BD MAX™ MRSA

REF **442953**

For *In Vitro* Diagnostic Use
For use with the BD MAX™ System

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2°C 25°C CE IVD R_X Only

INTENDED USE

The BD MAX™ MRSA assay performed on the BD MAX System is an automated qualitative *in vitro* diagnostic test for the direct detection of Methicillin-resistant *Staphylococcus aureus* (MRSA) DNA from nasal swabs in patients at risk for nasal colonization. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD MAX MRSA assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections. A negative result does not preclude nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

SUMMARY AND EXPLANATION OF THE PROCEDURE

MRSA is a major cause of healthcare acquired infections. Most transmissions occur in healthcare institutions as a result of contamination of the hands of healthcare workers, or from the healthcare environment which has been contaminated from patients carrying MRSA. While MRSA may cause infection with clinical manifestations ranging from pustules to sepsis and death,[1] it can also be found in the nose or on the skin of individuals (asymptomatic carriers). Treatment of MRSA infections has become challenging with the emergence of strains resistant to a broad range of antimicrobial agents. Methicillin-resistant strains of *Staphylococcus aureus* are frequently encountered in healthcare settings, and represent over 50% of hospital-acquired *Staphylococcus aureus* isolates in some North American hospitals.[2] Risk factors for infection with MRSA in healthcare settings include prolonged hospital stay, proximity to patients infected or colonized with MRSA, colonization with other resistant organisms such as Vancomycin-resistant enterococci (VRE) and *Clostridioides difficile (*formerly *Clostridium difficile*[8]*)*, exposure to multiple and/or prolonged broad-spectrum antibiotic treatments, exposure to high MRSA prevalence areas within the healthcare facility, and prior MRSA nasal infection or carriage. Early identification of patients with MRSA nasal carriage can be part of an effective infection prevention program for MRSA. Culture-based detection of MRSA requires isolation of pure colonies followed by either Oxacillin or Cefoxitin susceptibility testing, detection of the *mecA* gene or detection of the penicillin binding protein (PBP2a) encoded by the *mecA* gene. The culture based process takes a minimum of 24 hours with a median time to result closer to 48 hours in order to identify MRSA. With the rapidity at which MRSA infections can spread, especially in healthcare settings where carriers are common, providing MRSA nasal carriage results on the same day that the specimen was collected represents an advantage for infection prevention programs.

A nasal specimen is collected and transported to the laboratory using the recommended swab (refer to the Equipment and Materials Required But Not Provided section). The swab is placed in a BD MAX MRSA Sample Buffer Tube. The Sample Buffer Tube is vortexed to release cells from the swab into the buffer. The Sample Buffer Tube is placed into the BD MAX System and the following automated procedures occur: the bacterial cells are lysed, DNA is extracted on magnetic beads and concentrated, then an aliquot of the eluted DNA is added to PCR reagents which contain the MRSA-specific primers used to amplify the genetic target, if present. The assay also includes a Sample Processing Control. The Sample Processing Control 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 sample, the BD MAX Unitized Reagent Strip and the BD MAX PCR Cartridge 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.

PRINCIPLES OF THE PROCEDURE

The BD MAX System uses a combination of lytic and extraction reagents to perform cell lysis and DNA extraction. Following enzymatic cell lysis at elevated temperature, the released nucleic acids are captured by magnetic affinity beads. The beads with the bound nucleic acids are washed and the nucleic acids are eluted by heat in Elution Buffer. Eluted DNA is neutralized with Neutralization Buffer and transferred to the Master Mix Tube to rehydrate the PCR reagents. The reconstituted amplification reagent is dispensed into the BD MAX PCR Cartridge. Microvalves in the BD MAX PCR Cartridge are sealed by the system prior to initiating PCR to prevent evaporation and amplicon contamination.

The amplified DNA targets are detected using hydrolysis (TaqMan®) probes labeled at one end with a fluorescent reporter dye (fluorophore) and at the other end with a quencher moiety. Probes labeled with different fluorophores are used to detect MRSA and Sample Processing Control amplicons in two different optical channels of the BD MAX System: MRSA amplicons are detected in the FAM channel and Sample Processing Control amplicons are detected in the ROX channel. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'–3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The amount of fluorescence detected in the two optical channels used for the BD MAX MRSA assay is directly proportional to the quantity of the corresponding probe that is hydrolyzed. The BD MAX System measures these signals at the end of each amplification cycle, and interprets the data to provide a result.

REAGENTS AND MATERIALS

REF	Contents	Quantity
442953	**BD MAX™ MRSA Master Mix (A1)** *Dried PCR Master Mix containing Target- and Sample Processing Control-specific molecular probe (0.00132% w/v) and primers (0.004% w/v) and PCR enzyme (1.5E-15% w/v).*	24 tests (2 x 12 tubes)
	BD MAX™ MRSA Reagent Strips *Unitized Reagent Strips containing wash buffer with 0.1% v/v Triton® X-100 (0.7 mL), elution buffer (0.7 mL) and neutralization buffer (0.02% v/v Tween® 20) (0.7 mL) reagents and disposable pipette tips necessary for specimen processing and DNA extraction.*	24 tests
	BD MAX™ MRSA Extraction Tube (A2) *Freeze-dried pellet containing DNA magnetic affinity beads (2.7% w/v), Achromopeptidase (0.4% w/v) and Sample Processing Control.*	24 tests (2 x 12 tubes)
	BD MAX™ MRSA Sample Buffer Tube *(0.5% v/v Tween 20)*	24 tests (2 x 12 tubes)
	Septum Caps	25

