**BD MAX StaphSR Procedure**

1. **PRINCIPLE**
	1. The BD MAX™ StaphSR assay performed on the BD MAX™ System is an automated qualitative in vitro diagnostic test for the rapid detection of Staphylococcus aureus (SA) DNA and Methicillin-resistant Staphylococcus aureus (MRSA) from nasal swabs in patients at risk for nasal colonization. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and fluorogenic target-specific hybridization probes to detect and differentiate MRSA and SA DNA. The BD MAX™ StaphSR Assay is intended to aid in the prevention and control of MRSA and SA infections in healthcare settings. It is not intended to diagnose MRSA or SA infections nor guide or monitor treatment for MRSA/SA infections. A negative result does not preclude nasal colonization. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.
	2. S. aureus is a major cause of nosocomial infections with clinical manifestations ranging from pustules to sepsis and death. It is commonly found in the nose or on the skin of healthy individuals (asymptomatic carriers). Treatment of S. aureus infections has become a real challenge with the emergence of strains resistant to previously effective antimicrobial agents. Methicillin-resistant strains of S. aureus are frequently encountered in healthcare settings and represent early 60% of isolates from hospital-acquired S. aureus in some North American and European healthcare facilities. In hospital settings, MRSA may be transmitted from patient to patient through the contaminated hands of healthcare workers. Risk factors for colonization with MRSA in healthcare setting include prolonged hospital stay, proximity to patients infected with MRSA, exposure to multiple and prolonged broad-spectrum antibiotic treatments and MRSA carriage. MRSA infection is increased in patients colonized with MRSA.
	3. S. aureus is one of the leading causes of surgical site infections (SSI). Up to 26% of patients undergoing surgery develop an SSI. S. aureus has consistently been reported as the most frequent cause of SSI. It is responsible for 20% to 56% of SSI, among which MRSA represents up to 57% of isolates. The mortality rate associated with both pathogens varies from 5 to 22%. In most patients with SSI, the S. aureus infection is from an endogenous source.
	4. Traditional techniques used for the detection of S. aureus and MRSA require culture steps and isolation of pure colonies, followed by agglutination testing to identify S. aureus and either Oxacillin-susceptibility testing, detection of the gene for Methicillin-resistance (mecA) or detection of the penicillin binding protein (PBP 2a) to identify MRSA. A minimum of 24 hours is required to resolve the S. aureus and MRSA status, with a median time of more than 48 hours, when using these conventional methods.
	5. With the increased morbidity and mortality associated with S. aureus infections, the emergence of mecA drop-out strains and the spreading of a new Methicillin-resistance gene (e.g., mecC), the ability to rapidly detect and differentiate S. aureus and MRSA within hours instead of day(s) represents a definite advantage over current practices and allows for more effective patient treatment and management.
	6. A nasal specimen is collected and transported to the laboratory using the recommended swab (refer to “EQUIPMENT AND MATERIALS” section). The swab is placed in a BD MAX™ StaphSR Sample Buffer Tube. The Sample Buffer Tube is vortexed to release cells from the swab into the buffer. The Sample Buffer Tube is placed onto the BD MAX™ System and the following automated procedures occur: the bacterial cells are lysed, DNA is extracted on magnetic beads and concentrated, and then an aliquot of the eluted DNA is added to PCR reagents which contain the SA- and MRSA-specific primers used to amplify the genetic target, if present. The assay also includes a Sample Processing Control (SPC). The SPC is present in the Extraction Tube and undergoes the extraction, concentration, and amplification steps to monitor for inhibitory substances as well as process inefficiency due to instrument or reagent failure. No operator intervention is necessary once the clinical sample and reagent strip are loaded into the BD MAX™ System. The BD MAX™ System automates sample lysis, DNA extraction and concentration, reagent rehydration, nucleic acid amplification and detection of the target nucleic acid sequence using real-time polymerase chain reaction (PCR). Amplified targets are detected with hydrolysis probes labeled with quenched fluorophores. The amplification, detection and interpretation of the signals are done automatically by the BD MAX™ System.
