>SA POSITIVE</b>				
<b>MRSA NEGATIVE</b>	+	-	+	+/-
<b>SA POSITIVE</b>		+	-	
		-	-	
<b>MRSA NEGATIVE</b>	-	+	+/-	+
<b>SA NEGATIVE</b>		-	+/-	
<b>INVALID</b>	-	-	-	-
<b>ERROR</b>	NO RESULT	NO RESULT	NO RESULT	NO RESULT
No Result	NO RESULT	NO RESULT	NO RESULT	NO RESULT

# MRSA Positive/SA Positive

Test Result **MRSA POSITIVE:  
SA POSITIVE**

MRSA target DNA sequences are detected/SA target DNA sequence is detected.

- MRSA POSITIVE: All MRSA targets (*spa*, *mecA*, *SCC mec*) have a valid Ct.
- SA POSITIVE: The SA target (*spa*) has a valid Ct.
- SPC: NA (not applicable); SPC is ignored because MRSA amplification may compete with this control.
- Probe Check: PASS  
All probe check results pass.



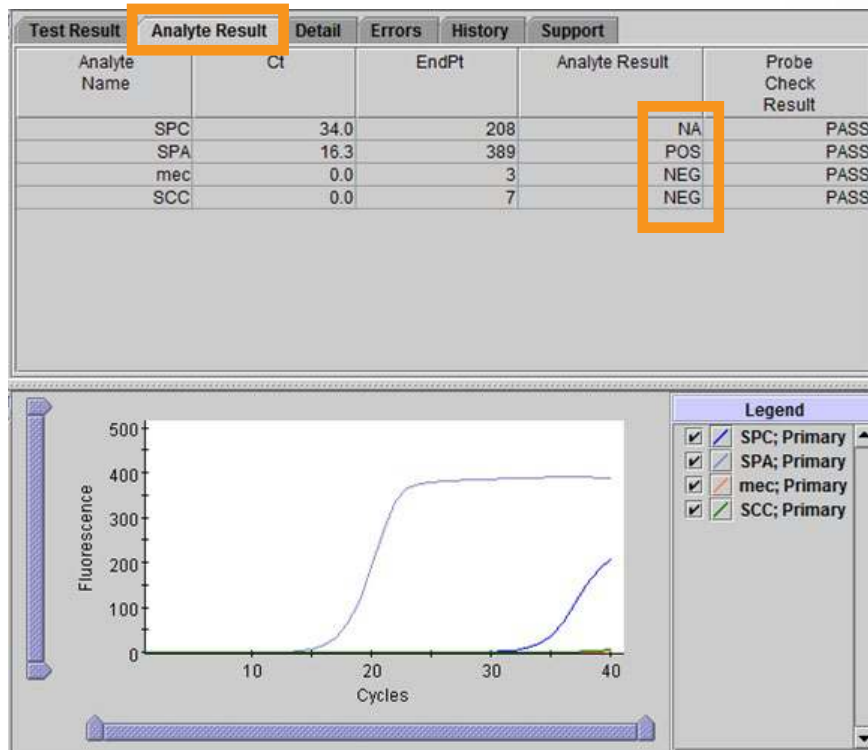
# MRSA Negative/SA Positive

Test Result **MRSA NEGATIVE**  
**SA POSITIVE**

MRSA target DNA sequences are not detected/SA target DNA sequence is detected.

- SA POSITIVE: The SA target has a valid Ct. Target DNA for *SCCmec* is not detected, target DNA for *mecA* may or may not be detected, or target DNA for *SCCmec* is detected and target DNA for *mecA* is not detected
- SPC: NA (not applicable)  
SPC is ignored because SA amplification can compete with this control.
- Probe Check: PASS  
All probe check results pass.

\*A Positive test result does not necessarily indicate the presence of viable organisms. It is, however, presumptive for the presence of SA.