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD BBL™ CultureSwab™ Liquid Stuart single or double swab (BD Cat. No. 220099 or 220109), Copan (Venturi) Transystem™ Liquid Stuart single or double swab (Copan Cat. No. 141C or 139C), or
- BD BBL™ CultureSwab™ Liquid Amies single or double swab (BD Cat. No. 220093 or 220105), Copan (Venturi) Transystem™ Liquid Amies single or double swab (Copan Cat. No. 140C or 138C)
- BD BBL™ CHROMagar™ Staph aureus (BD Cat. No. 214982), BD BBL™ CHROMagar™ MRSA (BD Cat. No. 215084), Mannitol Salt Agar (MSA) (BD Cat. No. 221773 or 221271) or equivalent media (optional)
- VWR Multi-Tube Vortexer (VWR Cat. No. 58816-115)
- NALGENE™ Cryogenic Vial Holder (VWR Cat. No. 66008-783)
- Gram staining reagent (optional)
- BD Trypticase™ Soy Broth (5 mL) with 6.5% NaCl (BD Cat. No. 221351) (optional)
- 5% sheep blood agar plate [e.g., BD Trypticase™ Soy Agar (TSA II) with 5% Sheep Blood, BD Cat. No. 221239 or 221261] (optional)
- Disposable gloves, powderless
- Sterile scissors (optional)
- Sterile gauze
- Stopwatch or timer
- BD MAX™ PCR Cartridges (BD Cat. No. 437519)

WARNINGS AND PRECAUTIONS

- The BD MAX MRSA assay is for *in vitro* Diagnostic Use.
- Do not use expired reagents and/or materials.
- Do not use the kit if the label that seals the outer box is broken upon arrival.
- Do not use reagents if the protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or is broken inside reagent pouches.
- Do not remove desiccant from reagent pouches.
- Close protective pouches of reagents promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing.
- Protect reagents against heat and humidity. Prolonged exposure to humidity may affect product performance.
- Do not use reagents if the foil has been broken or damaged.
- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not interchange or reuse caps, as contamination may occur and compromise test results.
- Check Unitized Reagent Strips for proper liquid fills (ensure that the liquids are at the bottom of the tubes) (refer to Figure 1).
- Check Unitized Reagent Strips to ensure that all pipette tips are present (refer to Figure 1).

- Proceed with caution when using chemical solutions as Master Mix and Extraction Tube barcode readability may be altered.
- 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.
- In cases where other PCR tests are conducted in the same general area of the laboratory, care must be taken to ensure that the BD MAX MRSA assay, any additional reagents required for testing, and the BD MAX System are not contaminated. Avoid microbial and deoxyribonuclease (DNase) contamination of reagents at all times. Gloves must be changed before manipulating reagents and cartridges.
- To avoid contamination of the environment by amplicons, do not break apart the BD MAX PCR Cartridges after use. The seals of the BD MAX PCR Cartridges are designed to prevent contamination.
- The laboratory should routinely perform environmental monitoring to minimize the risk of cross-contamination.
- Performing the BD MAX MRSA assay outside the recommended time and temperature ranges recommended for specimen transport and storage may produce invalid results. Assays not performed within the specified time ranges should be repeated.
- Additional controls may be tested according to guidelines or requirements of local, state, provincial and/or federal regulations or accrediting organizations.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in the CLSI Document M29[3] and in Biosafety in Microbiological and Biomedical Laboratories.[4]
- Wear protective clothing and disposable gloves while handling all reagents.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink, chew or eat in areas where specimens or kit reagents are being handled.
- Dispose of unused reagents and waste in accordance with local, state, provincial and/or federal regulations.
- Consult the BD MAX System User's Manual[7] for additional warnings, precautions and procedures.

STORAGE AND 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 °C for a maximum of 48 hours or at 2–8 °C for a maximum of 120 hours (5 days) before testing.

BD MAX MRSA components are stable at 2–25 °C through the stated expiration date. Do not use expired components.

BD MAX MRSA Master Mix and Extraction Tubes are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening.

- Reagent tubes are stable for up to 7 days at 2–25 °C after initial opening and re-sealing of the pouch.
- Unreconstituted Extraction and Master Mix reagent tubes are stable for up to 3 hours at 2–25 °C after being removed from their protective pouch.

INSTRUCTIONS FOR USE

Specimen Collection/Transport

Using a recommended swab transport device (refer to the Equipment and Materials Required But Not Provided section), 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 five times.
4. Insert the same swab(s) into the second nostril and repeat steps 2 and 3.
5. Place the swab(s) in its transport tube.
6. Label the transport tube.
7. Transport the swab(s) to the laboratory according to institutional and laboratory standard operating procedures (refer to the Storage and Stability section).

Specimen Preparation

NOTE: One (1) Sample Buffer Tube, one (1) Septum Cap, one (1) Master Mix (A1), one (1) Extraction Tube (A2) and one (1) Unitized Reagent Strip are required for each specimen and each External Control to be tested.

NOTE: For culturing clinical specimens prior to performing the BD MAX MRSA assay, refer to the Culturing of Clinical Specimens section.

1. Obtain the number of Sample Buffer Tubes (clear cap) corresponding to the number of specimens and External Controls to be run.
2. Label each Sample Buffer Tube with the appropriate patient identification making sure not to obscure, write, or label over the barcodes.
3. Remove the cap from the Sample Buffer Tube.
4. Remove the swab from the sample transport tube and place the swab in the corresponding Sample Buffer Tube.

5. 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.
6. Close the Sample Buffer Tube with a septum cap.
7. Place Sample Buffer Tube in a NALGENE Cryogenic Vial Holder 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.

BD MAX System Operation

NOTE: Refer to the BD MAX System User's Manual[7] for detailed instructions (Operation section).

NOTE: Testing of the BD MAX MRSA assay must be performed immediately after the vortexing step above (Specimen Preparation, Step 7). If retesting is necessary, re-vortex sample(s).

1. Power on the BD MAX System (if not already done) and log in by entering **<user name>** and **<password>**.
2. Gloves must be changed before manipulating reagents and cartridges.
3. Remove the required number of Unitized Reagent Strips from the BD MAX MRSA kit. Gently tap each Unitized Reagent Strip onto a hard surface to ensure that all liquids are at the bottom of the tubes.
4. Remove the required number of Extraction Tube(s) and Master Mix Tube(s) from their protective pouches. Remove excess air, and close pouches with the zip seal.
5. For each sample to be tested, place one (1) Unitized Reagent Strip on the BD MAX System Rack, starting with Position 1 of Rack A.
6. Snap one (1) Extraction Tube (white foil) into each Unitized Reagent Strip in Position 1 as shown in Figure 1.
7. Snap one (1) Master Mix Tube (green foil) into each Unitized Reagent Strip in Position 2 as shown in Figure 1.