2. **AVAILABILITY**
	1. Test will be run once per day, Monday through Friday
3. **SPECIMEN COLLECTION/TRANSPORT**
	1. Using a recommended swab transport device, nasal specimens should be collected according to institutional and laboratory standard operating procedures and/or the following:
		1. Moisten the swab(s) with two drops (approximately 50 μL) of sterile physiological saline or use dry.
		2. Carefully insert the swab(s) into the patient’s nostril [a swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nares].
		3. Roll the swab(s) along the mucosa inside the nostril 5 times.
		4. Insert the same swab(s) into the second nostril and repeat steps 2 and 3. Place the swab(s) in its transport tube.
		5. Label the transport tube.
		6. Transport the swab(s) to the laboratory.
4. **MATERIALS AND EQUIPMENT**
	1. Materials
		1. BBL™ CultureSwab Liquid Stuart single or double swab (BD catalog no.220099 or 220109), Copan (Venturi) Transystem® Liquid Stuart single or double swab (Copan, catalog no. 141C or 139C)
		2. Nalgene® Cryogenic Vial Holder (VWR, catalog no. 66008-783)
		3. Disposable gloves, powderless
		4. Sterile scissors (optional)
		5. Sterile Gauze
		6. Stopwatch or timer
		7. BD MAX™ PCR Cartridges (BD catalog no. 437519)
	2. Equipment
		1. VWR Multi-Tube Vortexer (VWR, catalog no. 58816-115)
		2. BD MAX system
		3. Vortex Genie
	3. Reagents
		1. BD MAX™ StaphSR Assay Kit (BD catalog no. 443419)
	4. Controls
		1. MRSA strain (ATCC™ 43300)
		2. Methicillin-susceptible Staphylococcus aureus strain (ATCC™ 29213)
		3. Staphylococcus epidermidis strain (ATCC 12228)
5. **STORAGE AND HANDLING**
	1. Specimen
		1. Collected specimens should be kept between 2 - 25°C during transport. Protect against freezing or exposure to excessive heat.
		2. Once in the lab, the specimens should be kept at 2-8°C.
			1. Specimens can be stored at 2-8°C for 5 days or at RT (25± 2°C) for 24hrs before testing.
	2. Reagents
		1. BD MAX™ StaphSR assay reagents and components are stable at 2-25°C through the stated expiration date. Do not use expired components.
		2. BD MAX™ StaphSR Master Mix and Extracting Tubes are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening.
			1. Reagent tubes are stable for up to 14 days at 2-25°C after initial opening and resealing of the pouch.
			2. Unconstituted Extraction and Master Mix reagent tubes are stable for up to 5 hours at 2-25°C after being removed from the protective pouch.
6. **QUALITY CONTROL**
	1. The External Positive Control is intended to monitor for substantial reagent failure.
	2. The External Negative Control is used to detect reagent or environmental contamination (or carry-over) from other specimens or SA or MRSA amplicons.
	3. Zeptometrix/Fisher controls are used for MRSA, MSSA, and Staph negative, stored in a 2-8°C refrigerator.
	4. Label 3 STAPHSR specimen buffer tubes: one as MRSA, 2ND as MSSA, and the 3rd as negative.
	5. Using a COPAN swab or nasal swab, take the appropriate control and dip the swab into the QC vial. Place the swab in the properly labeled buffer tube and break off at the score mark. Change gloves in between each QC target.
	6. An External Negative Control that yields a positive test result is indicative of a specimen handling and/or contamination problem. Review the specimen handling technique to avoid mix-up and/or contamination.
	7. An External Positive Control that yields a negative result is indicative of a specimen handling/preparation problem. Review the specimen handling/preparation technique.
	8. An External Control that yields an Unresolved, Indeterminate or Incomplete test result is indicative of a reagent or a BD MAX™ System failure. Check the BD MAX™ System monitor for any error messages. Refer to the "System Error Summary" section of the BD MAX™ System User’s Manual for interpretation of warning and error codes. If the problem persists, use reagents from an unopened pouch or use a new BD MAX™ StaphSR Assay kit.
