K132822

510(k) Summary

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BD Diagnostics BD MAX™ StaphSR

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Device:

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510(k) Number: K132822

Trade Name: BD MAX™ StaphSR

Common Name: *Staphylococcus aureus* and Methicillin-resistant *Staphylococcus aureus* detection assay

Type of Test: *Staphylococcus aureus* and Methicillin-resistant *Staphylococcus aureus* Qualitative Nucleic Acid Amplification Test from nasal swab specimens

Classification: II

Regulation Name: Antimicrobial susceptibility test powder

Regulation Number: 866.1640

Product Code: NQX, OOI

Panel: Microbiology (83)

Predicate Devices: BD MAX™ MRSA and BD GeneOhm™ StaphSR Assay

Predicate 510(k) Numbers: K120138 and K071026

Intended Use:

The BD MAX™ StaphSR assay performed on the BD MAX™ System is an automated qualitative *in vitro* diagnostic test for the direct detection and differentiation of *Staphylococcus aureus* (SA) and 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/SA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified 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 to recover organisms for epidemiological typing or for further susceptibility testing.

Indication for Use:

The BD MAX™ StaphSR assay performed on the BD MAX™ System is an automated qualitative *in vitro* diagnostic test for the direct detection and differentiation of *Staphylococcus aureus* (SA) and 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/SA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified 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 to recover organisms for epidemiological typing or for further susceptibility testing.

Special Conditions for Use Statement: For prescription use

Special Instrument Requirements: The BD MAX™ System

Device Description:

The BD MAX™ System and the BD MAX™ StaphSR assay are comprised of an instrument with associated hardware and accessories, disposable microfluidic cartridges, master mixes, unitized reagent strips, extraction reagents, and sample buffer tubes. The instrument automates sample preparation including target lysis, DNA extraction and concentration, reagent rehydration, and target nucleic acid amplification and detection using real-time PCR. The assay includes a Sample Processing Control (SPC) that is present in the Extraction Tube. The SPC monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances. The BD MAX™ System software automatically interprets test results. A test result may be called as [SA NEG, MRSA NEG (negative)], [SA POS, MRSA POS (MRSA positive)], [SA POS, MRSA NEG (SA positive)] or [SA UNR, MRSA 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.

Test Principle:

The BD MAX™ StaphSR assay performed on the BD MAX™ System is an automated *in vitro* diagnostic test for the direct, qualitative detection and differentiation of the *Staphylococcus aureus (SA)* and methicillin-resistant *Staphylococcus aureus* (MRSA) DNA from nasal swabs in patients at risk for nasal colonization.

A nasal specimen is collected and transported to the laboratory using the recommended swab. The swab is placed in a BD MAX™ StaphSR Sample Buffer Tube. The Sample

Buffer Tube is closed with a septum cap and vortexed. A worklist is created and the Sample Buffer Tube, the BD MAX™ StaphSR unitized reagent strip and the BD MAX™ PCR Cartridge are loaded onto the BD MAX™ System.

Following enzymatic cell lysis, the released nucleic acids are captured on magnetic beads. The beads, with the bound nucleic acids, are washed using Wash Buffer and the nucleic acids are eluted by heat in Elution Buffer. Eluted DNA is neutralized using Neutralization Buffer and transferred to a Master Mix to rehydrate PCR reagents. After reconstitution, the BD MAX™ System dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the BD MAX™ PCR Cartridge. Microvalves in the BD MAX™ PCR Cartridge are sealed by the system prior to initiating PCR to contain the amplification mixture, thus preventing evaporation and 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 a specific amplicon in the *SCCmec* right-extremity junction (MREJ), the genes for methicillin resistance *mecA* and *mecC*, the *nuc* gene encoding a thermostable nuclease of *S. aureus* and SPC amplicons in four different optical channels of the BD MAX™ System: MREJ amplicons are detected in the FAM channel, *mecA* and *mecC* amplicons are detected in the ROX channel, *nuc* amplicons are detected in the VIC channel and SPC amplicons are detected in the Cy5.5 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 four optical channels used for the BD MAX™ StaphSR 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.

Substantial Equivalence:

Table 1 shows the similarities and differences between the BD MAX™ StaphSR assay and the predicate devices.

Table 1: Substantial Equivalence Information

ITEM	DEVICE	PREDICATE	
	BD MAX™ StaphSR (K132822)	**BD GeneOhm StaphSR Assay (K071026)**	**BD MAX MRSA Assay (K120138)**
Intended Use	The BD MAX™ StaphSR assay performed on the BD MAX™ System is an automated qualitative *in vitro* diagnostic test for the direct detection and differentiation of *Staphylococcus aureus* (SA) and 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/SA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified 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 to recover organisms for epidemiological typing or for further susceptibility testing.	The BD GeneOhm™ StaphSR Assay is a qualitative *in vitro* diagnostic test for the rapid detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) directly from positive blood culture. The assay utilizes polymerase chain reaction (PCR) for the amplification of specific targets and fluorogenic target-specific hybridization probes for the real-time detection of the amplified DNA. The assay is performed on Gram positive cocci, identified by Gram stain, from positive blood cultures. The BD GeneOhm™ StaphSR Assay is not intended to monitor treatment for MRSA/SA infections. Subculturing of positive blood cultures is necessary for further susceptibility testing.	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.
Specimen type	Nasal swabs	Positive blood culture	Nasal swabs
Assay Format	Amplification: PCR Detection: Fluorogenic target-specific hybridization	Same	Same
Mode of Detection for Methicillin Resistance in *S.aureus*	Presence of SCC*mec* cassette at *orfX* junction and *mecA* or *mecC* genes	Presence of SCC*mec* cassette at *orfX* junction (specific to *S. aureus*)	Presence of SCC*mec* cassette at *orfX* junction (specific to *S. aureus*)
Mode of Detection for SA	Presence of *nuc* gene specific for SA	Same	Not detected
Interpretation of Test Results	Automated (Diagnostic software of BD MAX™ System)	Automated (Diagnostic software of SmartCycler® System)	Automated (Diagnostic software of BD MAX™ System)
Analysis Platform	BD MAX™ System	SmartCycler® System	BD MAX™ System
PCR Sample Preparation	Automated by the BD MAX™ System	Manual	Automated by the BD MAX™ System
Detection Probes	TaqMan® Probe	Molecular Beacon Probe	TaqMan® Probe