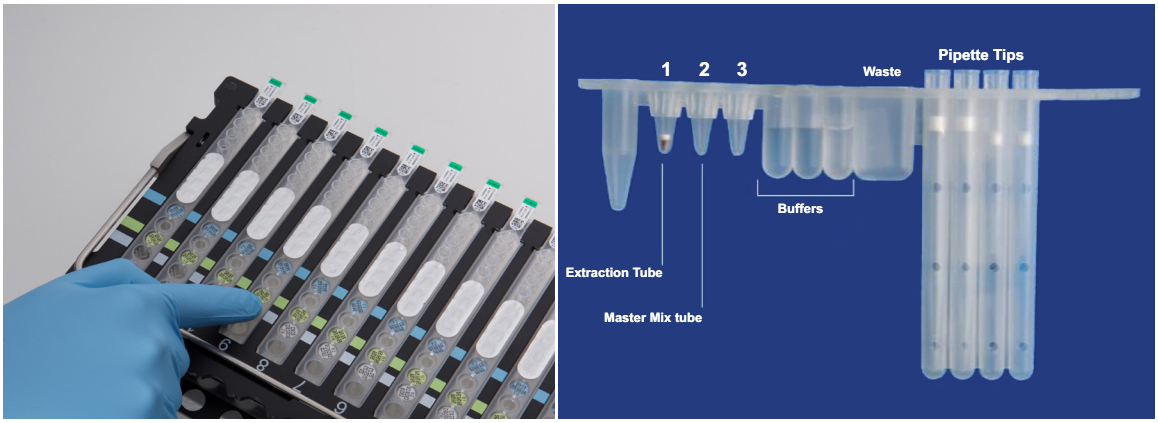

Figure 1: Snap BD MAX MRSA Extraction Tubes and Master Mix Tubes into Unitized Reagent Strips

8. Click on the Run icon, then Inventory. Enter the kit lot number for the BD MAX MRSA assay (for lot traceability) by either scanning the barcode with the scanner or by manual entry.

   NOTE: Repeat step 8 each time a new kit lot is used.
9. Navigate to the Worklist. Using the pull down menu select **<BD MAX MRSA>**.
10. Enter the Sample Buffer Tube ID, Patient ID and Accession Number (if applicable) into the Worklist, either by scanning the barcode with the scanner or by manual entry.
11. Select the appropriate kit lot number (found on the outer box) from the pull down menu.
12. Repeat steps 9 to 11 for all remaining Sample Buffer Tubes.
13. Place the Sample Buffer Tubes in the BD MAX System Rack(s) corresponding to the Unitized Reagent Strips assembled in steps 5 to 7.

    NOTE: Place the Sample Buffer Tubes in the sample rack(s) with the 1D barcode labels facing outward (this makes scanning Sample Buffer Tubes easier during sample login).
14. Place the required number of BD MAX PCR Cartridge(s) into the BD MAX System (refer to Figure 2).
    - Each BD MAX PCR Cartridge accommodates up to 24 samples.
    - The BD MAX System will automatically select the position and row on the BD MAX PCR Cartridge for each run. BD MAX PCR Cartridges may be used multiple times until all lanes have been utilized.
    - To maximize use of BD MAX PCR Cartridges, using 2000 Sample Mode, select Run Wizard under the Worklist tab for lane assignments.
    - Consult the BD MAX System User's Manual[7] for more details.

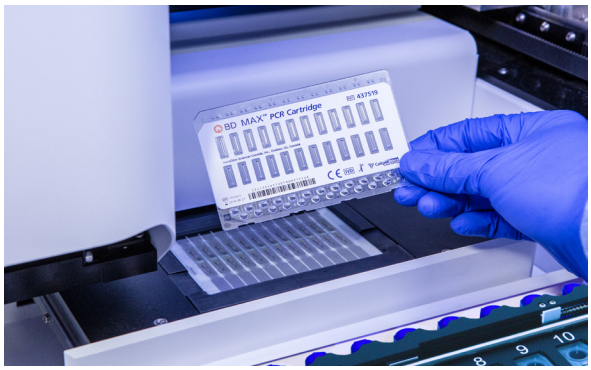

Figure 2: Load BD MAX PCR Cartridges

15. Load rack(s) into the BD MAX System (refer to Figure 3).

Figure 3: Load Rack(s) into the BD MAX System

16. Close the BD MAX System lid and click **<Start>** to begin processing.
17. **At the end of the run, check results immediately or store Sample Buffer Tubes at 2–8 °C for up to 120 hours (5 days) OR at 25 ± 2 °C for a maximum of 36 hours until the results are checked.**

NOTE: If a septum cap was damaged during the run, replace it with a new one before storing the sample.

NOTE: Prepared BD MAX MRSA Sample Buffer Tubes can be stored at 2–8 °C for a maximum of 120 hours (5 days) OR at 25 ± 2 °C for a maximum of 36 hours after the sample has been added to the Sample Buffer Tube. When an Indeterminate (IND), Unresolved (UNR), or Incomplete (INC) result is obtained, or when an External Control failure occurs, a repeat test from the prepared Sample Buffer Tube must be performed within this timeframe (refer to the Repeat Test Procedure section).

QUALITY CONTROL

Quality control procedures monitor the performance of the assay. Laboratories must establish the number, type and frequency of testing control materials according to guidelines or requirements of local, provincial, state, federal and/or country regulations or accreditation organizations in order to monitor the effectiveness of the entire analytical process. For general Quality Control guidance, the user may wish to refer to CLSI MM3 and EP12.[5,6]

1. External Control materials are not provided by BD. 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. (Refer to the table in the Results Interpretation section for the interpretation of External Control assay results.)
2. One (1) External Positive Control and one (1) External Negative Control should be run at least daily until adequate process validation is achieved on the BD MAX System in each laboratory setting. Reduced frequency of control testing should be in accordance with applicable regulations.
3. The External Positive Control is intended to monitor for substantial reagent failure. The External Negative Control is intended to detect reagent or environmental contamination (or carry-over) by target nucleic acids.

4. Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program.
   a. External Negative Control: Commercially available control material [e.g., a Methicillin-sensitive *Staphylococcus aureus* strain (ATCC® 25923)] or a previously characterized sample known to be negative. BD recommends that the External Negative Control be prepared prior to the External Positive Control in order to reduce the potential for contamination as a result of control preparation.
   b. External Positive Control: Commercially available control material [e.g., a reference MRSA strain (ATCC 43300)] or a previously characterized sample known to be positive.

   For the preparation of External Control suspensions, it is recommended that isolates be resuspended in a saline solution to a turbidity of 0.5 McFarland (~1 x 10^8 CFU/mL). Perform serial dilutions with saline to obtain a final suspension of ~8.0 x 10^3 CFU/mL. Dip a swab into the diluted bacterial suspension, express the liquid, and place the swab in the corresponding Sample Buffer Tube. Process and test as a sample (refer to the Specimen Preparation and BD MAX System Operation sections).
5. All External Controls should yield the expected results (positive for External Positive Control, negative for External Negative Control) and no failed external controls (Unresolved or Indeterminate results).
6. An External Negative Control that yields a positive test result is indicative of a specimen handling and/or contamination event. Review the specimen handling technique to avoid mix-up and/or contamination. An External Positive Control that yields a negative result is indicative of a specimen handling/ preparation problem. Review the specimen handling/preparation technique.
7. 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 Troubleshooting section of the BD MAX System User's Manual[7] for interpretation of warning and error codes. If the problem persists, use reagents from an unopened pouch or use a new assay kit.
8. Each Extraction Tube contains a Sample Processing Control which is a plasmid containing a synthetic target DNA sequence. The Sample Processing Control is extracted, eluted, and amplified along with any DNA present in the processed specimen, ensuring the predictivity of the assay. The Sample Processing Control 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. If the Sample Processing Control result fails to meet the acceptance criteria, the result of the specimen will be reported as Unresolved; however, any positive (POS) assay results will be reported and no targets will be called NEG. An Unresolved result is indicative of specimen-associated inhibition or reagent failure. Repeat any specimen reported as Unresolved according to the Repeat Test Procedure section below.

RESULTS INTERPRETATION

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. 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. IND (indeterminate) or INC (incomplete) results are due to BD MAX System failure. Results are based on the following decision algorithm:

Table 1: BD MAX MRSA Assay Result Interpetation

Assay Result Reported	Interpretation of Result
MRSA POS	MRSA DNA detected
MRSA NEG	No MRSA DNA detected
MRSA UNR	Unresolved – inhibitory specimen or reagent failure; no target or Sample Processing Control amplification
IND	Indeterminate result due to BD MAX System failure (with Warning or Error Codes[a])
INC	Incomplete Run (with Warning or Error Codes[a])

[a]Refer to the Troubleshooting section of the BD MAX System User's Manual[7] for interpretation of warning and error codes.

REPEAT TEST PROCEDURE

NOTE: Sufficient volume is available for one repeat test from the Sample Buffer Tube. For Sample Buffer Tubes stored at 2–25 °C, retesting must be performed within 36 hours following the initial Sample Buffer Tube inoculation with the sample. Alternatively, for Sample Buffer Tubes stored at 2–8 °C, retesting must be performed within 120 hours (5 days).

NOTE: New samples may be tested in the same run with repeat samples.

Unresolved Result

Unresolved results may be obtained in the event that an inhibitory substance prevents proper target or Sample Processing Control amplification. Sample(s) can be repeated from their corresponding Sample Buffer Tube(s) within the timeframes defined above. Vortex the sample(s) for one (1) minute and restart from the BD MAX System Operation section.

Indeterminate Result

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 timeframes defined above. Vortex the sample(s) for one (1) minute and restart from the BD MAX System Operation section. For the interpretation of warning or error code messages, refer to the BD MAX System User's Manual[7] (Troubleshooting section).

Incomplete Result

Incomplete results may be obtained in the event that the Specimen Preparation or the PCR failed to complete. Sample(s) can be repeated from their corresponding Sample Buffer Tube(s) within the timeframes defined above. Vortex the sample(s) for one (1) minute and restart following BD MAX System Operation section. For the interpretation of warning or error code messages, refer to the BD MAX System User's Manual[7] (Troubleshooting section).

External Control Failure

External Controls should yield expected results when tested. If samples have to be repeated due to an incorrect External Control result, they should be repeated from their Sample Buffer Tubes along with freshly prepared External Controls within the timeframes defined above. Vortex the samples for one (1) minute and restart from the BD MAX System Operation section.

CULTURING OF CLINICAL SPECIMENS

In order to perform antimicrobial susceptibility testing or epidemiological typing, clinical specimens may be cultured from the collection device (swab) prior to performing the specimen preparation procedure (using the Streak-Plate method) or after the specimen preparation procedure (using the Enrichment Broth method). Swabs may be stored at 2–8 °C for up to 36 hours in Sample Buffer Tubes before culturing, following hospital procedures.