	9. Refer to IQCP for details on quality control assessment.
	10. External Positive and Negative Controls are not used by the BD MAX™ System software for the purpose of sample test result interpretation. External Controls are treated as if they were patient samples.
	11. Each BD MAX™ StaphSR Assay Extraction Tube contains a Sample Processing Control (SPC) which is a plasmid containing a synthetic target DNA sequence.
		1. The SPC will be extracted, eluted and amplified along with any DNA present in the processed specimen, ensuring the predictively of the assay. The SPC monitors the efficiency of DNA capture, washing and elution during the sample processing steps, as well as the efficiency of DNA amplification and detection during PCR analysis.
		2. If the SPC result fails to meet the acceptance criteria, the result of the specimen will be reported as Unresolved. An Unresolved result is indicative of a inhibitory specimen or a processing or reagent failure. Repeat any specimen reported as Unresolved according to the "REPEAT TEST PROCEDURE" section below.
	12. Environmental wipe testing is performed monthly. All test areas are swabbed and run as test patients. Refer to Monthly BD MAX™ Environmental Testing sheet for directions.
	13. Positivity Rate is monitored monthly.
7. **TEST PROCEDURE**
	1. Use 10% bleach, DI water and 70% ethanol to clean the BD MAX™ and surrounding bench area.
		1. DO NOT clean the mirror within the BD MAX™. Lightly dust with clean gauze only if needed.
	2. Run a pending report using test code NAPAT, back dating at least 1 week. Account for all pending specimens. Number each swab as well as each corresponding buffer tube used from the STAPHSR kit.
	3. BD MAX™ operation:
		1. Put on clean gloves then log into BD MAX™ using your personal “username” and “password”.
		2. Remove the required number of BD MAX™ StaphSR Reagent Strips from the BD MAX™ StaphSR kit. Gently tap each strip onto a hard surface to ensure that all the liquids are at the bottom of the tubes and place in the metal BD MAX™ system rack. Push strip in and down to lock into place.
		3. Remove the required number of StaphSR Extraction Tube(s) and StaphSR Master Mix tube(s) from their protective pouches. Remove excess air, and close pouches with the zip seal. Once opened, bags expire after 14 days. Write an outdate of 14 days on the bag to ensure integrity of Extraction Tubes.
		4. For each sample to be tested, place one (1) BD MAX™ Reagent Strip on the BD MAX™ System Rack, starting with Position 1 of Rack A and continuing sequentially with no open spaces.
		5. Place one (1) BD MAX™ StaphSR Extraction Tube (white foil seal) into Position 1 of each of the BD MAX™ StaphSR Strips as shown in Figure 1 below.
		6. Place one (1) BD MAX™ StaphSR Master Mix Tube (green foil seal) into Position 2 of each of the BD MAX™ StaphSR Strips as shown in Figure 1 below.
			1. Using the top of a marker cap, snap all buffer tubes into the strips.
		7. Place one sample buffer tube for each specimen to be run into an UNWIRE red or white test tube rack (small). Number tubes according to numbered nasal swabs without marking the tubes barcodes.

Figure 1: Snap BD MAX™ EBP Extraction tubes and Master Mix tubes into reagent strips.



* + 1. Write Click the RUN tab at the bottom of the screen and fill in the appropriate fields.
			1. Test: choose BD MAX™ StaphSR 55 from the drop-down list.
			2. Lot number: use the drop-down list and choose the lot number from the in use StaphSR kit.
			3. External Control: this should be left blank while entering patient specimen information.
		2. With the curser in the Sample Tube window, scan the 2-D barcode on the side of the tube.
		3. The curser will automatically move to the Accession window. Scan the accession number from the patient sample. Continue in this manner until all specimens are logged into BD MAX™.
		4. Place the required number of BD MAX™ PCR Cartridge(s) into the BD MAX™ System (see Figure 2 below).
			1. Each cartridge accommodates 2 runs of up to 12 samples for a total of 24 samples.
			2. BD MAX™ cartridges may be used multiple times until all lanes have been utilized.
			3. Use Run Wizard to utilize as many spaces as possible on the PCR card. Refer to BD MAX™ manual for detailed instructions.