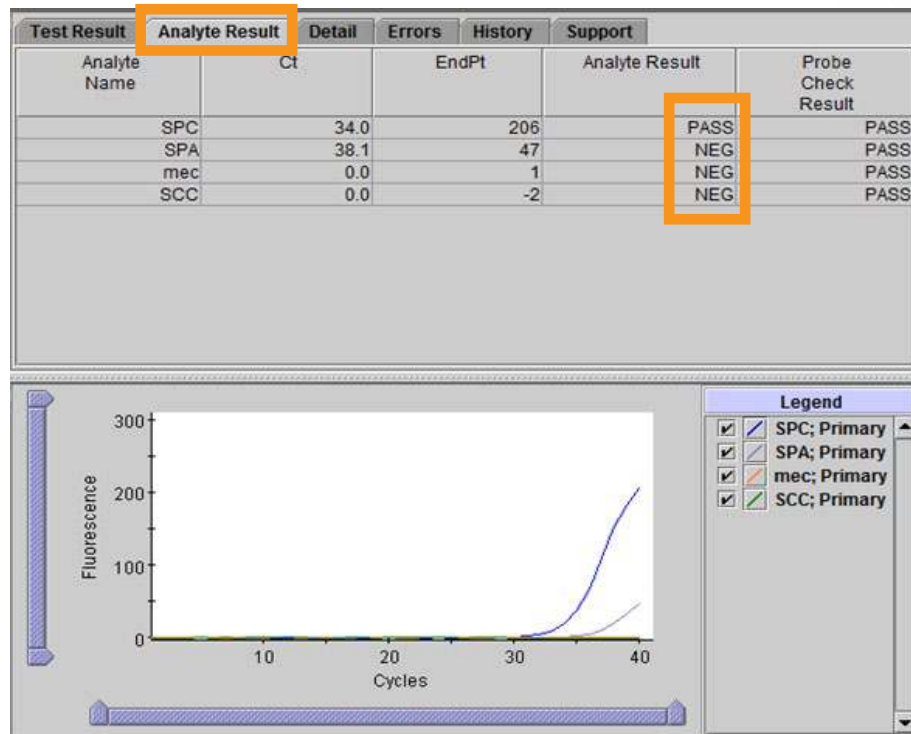


# MRSA Negative/SA Negative

Test Result **MRSA NEGATIVE;  
SA NEGATIVE**

*Staphylococcus aureus* and MRSA target DNA sequences are not detected. SPC meets acceptance criteria.

- MRSA/SA NEGATIVE:  
*Staphylococcus aureus* target DNA is not detected. Target DNA for *mecA* may or may not be detected, or target DNA for SCC*mec* may or may not be detected
- SPC: PASS; SPC has a valid Ct.
- Probe Check: PASS  
All probe check results pass.



# Troubleshooting





# Factors That Negatively Affect Results

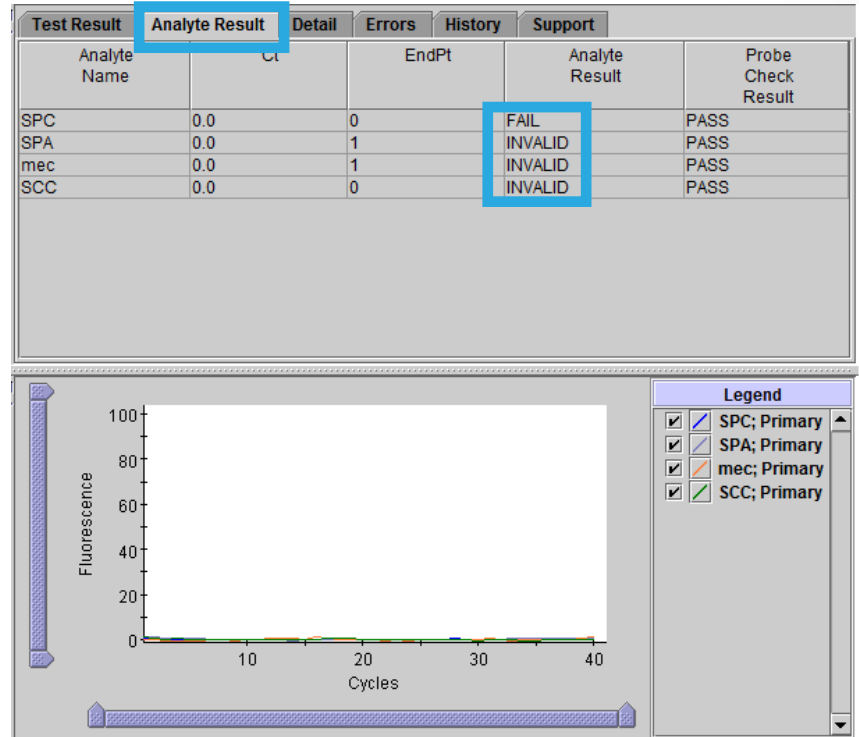
- Improper specimen collection
  - The bacterial load in the specimen is below the detection limit of the test
  - Performance with other specimen types has not been assessed
- Improper transport or storage of collected specimen
  - Storage and transport conditions are specimen specific
  - Refer to the Package Insert for the appropriate handling instructions
- Improper testing procedure
  - Modification to the testing procedures may alter the performance of the test
  - Careful compliance with the package insert is necessary to avoid erroneous results

# INVALID

Test Result **INVALID**

Presence or absence of MRSA/SA target DNA sequences cannot be determined. SPC does not meet the acceptance criteria, the sample was not correctly processed, or PCR was inhibited.