LIMITATIONS OF THE PROCEDURE

- This product is intended for use with nasal swab specimens collected using specimen collection and transport devices listed in the Equipment and Materials Required But Not Provided section.
- This product can only be used on the BD MAX System by trained laboratory personnel.
- Erroneous test results may occur from improper specimen collection, handling or storage, technical error, sample mix-up or because the number of organisms in the specimen is below the analytical sensitivity of the test.
- Screening determines the colonization status at a given time. Colonization may vary depending upon patient treatment (e.g., decolonization regime), patient status (e.g., transient MRSA colonization) or exposure to high-risk environments (e.g., contact with MRSA carrier and/or prolonged hospitalization). Colonization status should be monitored according to institutional policies.
- A BD MAX MRSA positive result does not necessarily indicate eradication treatment failure since DNA presence may persist. A negative result following a previously positive test result may indicate eradication treatment success or may occur due to intermittent colonization.
- A positive test result does not necessarily indicate the presence of viable organisms. A positive result is indicative of the presence of MRSA DNA. The BD MAX MRSA assay simultaneously detects the SCC*mec* cassette (carrying the *mecA* gene) and a *Staphylococcus aureus* specific sequence located within the *orfX* gene.
- Twenty (20) MREJ genotypes (MREJ genotypes i to xx) have been described in the literature based on sequence analyses of the SCC*mec/orfX* junction of different clinical isolates of MRSA. The MREJ genotype does not correlate with the SCC*mec* type, i.e., different MREJ genotypes can be associated with each of the known SCC*mec* types. The BD MAX MRSA assay is designed to detect MREJ genotypes i, ii, iii, iv, v, and vii only; these six (6) MREJ genotypes account for more than 98% of worldwide strains tested by BD to date. The BD MAX MRSA assay may not detect other MREJ genotypes, resulting in false negative results.
- Methicillin-resistant *Staphylococcus aureus* strains that carry the $mecA_{LGA251}$ gene mutation, a novel *mecA* variant, may not be detected by the BD MAX MRSA assay, resulting in false negative results.
- The BD MAX MRSA assay does not detect the *mecA* gene directly nor the penicillin-binding protein (PBP2a) encoded by this gene. A false positive MRSA result may occur if an "empty cassette" *Staphylococcus aureus* variant is present.
- The BD MAX MRSA assay does not detect Borderline Oxacillin Resistant *Staphylococcus aureus* (BORSA). The mechanism of oxacillin resistance in BORSA strains is due to an increased production of β-lactamases, not the *mecA* gene. BORSA strains are rare in the United States.
- The BD MAX MRSA 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, not the *mecA* gene. MOD-SA strains are rare in the United States.
- Out of 213 non-target organisms tested during the Analytical Specificity study, 5 strains initially gave a false positive result, but were later proven to be due to contamination. Upon repeat, all 5 strains generated the expected negative results.
- 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.
- Tobramycin at high concentration may cause slight inhibition in the BD MAX MRSA assay (refer to the Interfering Substances section for further details).
- 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.
- BD MAX MRSA 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 in obtaining final results.
- 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 MRSA assay.
- As with all *in vitro* diagnostic tests, positive and negative predictive values are highly dependent on prevalence. BD MAX MRSA assay performance may vary depending on the prevalence and population tested.

- The BD MAX MRSA assay requires use of only two optical channels from the BD MAX System; Green (475–520 nm) and Orange (585–630 nm) for detection of the FAM and ROX fluorophores, respectively. Performance of the remaining optical channels has not been established with this assay.

EXPECTED VALUES

In the BD MAX MRSA assay clinical study a total of 1,903 specimens were tested from 4 geographically diverse U.S. clinical sites, using Direct/Enriched culture. The study population was grouped into in-patient and out-patient categories. The number and percentage of positive cases as determined by the reference method are presented in the table below:

Table 2: Compliant Clinical Trial Enrollment Summary by Patient Group

		MRSA By Direct/Enriched Culture		
Group	**Total N**	**Number Positive**	**Number Negative**	**Prevalence[a]**
In-Patient	1,473	133	1,340	9.0% (133/1,473)
Out-Patient	430	26	404	6.0% (26/430)
Total	1,903[b]	159	1,744	8.4% (159/1,903)

[a]Prevalence calculated using reference method only.

[b]Total specimens based on compliant reference method results.

PERFORMANCE CHARACTERISTICS

Clinical Performance

Clinical performance characteristics of the BD MAX MRSA assay were determined in a multi-site prospective investigational study. Four (4) investigational centers participated in the study. To be enrolled in the study, patients had to be eligible for MRSA testing according to institutional policies. Eligibility requirements for targeted screening as per clinical site policies included, but were not limited to: patients admitted into the particular healthcare system; patients admitted to the Intensive Care Unit; patients transferred to the Intensive Care Unit; pre-elective surgery patients; and patients being admitted from long term care facilities. Specimens from patients previously enrolled in the study were excluded.

The Comparative Reference Method consisted of direct culture complemented by enriched culture. Enriched culture analysis was completed for all specimens that were negative for MRSA by direct culture. Presumptive *Staphylococcus aureus* colonies observed on selective (*Staphylococcus aureus*) chromogenic media were subcultured onto Blood Agar (BA). Identification was confirmed with an agglutination test, while Methicillin-resistance was confirmed by Cefoxitin disk (30 µg) diffusion susceptibility testing. Enrichment in BD Trypticase™ Soy Broth with 6.5% NaCl (TSB 6.5% NaCl) was completed in the event that Methicillin-resistant *Staphylococcus aureus* was not confirmed by the initial direct culture method. Turbid TSB 6.5% NaCl broth was used to inoculate additional chromogenic media and BA plates; MRSA confirmation was performed as described above.

There were 1,881 reportable results (refer to Tables 3 and 5); 106 nasal swab specimens were excluded from performance analysis due to non-compliance with the clinical study protocol. In comparison to the Reference Method (Direct/Enriched Culture), the BD MAX MRSA assay identified 93.0% of the MRSA positive specimens and 95.9% of the MRSA negative specimens (refer to Table 4). For the population tested, this resulted in a Negative Predictive Value (NPV) of 99.3% and a Positive Predictive Value (PPV) of 67.3%.

