

BD MAX™ StaphSR - Simplified Protocol



- For more detailed information see Instructions for Use: bd.com/e-labeling
- To access sample preparation video, please scan the QR code.

1. Reagent, Storage and Stability

Ref.	Name	Storage	Stability	Quantity
443419	BD MAX™ StaphSR	2–25°C	Unopened reagents: up to expiration date. Opened reagent pouches: up to 14 days and re-sealing of the pouch.	24 tests: Sample Buffer Tubes, Septum caps, Strips, Extraction tubes and Master Mix tubes
437519	BD MAX™ PCR Cartridges	2–25°C	Until expiration date.	24 cartridges

2. Specimen Stability

- Collected specimens should be kept between 2°C and 25°C during transport. Protect against freezing or exposure to excessive heat.
- Specimens can be stored at 25 ± 2 °C for a maximum of 48 hours or at 2–8 °C for a maximum of 120 hours (5 days) before testing.

3. Specimen Collection and Transport

Using an approved swab transport device, nasal specimens should be collected according to institutional and laboratory standard operating procedures and/or the following:

- Moisten the swab(s) with two drops (approximately 50 µL) of sterile physiological saline or use dry.
- 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).
- Roll the swab(s) along the mucosa inside the nostril 5 times.
- Insert the same swab(s) into the second nostril and repeat steps b and c.
- Place the swab(s) in its transport tube, label the transport tube, and transport the swab(s) to the laboratory according to institutional and laboratory standard operating procedures.

4. Sample Preparation

- Label a bar-coded BD MAX™ Sample Buffer Tube (clear cap) with the appropriate specimen identification. Do not obscure, write or label over the 2D-barcode.
- Remove the clear cap from the Sample Buffer Tube and inoculate as follows:
 - Remove the swab from the sample transport tube and place the swab in the corresponding Sample Buffer Tube.
 - Hold the swab by the stem near the rim of the Sample Buffer Tube (use sterile 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.
- Close the inoculated Sample Buffer Tube using a Septum Cap.
- Vortex all prepared Sample Buffer Tubes at maximum speed for one (1) minute.
- Proceed to the BD MAX™ Rack and BD MAX™ System Run section below.

bd.com

BD and the BD MAX are trademarks of Becton, Dickinson and Company.
© 2022 BD. All rights reserved.

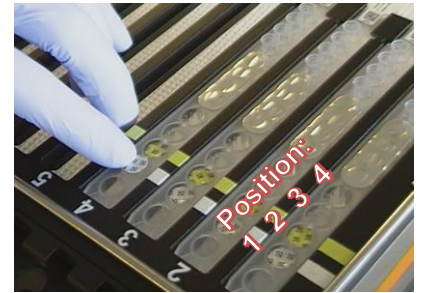


The BD MAX™ System, the BD MAX™ StaphSR Assay are in vitro diagnostic medical devices, bearing a CE mark. BD-77182

BD MAX™ StaphSR - Simplified Protocol

5. BD MAX™ Rack and BD MAX™ System Run

- a. For each sample to be tested, place one Unitized Reagent Strip into the BD MAX™ Rack.
- b. Snap one Extraction Tube (white foil) into each Strip in Position 1.
- c. Snap one Master Mix Tube (green foil) into each Strip in Position 2.
- d. Leave Strip Position 4 unfilled.
- e. Create the Worklist making sure to select the correct Test:
 - < **BD MAX StaphSR 55** >
- f. Place the prepared Sample Buffer Tubes in the BD MAX™ Rack corresponding to the appropriate assembled Strip.
- g. Place the assembled BD MAX™ Rack(s) and required number of BD MAX™ PCR Cartridge(s) into the instrument.
- h. Close BD MAX™ door and Start run.



6. Results and Repeats

- a. The BD MAX™ System software automatically interprets test results and reports results for each sample.
 - i. A test result may be called as NEG (negative), POS (positive) or UNR (unresolved) based on the amplification status of the target and of the Sample Processing Control.
 - ii. In the case of an IND, INC and UNR, it is recommended to repeat the test.
- b. Prepared Sample Buffer Tubes can be stored at 2–8°C for up to 120 hours (5 days) or at 25 ± 2°C for a maximum of 36 hours. Sufficient volume is available for one repeat test from the Sample Buffer Tube.

	BD MAX StaphSR 55
Channel 475/520 LIS code	MREJ MRSA
Channel 530/565 LIS code	<i>nuc</i> gene SA
Channel 585/630 LIS code	<i>mecA&C</i> genes MRSA
Channel 630/665	
Channel 680/715	Sample Processing Control

		Time in minutes	number of samples					
Assay	PCR time		24	20	16	12	8	4
StaphSR	61	prep time	76	70	65	56	48	39
		time to results	137	132	126	116	108	100