- INVALID: Presence or absence of *Staphylococcus aureus* DNA cannot be determined.
- SPC– FAIL: SPC target result is negative, and the SPC Ct is not valid.
- Probe Check: PASS  
All probe check results pass.



# ERROR

Test Result **ERROR**

Presence or absence of MRSA/SA target DNA sequences cannot be determined.

- MRSA: NO RESULT
- SA: NO RESULT
- SPC: NO RESULT
- Probe Check: FAIL\*  
One or more of the probe check results failed.

\*If the probe check passed, a system component failed.

#	Description	Detail	Time
1	Post-run analysis error	Error 5007: SCC) probe check failed. Probe check value of 0 for reading number 2 was below the minimum of 33	01/25/15 05:07:22
2	Post-run analysis error	Error 5007: [SPC) probe check failed. Probe check value of 0 for reading number 2 was below the minimum of 222	01/25/15 05:07:22

# NO RESULT

Test Result **NO RESULT**

Presence or absence of MRSA/SA target DNA sequences cannot be determined. Insufficient data were collected to produce a test result.

- MRSA: NO RESULT
- SA: NO RESULT
- SPC: NO RESULT
- Probe Check: NA (not applicable)

Test Result					Analyte Result					Detail					Errors					History					Support				
Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result																									
SPC	0.0	0	NO RESULT	NA																									
SPA	0.0	0	NO RESULT	NA																									
mec	0.0	0	NO RESULT	NA																									
SCC	0.0	0	NO RESULT	NA																									

# SA Nasal Complete Retest Procedure

- Obtain the residual swab and follow the cartridge preparation as before.

## Xpert Cartridge Preparation

- Xpert MRSA
- Xpert MRSA/SA SSTI
- Xpert vanA
- Xpert C. difficile
- Xpert C. difficile/Epi
- Xpert SA Nasal Complete
- Xpert Norovirus

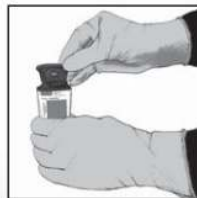
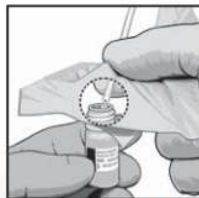
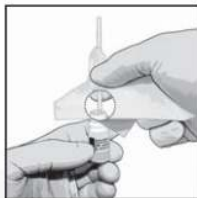
Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit [www.cephheid.com](http://www.cephheid.com) or [www.cephheidinternational.com](http://www.cephheidinternational.com)

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- 2 Insert the swab into the Sample Reagent vial.
- 3 Break the swab at the score mark near the mouth of the vial.
- 4 Recap the Sample Reagent vial and vortex for 10 seconds.
- 5 Open the Xpert cartridge lid.
- 6 Aspirate all of the Sample Reagent vial contents with a disposable transfer pipette.
- 7 Empty the pipette into the sample chamber.
- 8 Close the Xpert cartridge lid.
- 9 Start the test within the timeframe specified in the package insert.



Note: Do not hold the swab below the score mark. Use gauze or its equivalent to minimize the risk of contamination.

# Limitations

- Refer to the Package Insert for a complete list of limitations.

# Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
  - Product name
  - Lot number
  - Serial number of the System
  - Error messages (if any)
  - Software version and, if applicable, Computer Service Tag number
- Log your complaint online using the following link <http://www.cepheid.com/us/support> :Create a Support Case

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222	<a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a>
Australia and New Zealand	+ 1800 130 821 (AU) + 0800 001 028 (NZ)	<a href="mailto:techsupportANZ@cepheid.com">techsupportANZ@cepheid.com</a>
Brazil and Latin America	+ 55 11 3524 8373	<a href="mailto:latamsupport@cepheid.com">latamsupport@cepheid.com</a>
China	+ 86 021 5406 5387	<a href="mailto:techsupportchina@cepheid.com">techsupportchina@cepheid.com</a>
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Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>



Thank You.



[www.Cepheid.com](http://www.Cepheid.com)