Table 3: Results Obtained with the BD MAX MRSA Assay in Comparison to the Reference Method

All Sites		**Reference Method**		
		+	-	**Total**
BD MAX MRSA assay	+	146	71	217
	-	11	1,653	1,664
	Total	157	1,724	1,881[a]

[a]The total number of specimens that were reference and PCR method compliant

Table 4: Performance Obtained using the BD MAX MRSA Assay in Comparison to the Reference Method

Clinical Sites	**Prevalence[a]**	**Sensitivity with 95% CI[b]**	**Specificity with 95% CI[b]**
Site 1	5.6% (28/496)	100% (28/28) (87.9%, 100%)	95.8% (435/454) (93.6%, 97.3%)
Site 2	4.6% (23/505)	91.3% (21/23) (73.2%, 97.6%)	96.5% (465/482) (94.4%, 97.8%)
Site 3	13.2% (55/417)	90.9% (50/55) (80.4%, 96.1%)	95.8% (346/361) (93.3%, 97.5%)
Site 4	10.9% (53/485)	92.2% (47/51) (81.5%, 96.9%)	95.3% (407/427) (92.9%, 96.9%)
Overall[c]	8.4% (159/1,903)	93.0% (146/157) (87.9%, 96.0%)	95.9% (1,653/1,724) (94.8%, 96.7%)

[a]Prevalence based on reference method only.

[b]CI: Confidence Intervals

[c]1,903 specimens were reference method compliant.

In comparison to the direct culture, the BD MAX MRSA assay identified 95.0% of the MRSA positive specimens and 95.2% of the MRSA negative specimens (refer to Table 6).

Table 5: Results Obtained with the BD MAX MRSA Assay in Comparison to Direct Culture

All Sites		Direct culture		
		+	-	Total
BD MAX MRSA Assay	+	133	84	217
	-	7	1,657	1,664
	Total	140	1,741	1,881

Table 6: Performance Obtained using the BD MAX MRSA Assay in Comparison to Direct Culture

Clinical Sites	Positive Agreement with 95% CI[a]	Negative Agreement with 95% CI[a]
Site 1	100% (22/22) (85.1%, 100%)	94.6% (435/460) (92.1%, 96.3%)
Site 2	95.5% (21/22) (78.2%, 99.2%)	96.5% (466/483) (94.4%, 97.8%)
Site 3	94.1% (48/51) (84.1%, 98.0%)	95.3% (348/365) (92.7%, 97.1%)
Site 4	93.3% (42/45) (82.1%, 97.7%)	94.2% (408/433) (91.6%, 96.1%)
Overall	95.0% (133/140) (90.0%, 97.6%)	95.2% (1,657/1,741) (94.1%, 96.1%)

[a]CI: Confidence Intervals

Out of 1,884 compliant nasal swab specimens tested with the BD MAX MRSA assay, 10 (0.5%) were reported as Unresolved after initial testing (refer to Table 7). The Unresolved Rate after repeat testing is based upon 1,882 specimen results (2 specimens with initial Unresolved results were not retested). All specimens had reportable results after repeat testing.

Table 7: Unresolved Rates

Clinical Sites	Initial Unresolved Rates with 95% CI[a]		Unresolved Rates After Repeat with 95% CI[a]	
Site 1	0.8% (4/484)	(0.3%, 2.1%)	0.0% (0/483)	(0.0%, 0.8%)
Site 2	0.0% (0/505)	(0.0%, 0.8%)	0.0% (0/505)	(0.0%, 0.8%)
Site 3	0.2% (1/416)	(0.0%, 1.3%)	0.0% (0/416)	(0.0%, 0.9%)
Site 4	1.0% (5/479)	(0.4%, 2.4%)	0.0% (0/478)	(0.0%, 0.8%)
Overall	0.5% (10/1,884)[b]	(0.3%, 1.0%)	0.0% (0/1,882)	(0.0%, 0.2%)

[a]CI: Confidence Intervals

[b]1,884 specimens were PCR method compliant.

Out of 1,913 nasal swab specimens tested with the BD MAX MRSA assay, 24 (1.3%) were reported as Indeterminate after initial testing; after repeat testing 2 (0.1%) remained Indeterminate. Seventy-three (3.8%) specimens were reported as Incomplete after initial testing; after repeat testing no (0.0%) specimens were reported as Incomplete.

Analytical Sensitivity

The analytical sensitivity (Limit of Detection or LoD) for the BD MAX MRSA assay was determined as follows: simulated positive specimens were prepared by soaking swabs in a wide range of MRSA bacterial suspensions prepared and quantified from cultures of 6 MRSA strains representing 6 MREJ genotypes (i, ii, iii, iv, v, and vii) and 4 SCC*mec* types (I, II, III, IV). The swabs were then eluted in pooled negative clinical nasal matrix. Each MRSA strain was tested in replicates of 24 per concentration by 2 different operators using 3 different production lots of the BD MAX MRSA assay. Analytical sensitivity (LoD), defined as the lowest concentration at which 95% of all replicates tested positive, ranged from 273 to 645 CFU/swab (refer to Table 8).

Table 8: Limit of Detection of the BD MAX MRSA Assay

MRSA Strain	MREJ Genotype	SCCmec Type	LoD Concentration [CFU/swab (95% CI[a])]
1	type i	I	645 (314, 1,326)
2	type ii	II	400 (237, 678)
3	type iii	III	346 (197, 608)
4	type iv	III	490 (264, 908)
5	type v	IV	273 (148, 504)
6	type vii	II	357 (215, 594)

[a]CI: Confidence Intervals

Analytical Inclusivity

An analytical inclusivity study was performed using a variety of Methicillin resistant *Staphylococcus aureus* strains, taking into account geographic origin, MREJ genotype, SCCmec type, pulse field gel electrophoresis (PFGE) type, temporal diversity and susceptibility pattern. Seventy-seven (77) strains from 30 countries were tested in this study, including strains from public collections and from well-characterized clinical isolates, including Vancomycin-resistant *Staphylococcus aureus* (VRSA) and Vancomycin- intermediate *Staphylococcus aureus* (VISA) strains.

The BD MAX MRSA assay detected all of the MREJ types i, ii, iii, iv, v, and vii (wild and mutant) when tested at low bacterial load (2–3x LoD). The BD MAX MRSA assay detected MRSA SCC*mec* types I, II, III, IV, V and VI, VII and VIII, as well as MRSA PFGE types USA 100 to 800, 1000 and 1100 at 2–3x LoD. All Methicillin resistant *Staphylococcus aureus* strains displaying additional resistance to vancomycin (VRSA and VISA) were also detected.