Figure 2: Insert PCR Cartridges into the instrument.



* 1. Specimen Preparation
		1. One (1) Sample Buffer Tube, one (1) Septum Cap, one (1) Master Mix (B7), one (1) Extraction Tube (B8) and one (1) Reagent Strip are required for each specimen and each External Control to be tested.
		2. Obtain the number of Sample Buffer Tubes corresponding to the number of specimens and external controls to be run.
		3. Label each Sample Buffer Tube (clear cap) with the appropriate patient identification making sure not to obscure, write, or label over the barcodes.
			1. Remove the cap from the Sample Buffer Tube.
			2. Remove the swab from the sample transport tube and place the swab in the corresponding Sample Buffer Tube.
			3. Hold the swab by the stem near the rim of the tube (use gauze to minimize risk of contamination). Lift the swab approximately one (1) cm from the bottom of the Sample Buffer Tube and bend the stem against the edge of the tube to break it. Alternative method: use sterile scissors to cut the stem.
			4. Close the Sample Buffer Tube with a septum cap.
			5. Place Sample Buffer Tube in a rack and vortex at maximum speed for one (1) minute with the Multi-Tube Vortexer. Up to 24 samples can be processed simultaneously with the Multi-Tube Vortexer.
1. **INTERPRETATION**
	1. Results are available on the Results tab in the Results window on the BD MAX™ System monitor. The BD MAX™ System software automatically interprets test results.
	2. A test result may be called as SA NEG and MRSA NEG (negative), SA POS and MRSA POS (MRSA positive), SA POS and MRSA NEG (SA positive) or SA UNR and MRSA UNR (unresolved) based on the amplification status of the target and of the Sample Processing Control.
	3. IND (indeterminate) or INC (incomplete) results are due to BD MAX™ System failure. Results are based on the following decision algorithm (Table 1).

Table 1: BD MAX™ MRSA Assay Decision Algorithm

|  |  |
| --- | --- |
| **ASSAY RESULT REPORTED** | **INTERPRETATION OF RESULT** |
| **SA POS****MRSA POS** | MRSA DNA detected |
| **SA POS****MRSA NEG** | SA DNA detected;No MRSA DNA detected |
| **SA NEG****MRSA NEG** | No SA and no MRSA DNA detected |
| **SA UNR****MRSA UNR** | No target amplification; no SPC amplification |
| **IND** | Indeterminate BD MAX™ System failure(with Warning or Error Codes\*) |
| **INC** | Incomplete Run(with Warning or Error Codes\*) |

* 1. SA POS, MRSA POS (SA and MRSA DNA detected)
		1. Fluorescence signal is detected for both MREJ (S. aureus specific) and mecA/ mecC targets.
		2. nuc gene target is or is not detected since it has been shown that, in rare instances, the nuc gene may be absent for MRSA.
		3. SPC is ignored since MRSA target amplification overrides this control.
	2. SA POS, MRSA NEG (SA DNA detected; MRSA DNA not detected)
		1. Fluorescence signal is detected for the nuc gene target only (indicative of an SA strain) or
		2. Fluorescence signal is detected for the nuc gene and mecA/mecC targets in the absence of MREJ sequences (indicative of an SA strain present with co-colonization of a non-SA methicillin-resistant bacterial strain or
		3. Fluorescence signal is detected for the nuc gene and MREJ targets (indicative of an empty cassette variant) or
		4. Fluorescence signal is detected for the MREJ target only (indicative of a S. aureus empty cassette variant. MREJ is specific to S. aureus species and thus is indicative of an SA strain. The presence of the nuc gene target is or is not detected for an empty cassette variant).
		5. SPC is ignored since SA target amplification overrides this control.
	3. SA NEG, MRSA NEG (SA DNA not detected; MRSA DNA not detected)
		1. Fluorescence signal is not detected by the BD MAX™ StaphSR Assay for any target (nuc, mecA/mecC and MREJ targets) and fluorescence signal is detected for the SPC.
		2. Fluorescence signal is detected for the mecA/mecC gene only (The mecA and mecC genes are not unique to S. aureus species and can be found in other bacterial genera (e.g., S. epidermidis).
