Test Definition: MRSAP

Methicillin Resistant Staphylococcus aureus, PCR, Nasal

Overview

Useful For

Rapid screening test for *Staphylococcus aureus* nasal carriage that, if positive, indicates whether the *S aureus* is methicillin susceptible or resistant

This test should **not be used** to guide or monitor treatment for methicillin-resistant *S aureus* or *S aureus* infections.

Highlights

This test provides rapid presurgical screening of patients for colonization of *Staphylococcus aureus* and methicillin-resistant *S aureus* in the nasal cavity

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Swab

Specimen Required

Specimen Type: Nasal cavity swab
Supplies: BD E-Swab (T853)
Container/Tube:
Preferred: BD Liquid Amies Elution Swab (E-Swab)
Acceptable: Copan Liquid Amies Elution Swab (ESwab); Cepheid nasal sample collection device (dual swab in liquid Stuart media); or Copan swab and transport systems (LQ Stuart or LQ Amies) (scored swabs only)
Specimen Volume: Entire collection
Collection Instructions:
1. Ask the patient to blow their nose prior to collection.
2. Use one swab for both right and left nares.
3. Insert the white Dacron swab tip (do not insert any further in) into the anterior nares.
4. Rotate the swab for 3 seconds against the nasal mucosa. Apply slight pressure on the outside of the nose with your finger to ensure good contact.
5. Repeat the process on the other nostril.
6. Insert the swab back into the carrier. The swabs should go all the way into the transport container. Tightly cap the container.

7. Label the transport container with patient label and send refrigerate.

Forms
If not ordering electronically, complete, print, and send a Kidney Transplant Test Request with the specimen.

Specimen Minimum Volume
See Specimen Required.

Reject Due To

Incorrect swab collection/non-scored swabs	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Swab	Refrigerated (preferred)	5 days	
	Ambient	24 hours	

Clinical & Interpretive

Clinical Information
Staphylococcus aureus causes a variety of human infections and is a major cause of hospital acquired infection of surgical wounds and infections associated with indwelling medical devices. Mayo Clinic has established a program to reduce the number of *S aureus* surgical infections, which involves surgical patients being tested for *S aureus* and treated, if positive, prior to surgery. This assay not only detects *S aureus,* but, if positive, indicates whether *S aureus* is methicillin susceptible or resistant.

Reference Values
Negative for *Staphylococcus aureus*
Negative for methicillin-resistant *S aureus*

Interpretation
A positive result indicates presence of DNA from *Staphylococcus aureus.* The assay also detects the gene for methicillin resistance (*mec*A).

A negative result indicates the absence of detectable *S aureus* DNA in the specimen.

Cautions
Results from the Xpert SA Nasal Complete Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician and should be used as an adjunct to nosocomial infection control efforts to identify patients needing enhanced precautions. Results should not be used to guide or monitor treatment for methicillin-resistant *Staphylococcus aureus* (MRSA) or *S aureus* infections.

Erroneous test results might occur from improper specimen collection, failure to follow the recommended specimen collection, handling and storage procedures, technical error, sample mix-up, or because the number of organisms in the specimen is too low to be detected by the test.

A positive test result does not necessarily indicate the presence of viable organisms. It is, however, presumptive for the presence of *S aureus* or MRSA.

An Xpert SA Nasal Complete Assay positive result does not necessarily indicate intervention eradication failure since nonviable DNA may persist. A negative result following a previously positive test result may or may not indicate eradication success.

A negative result does not negate the presence of MRSA or *S aureus*.

Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

The performance characteristics were not established by Cepheid for patients 21 years of age or younger.

Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown *S aureus* or MRSA variants resulting in a false-negative result.

In samples containing both MRSA and methicillin-susceptible *S aureus*, the Xpert SA Nasal Complete Assay may not detect the MRSA organisms. The pivotal clinical study included one sample with documented mixed infection; the Xpert SA Nasal Complete Assay identified the sample as MRSA positive/*S aureus* positive.

In a mixed culture, the analytical limit of MRSA detection is variable when extremely high concentrations of *S aureus* are present. Competition from *S aureus* was observed at a MRSA: *S aureus* ratio of 1:1x10(6) in 7 of 8 SCC*mec* types tested. For SCC*mec* type VIII, competition from SA was observed at a MRSA: *S aureus* ratio of 1:1x10(3).

Inhibition of the SA Nasal Complete Assay resulting in invalid test results has been observed in the presence of inhaled nasal steroids Flonase and Nasonex in SA negative samples at concentrations greater than 5% (volume to volume [v/v}), and 10% (v/v), respectively.