Evaluation of a Well Characterized Challenge Strain Panel

An additional analytical study was carried out to evaluate the analytical performance of the BD MAX MRSA assay using a well characterized challenge strain panel containing the following:

- MRSA strains with high and low Oxacillin minimum inhibitory concentrations (MICs), including PFGE types USA 100, 300, and 400
- BORSA strains (borderline Oxacillin-resistant *Staphylococcus aureus* strains)
- Methicillin-sensitive *Staphylococcus aureus* (MSSA) strains
- Methicillin-resistant *Staphylococcus epidermidis* (MRSE) strains

The challenge panel used in this study was composed of 17 MRSA, 4 BORSA, 1 MRSE and 5 MSSA strains. All the MRSA strains tested (including PFGE types USA 100, 300 and 400) exhibited positive results when tested at low bacterial load (2–3x LoD). All BORSA, MSSA and MRSE strains tested exhibited negative results when tested at high bacterial loads.

Analytical Specificity

The BD MAX MRSA assay was performed on samples containing high levels of non-target organisms, using the BD MAX System, to demonstrate the specificity of the assay for detection of MRSA.

- Fifty-seven (57) out of 57 strains of various non-staphylococcal species tested at a concentration of at least 10^6 CFU/mL produced negative results with the BD MAX MRSA assay.
- Forty-five (45) Coagulase-Negative staphylococcal strains (CoNS) and Coagulase-Positive staphylococcal strains representing 29 species were tested at a concentration of 0.5 McFarland with the BD MAX MRSA assay. Forty-five (45) of the 45 strains tested exhibited negative results with the BD MAX MRSA assay.
- One hundred-eleven (111) out of 111 MSSA strains tested at extremely high concentrations (>10^6 CFU/swab), produced negative results with the BD MAX MRSA assay.
- Seventeen (17) viruses representing 12 different viral species were tested at ≥10^5 PFU/mL. All 17 viruses produced negative results with the BD MAX MRSA assay.

Interfering Substances

Twenty (20) biological and chemical substances occasionally used in the nares or found in nasal swab specimens were evaluated for potential interference with the BD MAX MRSA assay (refer to Table 9). MRSA negative specimens and MRSA positive specimens at 2–3x LoD were tested with the highest amount of each compound likely to be found at the sampling site or on the nasal swab specimens. Results demonstrated no reportable interference with any substance except for Tobramycin that showed slight inhibition in the BD MAX MRSA assay, however, expected assay results were still obtained.

Table 9: Endogenous and Commercial Exogenous Substances Tested with the BD MAX MRSA Assay

Substance	Result[a]	Substance	Result[a]
Mucin, from bovine submaxillary glands	NI	Rhinocort aqua	NI
Dexamethasone Sodium Phosphate Ophtalmic Solution USP, 0.1% Dexamethasone Phosphate Equivalent	NI	Nasonex	NI
Chloraseptic	NI	Fluticasone Propionate	NI
Taro-Mupirocin, Mupirocin Ointment USP, 2%	NI	Luffeel	NI
Long Lasting Dristan Nasal Mist	NI	Zicam No-Drip Liquid Nasal Gel Extreme Congestion Relief	NI
Neo-Synephrine	NI	Relenza	NI
Otrivin Complete Nasal Care	NI	Tobramycin	[b]
Beconase AQ	NI	Blood	NI
Flunisolide Nasal Solution USP, 0.025%	NI	MSSA (ATCC 29213)	NI
Nasacort AQ	NI	CNS (ATCC 35983)	NI

[a]NI: No reportable interference with the BD MAX MRSA assay.

[b]Tobramycin showed slight inhibition (delay of Second Derivative Peak Abscissa) in the BD MAX MRSA assay, however, expected assay results were still obtained.

Precision

Within-laboratory precision was evaluated for the BD MAX MRSA assay at one (1) site. The Precision panel consisted of 4 sample categories near the LoD. Each sample contained simulated nasal flora [*Staphylococcus epidermidis* (ATCC 14990)]. Two MRSA strains were tested in each of the following 4 categories:

- Moderate Positive (MP): 2–5x LoD
- Low Positive (LP): 1–2x LoD
- High Negative 1:10 (HN1:10): 10-fold dilution of 1x LoD
- High Negative 1:100 (HN1:100): 100-fold dilution of 1x LoD

A fifth category consisted of negative (Neg) samples (simulated nasal flora and no MRSA).

Testing was performed in duplicate, over 12 days, with 2 runs per day, by 2 technologists. Precision study results for Neg, LP, and MP samples demonstrated 98.6%, 100%, and 100% agreement, respectively. Precision study results for HN1:100 and HN1:10 demonstrated agreement of 80.6% and 37.5%, respectively.

Reproducibility

The reproducibility study was performed using the same sample categories as defined above for the Precision Study.

Samples in each category were tested in triplicate, on 5 distinct days, wherein each day 2 panels were tested by 2 technologists, at 3 clinical sites using 1 lot of reagents (Site-to-Site). One (1) of these clinical sites participated in an extended study where 2 additional lots of reagents were tested (Lot-to-Lot). Results are shown for each sample category with the data from both MRSA strains pooled.

For Site-to-Site Reproducibility, the overall percent agreement was 100% for MP, LP, and Neg categories, 82.2% and 31.1% negative agreement for HN1:100 and HN1:10 categories, respectively (refer to Table 10).

For Lot-to-Lot Reproducibility, the overall percent agreement was 100% for MP, LP, and Neg categories, 83.3% and 34.4% negative agreement for HN1:100 and HN1:10 categories, respectively (refer to Table 11).

Second Derivative Peak Abscissa (SDPA), an internal criteria used to determine a final assay result, was selected as an additional means of assessing assay reproducibility. Overall mean SDPA values with variance components (SD and %CV) are shown in Tables 10 and 11.