	4. SA UNR, MRSA UNR (Unresolved result)
		1. Fluorescence signal is not detected for nuc gene, mecA/mecC or MREJ targets and
		2. Fluorescence signal not detected for the SPC (inhibitory specimen or reagent failure).
	5. IND (Indeterminate result)
		1. BD MAX™ System failure with Warning or Error Codes. Refer to the “Troubleshooting” section of the BD MAX™ System User’s Manual for interpretation of warning and error codes.
	6. INC (Incomplete run)
		1. BD MAX™ System failure with Warning or Error Codes. Refer to the “Troubleshooting” section of the BD MAX™ System User’s Manual for interpretation of warning and error codes.
1. **REPEAT TESTING PROCEDURE:**
	1. Only one repeat is allowed on the BD MAX™ System from the Sample Buffer Tube due to the sample volume available. For Sample Buffer Tubes stored at 25 ˚C, retesting must be performed within 36 hours of the steps covered in the “SPECIMEN PREPARATION” section above. Alternatively, for Sample Buffer Tubes stored at 2-8 ˚C, retesting must be performed within 120 hours (5 days) of the steps covered in the “SPECIMEN PREPARATION” section above.
	2. UNRESOLVED RESULT
		1. Unresolved results may be obtained in the event that an inhibitory substance prevents proper target, or SPC amplification. Sample(s) can be repeated from their corresponding Sample Buffer Tube(s) within the timeframe defined above. Vortex the sample(s) for one (1) minute and restart from the “BD MAX™ Operation” section.
	3. INDETERMINATE RESULT
		1. Indeterminate results may be obtained in the event that a System failure occurs. Sample(s) can be repeated from their corresponding Sample Buffer Tube(s) within the timeframe defined above. Vortex the sample(s) for one (1) minute and restart from the “BD MAX™ Operation” section. For the interpretation of warning or error code messages, refer to the BD MAX™ Software User’s Manual (“Troubleshooting” section).
	4. INCOMPLETE RESULT
		1. Incomplete results may be obtained in the event that the Sample Preparation or the PCR did not reach its expected time points. Sample(s) can be repeated from their corresponding Sample Buffer Tube(s) within the timeframe defined above. Vortex the sample(s) for one (1) minute and restart from “BD MAX™ Operation” section. For the interpretation of warning or error code messages, refer to the BD MAX™ System User’s Manual (“Troubleshooting” section).
	5. EXTERNAL CONTROL FAILURE
		1. External Controls should yield expected results when tested. If specimens have to be repeated due to an incorrect External Control result, they should be repeated from their Sample Buffer Tube along with freshly prepared External Controls within the timeframe defined above. Vortex the samples for one (1) minute and restart from the “BD MAX™ Operation” section.
2. **SOFT RESULTING**
	1. Resulting positive and negative targets
		1. From SoftLab, go to “interfaces”, and “Instrument Menu”.
		2. Select “RBDMX, RBDMX2, or “BD MAX™”
		3. Select “Loadlist and todays results”, “Not Posted”, “By Sequence”.
		4. Each order will be highlighted individually. Verify the result against the instrument printout.
		5. To add result comments, i.e., Phone reports
			1. Highlight the order number on left of screen.
			2. At bottom of screen click on Lab Results
			3. Open “Comment” box and add comment/phone report using @CALM.
			4. Click back to Instrument tab and save when asked.
			5. If specimen is positive for MRSA update the ESO box under ORDER ENTRY (before posting).
			6. Click Post All to verify the report.
			7. Order number should disappear from list on left.
	2. Resulting Invalids
		1. Invalid specimens must be manually resulted in result entry.
			1. Go to result entry.
			2. In the Order: box, enter the Order number, select Next.
			3. Select “invalid” from the NAPAT window for the two targets.
			4. Open the comment box and free text “Refer to nasal culture”.
			5. Select Verify All.
			6. Click on the order entry button. Order a CXNAS at no charge.
			7. Track and ship sample to Microbiology lab.
3. **LIMITATIONS OF TEST**
	1. This product is intended for use with nasal swab specimens collected using specimen collection and transport devices listed in the “EQUIPMENT AND MATERIALS” section. Performance of the BD MAX™ StaphSR assay using Liquid Amies single or double swab transport device has not been established.