Inhibition of the SA Nasal Complete Assay resulting in false-negative test results has been observed in the presence of inhaled nasal steroids Flonase and Nasonex in MRSA positive samples at concentrations greater than 1% (v/v) and 5% (v/v), respectively.

The Xpert SA Nasal Complete Assay may generate a false-positive MRSA result when testing a mixed infection nasal specimen containing both methicillin-resistant coagulase-negative *Staphylococcus* species and empty cassette *S aureus*.

The Xpert SA Nasal Complete Assay may generate false-negative MRSA results when testing borderline oxacillin-resistant *S aureus* (BORSA). The mechanism of oxacillin resistance in BORSA strains is due to an increased production of beta-lactamases, not *mecA*. BORSA with oxacillin minimum inhibitory concentrations (MIC) of 4 to 8 mcg/mL are considered borderline resistant but would be reported as MRSA negative by the Xpert SA Nasal Complete Assay. BORSA

strains are rare in the United States.

The Xpert SA Nasal Complete Assay may generate false-negative MRSA results when testing modified *S aureus* (MOD-SA). The mechanism of oxacillin resistance in MOD-SA strains is due to changes in affinity of penicillin binding proteins for oxacillin, not *mecA*. MOD-SA with oxacillin MIC of 4 to 8 mcg/mL are considered borderline resistant but would be reported as MRSA negative by the Xpert SA Nasal Complete Assay. MOD-SA strains are rare in the United States.

There may be an association with false-positive results in specimens containing blood.

Xpert SA Nasal Complete assay results may sometimes be invalid due to a failed SPC control, error, or no result and require retesting, which can lead to a delay in obtaining final results.

As with all in vitro diagnostic tests, positive and negative predictive values are highly dependent on prevalence. Xpert SA Nasal Complete assay performance may vary depending on the prevalence and population tested.(1)

Clinical Reference

1. Xpert SA Nasal Complete 300-8799. Package insert: Cepheid; Rev H, 09/2019
2. Muto C, Jernigan J, Ostrowsky BE, et al: SHEA guideline for preventing nosocomial transmission of multidrug-resistant strains of *Staphylococcus aureus* and *Enterococcus*. Infect Control Hosp Epidemiol. 2003 May;24(5):362-386
3. Carr AL, Daley MJ, Givens Merkel K, Rose DT. Clinical utility of methicillin-resistant Staphylococcus aureus nasal screening for antimicrobial stewardship: A review of current literature. Pharmacotherapy. 2018 Dec;38(12):1216-1228. doi: 10.1002/phar.2188
4. Saraswat MK, Magruder JT, Crawford TC, et al: Preoperative Staphylococcus aureus screening and targeted decolonization in cardiac surgery. Ann Thorac Surg. 2017 Oct;104(4):1349-1356. doi: 10.1016/j.athoracsur.2017.03.018
5. Chen AF, Wessel CB, Rao N. Staphylococcus aureus screening and decolonization in orthopaedic surgery and reduction of surgical site infections. Clin Orthop Relat Res. 2013;471(7):2383-2399. doi: 10.1007/s11999-013-2875-0

Performance

Method Description

The GeneXpert Dx System automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time polymerase chain reaction (PCR). The system uses single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.

The Cepheid Xpert SA Nasal Complete Assay performed in the GeneXpert System is a qualitative in vitro diagnostic test designed for rapid detection of *Staphylococcus aureus* and methicillin-resistant *S aureus* (MRSA) from nasal swabs in patients at risk for nasal colonization. The test utilizes automated PCR for qualitative detection of proprietary sequences for the staphylococcal protein A (*spa*) gene, the gene for methicillin resistance (*mecA*), and the staphylococcal MRSA/SA *S aureus* DNA cassette chromosome mec (*SCCmec*) inserted into the *S aureus* chromosomal attB site. The assay includes a sample processing control to ensure the sample was processed correctly and to monitor for the presence of inhibitors

in the PCR reaction. A probe check control verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.(Package insert: Xpert SA Nasal Complete 300-8799. Cepheid; Rev H, 09/2019)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
1 day

Specimen Retention Time
5 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87641

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
MRSAP	Staph aureus/MRSA, Nasal, PCR	72887-3

Result ID	Test Result Name	Result LOINC® Value
MRSAC	MRSA, PCR	72887-3
MSSAC	Staphylococcus aureus, PCR	79447-9