Table 10: Site-To-Site Reproducibility Study Results using One Lot of the BD MAX MRSA Assay

Category	SITE						Overall Percent Agreement		SDPA Values[a]		
	Site 1		Site 2		Site 3						
	Percent Agreement		Percent Agreement		Percent Agreement				Overall Mean	SD	%CV
Neg	30/30	100%	30/30	100%	30/30	100%	100%	(95.9%, 100%)	31.8	0.47	1.5
HN1:100[b]	22/30	73.3%	27/30	90.0%	25/30	83.3%	82.2%	(73.1%, 88.8%)	32.1	0.85	2.7
HN1:10[b]	12/30	40.0%	3/30	10.0%	13/30	43.3%	31.1%	(22.5%, 41.3%)	31.8	0.45	1.4
LP	60/60	100%	60/60	100%	60/60	100%	100%	(97.9%, 100%)	31.7	0.66	2.1
MP	30/30	100%	30/30	100%	30/30	100%	100%	(95.9%, 100%)	30.4	0.73	2.4

[a]For the Neg category, SDPA values reported are for the Sample Processing Control. For other categories, SDPA values reported are for the MRSA target.

[b]For the High Negative categories, the expected assay result was deemed to be negative. Therefore, percent agreement was calculated for negative results.

Table 11: Lot-To-Lot Reproducibility Study Results using Three Lots of the BD MAX MRSA Assay

Category	LOT						Overall Percent Agreement		SDPA Values[a]		
	Lot 1		Lot 2		Lot 3						
	Percent Agreement		Percent Agreement		Percent Agreement				Overall Mean	SD	%CV
Neg	30/30	100%	30/30	100%	30/30	100%	100%	(95.9%, 100%)	31.2	0.75	2.4
HN1:100[b]	26/30	86.7%	24/30	80.0%	25/30	83.3%	83.3%	(74.3%, 89.6%)	31.4	0.79	2.5
HN1:10[b]	6/30	20.0%	12/30	40.0%	13/30	43.3%	34.4%	(25.4%, 44.7%)	31.6	0.71	2.2
LP	60/60	100%	60/60	100%	60/60	100%	100%	(97.9%, 100%)	31.6	0.73	2.3
MP	30/30	100%	30/30	100%	30/30	100%	100%	(95.9%, 100%)	30.5	0.66	2.2

[a]For the Neg category, SDPA values reported are for the Sample Processing Control. For other categories, SDPA values reported are for the MRSA target.

[b]For the High Negative categories, the expected assay result was deemed to be negative. Therefore, percent agreement was calculated for negative results.

Carryover / Cross-Contamination

A study was conducted to investigate within-run carryover and between-run carryover while processing specimens with high MRSA bacterial load in the BD MAX MRSA assay. A panel made of one high positive member and one negative member was used to prepare numerous samples. An MREJ type v MRSA strain was used for the high positive MRSA panel member (8×10^7 CFU/swab). The negative member did not contain any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were tested by alternating negative and positive samples. Three (3) operators performed 3 consecutive runs for a total of 9 runs of 24 samples. There were no false positive results due to carry-over contamination.

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Change History

Revision	Date	Change Summary
(08)	2020-05	Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling. Changed nomenclature of *Clostridium* to *Clostridioides*. Added detail to Reagents and Materials section. Updated Instructions for Use. Updated Figures 1, 2, and 3. Corrected any reference to System Error Summary section to Troubleshooting section. Clarified Limitations of the Procedure section. Updated Australia and New Zealand Sponsor addresses. Made typographical edits.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary

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YYYY-MM-DD / YYYY-MM (MM = end of month)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned)
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
EEEE-MM-HH / EEEE-MM (ΜΜ = τέλος του μήνα)
AAAA-MM-DD / AAAA-MM (MM = fin del mes)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
YYYY-MM-DD/YYYY-MM(MM = 월말)
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet av månaden)
YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
PPPP-MM-ДД / PPPP-MM (ММ = кінець місяця)
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Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Kataloognumber / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Каталог нөмірі / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalógové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号

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IVD

In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisas / Medicīnas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicínska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / İn Vitro Diyagnostik Tıbbi Cihaz / Медичний пристрій для діагностики in vitro / 体外诊断医疗设备

Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу /온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperatuurlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制

LOT

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号（亚批）

Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Küllaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттері үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor “n” testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conţinut suficient pentru <n> teste / Достаточно для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测

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Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Límite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі руқсат шеті / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža /Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite mínimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

CONTROL

Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolė / Kontrole / Controle / Controlo / Контроль / kontroll / Контроль / 对照

CONTROL +

Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controlo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂

CONTROL –

Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negatív kontroll / Controllo negativo / Неративтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE EO

Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдісі – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

STERILE R

Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация әдісі – сәуле түсіру / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилізації: опроміненням / 灭菌方法：辐射

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiailag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Bioloģiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险

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Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Límite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы шеті / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górna granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Övre temperaturgräns / Sıcaklık üst sınırı / Максимальна температура / 温度上限

Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevares tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávajte v suchu / Držite na suvom mestu / Förvaras torrt / Kuru bir şekilde muhafaza edin / Берегти від вологи / 请保持干燥

Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeuhrzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забору / 采集时间

Peel / Обелете / Otevřete zde / Åbn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ұстіңгі қабатын алып таста / 벗기기 / Plėšti čia / Atīrmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeşte / Отклеить / Odtrhnite / Oljuštiti / Dra isär / Ayırma / Відклеїти / 撕下

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Keep away from heat / Пазете от топлина / Nevystavujte přílišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Салқын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávajte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isıdan uzak tutun / Берегти від дії тепла / 请远离热源

Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Кесіңіз / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupaţi / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下

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µL/test / µL/тест / µL/Test / µL/εξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/аналіз / µL/检测

Keep away from light / Пазете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriţi de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Берегти від дії світла / 请远离光线

Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrži hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтектес сутеги пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobađa se vodonik / Genererad vätgas / Açığa çıkan hidrojen gazı / Реакція з виділенням водню / 会产生氢气

Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттің идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Ідентифікатор пацієнта / 患者标识号

Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραυστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Õrn, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkités atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulaţi cu atenţie. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

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