	2. This product should only be used with the BD MAX™ System.
	3. Erroneous results may occur from improper specimen collection, handling, storage, technical error, sample mix-up or because the number of organisms in the specimen is below the analytical sensitivity of the test.
	4. Good laboratory technique is essential to the proper performance of this assay. Due to the high analytical sensitivity of this test, extreme care should be taken to preserve the purity of all materials and reagents.
	5. Screening determines the colonization status at a given time. Colonization may vary depending on patient treatment (e.g., decolonization regime), patient status (e.g., transient SA or MRSA carrier and/or prolonged hospitalization). Colonization status should be monitored according to institutional policies.
	6. The BD MAX™ StaphSR assay is designed to detect MREJ genotypes i, ii, iii, iv, v, vi, vii, ix, xiii, xiv, and xxi which represents most of mecA and mecC harboring MRSA strains (belonging to different SCCmec/MREJ types) accounting for more than 98% of worldwide strains tested by BD to date. The ability of BD MAX™ StaphSR assay to detect other MREJ genotypes is unknown.
	7. The BD MAX™ StaphSR assay does not report Borderline Oxacillin Resistant Staphylococcus aureus (BORSA) as MRSA (it will report as SA only). The mechanism of oxacillin resistance in BORSA strains is due to an increased production of β-lactamases, not the mecA or mecC gene. BORSA strains are rare.
	8. The BD MAX™ StaphSR assay performance in detecting modified Staphylococcus aureus (MOD-SA) is not known as those strains have not been evaluated. The mechanism of oxacillin resistance in MOD-SA strains is due to changes in affinity of penicillin binding proteins for oxacillin. MOD-SA strains are rare.
	9. The BD MAX™ StaphSR assay will generate a false positive MRSA result when testing a co-colonized nasal specimen containing both a methicillin-resistant coagulase negative Staphylococcus (MRCoNS) and an “empty cassette” methicillin-susceptible SA variant. Co-colonization with MRCoNS and an “empty cassette” methicillin-susceptible SA is rare. • As with all PCR-based in vitro diagnostic tests, extremely low levels of target below the LoD of the assay may be detected, but results may not be reproducible.
	10. Tobramycin may cause inhibition in the BD MAX™ StaphSR assay (refer to the Interfering Substances section for further details).
	11. False negative results may occur due to loss of nucleic acid from inadequate collection, transport or storage of specimens, or due to inadequate bacterial cell lysis. The Sample Processing Control has been added to the test to aid in the identification of specimens that contain inhibitors to PCR amplification and as a control for reagent integrity and of the assay system as a whole. The Sample Processing Control does not indicate if nucleic acid has been lost due to inadequate collection, transport or storage of specimens, or if bacterial cells have been adequately lysed.
	12. In a mixed culture, the detection of MRSA or SA is variable when high concentrations of MRSE are present. Competition from MRSE was observed at an MRSA:MRSE ratio of 1: ≥1 x 10² and at an SA:MRSE ratio of 1: ≥1 x 10⁵.
	13. In a mixed culture, the detection of MRSA is variable when high concentrations of MSSA are present. Competition from MSSA was observed at an MRSA:MSSA ratio of 1: ≥1 x 10³.
	14. BD MAX™ StaphSR assay results may sometimes be unresolved due to an invalid Sample Processing Control, or be Indeterminate or Incomplete due to instrument failure, and require retesting that can lead to a delay obtaining final results.
	15. A positive test result does not necessarily indicate the presence of viable organisms. A positive result is indicative of the presence of SA or MRSA DNA. The BD MAX™ StaphSR Assay simultaneously detects the mecA/mecC gene carried within the SCCmec cassette and a S. aureus specific sequence located within the junction of the SCCmec cassette and the orfX gene (MREJ). The BD MAX™ StaphSR Assay also detects S. aureus-specific nuc gene.
	16. The BD MAX™ StaphSR Assay is designed to detect MREJ genotypes I, ii, iii, iv, v, vi, vii, ix, xiii, xiv and xxi which represents most of mecA and mecC harboring MRSA strains (belonging to different SCC/mec/MREJ types) accounting for more than 98% of worldwide strains tested by BD to date. Polymorphisms or mutations in regions detected by this assay may impair detection of new or unknown MRSA variants results in a false negative result.
	17. The BD MAX™ StaphSR Assay performance in detecting modified S. aureus (MOD-SA) is not known as those strains have not been evaluated. The mechanism of Oxacillin-resistance in MOD-SA strains is due to changes in affinity of penicillin-binding proteins or Oxacillin, not the mecA gene. MOD-SA strains are rare in the United States.
	18. As with all PCR-based in vitro diagnostic tests, extremely low levels of target below the LoD of the assay may be detected, but results may not be reproducible.
	19. Tobramycin at high concentration may cause slight inhibition in the BD MAX™ StaphSR Assay.
	20. False negative results may occur due to loss of nucleic acid from inadequate collection, transport, or storage of specimens, or due to inadequate bacterial cell lysis. The Sample Processing Control has been added to the test to aid in the identification of specimens that contain inhibitors to PCR amplification. The Sample Processing Control does not indicate if nucleic acid has been lost due to inadequate collection, transport or storage of specimens, or if bacterial cells have been adequately lysed.
	21. Mutations or polymorphisms in primer- or probe-binding regions may affect detection of new or unknown MRSA variants, resulting in a false negative result with the BD MAX™ StaphSR Assay. Specifically, the detection of the MRSA ST93-IV Queensland clone may be compromised and result in a false negative MRSA result.
	22. As with all in vitro diagnostic tests, positive and negative predictive values are highly dependent on prevalence. BD MAX™ StaphSR Assay performance may vary depending on the prevalence and population tested.
	23. The BD MAX™ StaphSR Assay requires use of four (4) optical channels from the BD MAX™ System; FAM channel (475-520nm), ROX channel (585-630nm), VIC channel (530/565nm) and Cy5.5 channel (680/715nm). Performance of the remaining optical channel has not been established with this assay.
4. **NOTES**
	1. Unitized Reagent Strips must be checked for proper liquid fills and to ensure all pipette tips are present.
	2. Always check that there are sufficient tests remaining on the PCR cards before starting the run. If the BD MAX™ is unable to start the PCR step, an internal clock will begin, and the run will abort if the issue is not resolved in time.
	3. The following conditions may cause erroneous results. **Do Not:**
		1. Use any part of the BD MAX™ STAPHSR kit after the stated expiration date.
		2. Use a kit where the outer seal has been broken at time of delivery.
		3. Use reagents if the protective pouched are opened or broken upon arrival.
		4. Use reagents if desiccant is not present or is broken in pouch.
		5. Remove desiccant from pouch.
		6. Use reagents if the protective foil cover on the tube is broken or damaged.
		7. Mix reagents across different lots or mix them between different pouches.
	4. Kits should be kept free from excessive heat and humidity. Prolonged exposure to increased humidity may affect product performance.
	5. Do not interchange or reuse buffer tube clear caps or septum caps to avoid contamination.
	6. Performing the BD MAX™ StaphSR outside the recommended time or temperature ranges for specimen transport and storage may produce invalid results. Assays not performed within specific time frames should be repeated.
	7. Clean gloves should be worn whenever handling kit components to avoid contamination from handling nasal swabs specimens. Gloves should be changed as soon as they become visibly contaminated.
	8. In cases where other PCR tests are conducted in the same area, care must be taken to ensure the assay and its reagents are not contaminated by microbial DNA or DNase. Gloves must ALWAYS be changed before handling reagents and cartridges.
5. **TECHNICAL SUPPORT**
	1. Technical Support- 800-638-8663
	2. technical\_services@bd.com
6. **REFERENCES**
	1. BD MAX™ StaphSR PI ver. P0207(06) 2022-11
	2. BD MAX™ StaphSR Validation Report
7. **REVISIONS**
	1. 10/18/2023: Updated procedure after moving to Coro.