ITEM	DEVICE	PREDICATE	
	BD MAX™ StaphSR (K132822)	**BD GeneOhm StaphSR Assay (K071026)**	**BD MAX MRSA Assay (K120138)**
Assay Controls	Specimen Processing Control (SPC)	Positive PCR control (DNA from *S.aureus* ATCC 43300). Negative control (DNA from *S.epidermidis* ATCC 14990). Internal Control	Specimen Processing Control (SPC)

Analytical Performance:

Precision
Within-laboratory precision was evaluated for the BD MAX™ StaphSR assay at one (1) site. The Precision panel consisted of 4 sample categories near the LoD. Each specimen contained simulated nasal matrix. MRSA and MSSA strains were tested as follows:

- Moderate Positive (MP) MRSA (MREJ Type ii): ≥ 2 and ≤ 5 x LoD
- Low Positive (LP) MRSA (MREJ Type ii): ≥ 1 and < 2 x LoD
- Low Positive (LP) MRSA (MREJ Type vii): ≥ 1 and < 2 x LoD
- Low Positive (LP) MSSA: ≥ 1 and < 2 x LoD
- High Negative (HN) MRSA (MREJ Type ii): < 1 x LoD
- High Negative (HN) MSSA: < 1 x LoD
- True negative (TN): Negative specimens (no target)

Testing was performed in duplicate, over 12 days, with 2 runs per day, by 2 different technologists. Precision study results for TN, MP, LP, and HN MRSA samples demonstrated 100%, 100%, 97.9%, and 27.1% agreement, respectively. Precision study results for LP and HN MSSA samples demonstrated 100%, and 56.2% agreement, 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 different 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 and MSSA strains.

For Site-to-Site Reproducibility, the overall percent agreement was 100% for MRSA MP and TN categories; 96.7% and 97.8% for MRSA LP and MSSA LP, respectively; and 36.7% and 30.0% for MRSA HN and MSSA HN, respectively (Table 2).

Table 2. Site-To-Site Reproducibility Study Results Using One Lot of the BD MAX™ StaphSR Assay

Category	SITE						Overall Percent Agreement	
	Site 1		Site 2		Site 3			
	Percent Agreement	Count	Percent Agreement	Count	Percent Agreement	Count		
HN[1] MSSA	16.7%	5/30	23.3%	7/30	50.0%	15/30	30.0%	(21.5%, 40.1%)[2]
HN MRSA	40.0%	12/30	26.7%	8/30	43.3%	13/30	36.7%	(27.4%, 47.0%)
LP MSSA	96.7%	29/30	100.0%	30/30	96.7%	29/30	97.8%	(92.3%, 99.4%)
LP MRSA	95.0%	57/60	98.3%	59/60	96.7%	58/60	96.7%	(92.9%, 98.5%)
MP MRSA	100.0%	30/30	100.0%	30/30	100.0%	30/30	100.0%	(95.9%, 100.0%)
TN	100.0%	30/30	100.0%	30/30	100.0%	30/30	100.0%	(95.9%, 100.0%)

[1]Percent Agreement correlates to the percent of negative results.
[2]Confidence Interval

For Lot-to-Lot Reproducibility, the overall percent agreement was 100% for MRSA MP and TN; 96.7% for MRSA LP and MSSA LP; 40.0% and 44.4% for MRSA HN and MSSA HN, respectively (Table 3).

Table 3. Lot-To-Lot Reproducibility Study Results using Three Lots of the BD MAX™ StaphSR Assay

Category	LOT						Overall Percent Agreement	
	Lot 1		Lot 2		Lot 3			
	Percent Agreement	Count	Percent Agreement	Count	Percent Agreement	Count		
HN[1] MSSA	50.0%	15/30	36.7%	11/30	46.7%	14/30	44.4%	(34.6%, 54.7%)[2]
HN MRSA	43.3%	13/30	43.3%	13/30	33.3%	10/30	40.0%	(30.5%, 50.3%)
LP MSSA	96.7%	29/30	93.3%	28/30	100.0%	30/30	96.7%	(90.7%, 98.9%)
LP MRSA	96.7%	58/60	96.7%	58/60	96.7%	58/60	96.7%	(92.9%, 98.5%)
MP MRSA	100.0%	30/30	100.0%	30/30	100.0%	30/30	100.0%	(95.9%, 100.0%)
TN	100.0%	30/30	100.0%	30/30	100.0%	30/30	100.0%	(95.9%, 100.0%)

[1]Percent Agreement correlates to the percent of negative results.
[2]Confidence Interval

Site-to-Site and Lot-to-Lot Reproducibility performance was acceptable for the LP, MP, and TN sample categories. No specific acceptance criteria was defined for the high negative sample category.

Second Derivative Peak Abscissa (SDPA), an underlying numerical value 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 Table 4.

Table 4. Site-to-Site and Lot-to-Lot Reproducibility Study Underlying Numerical SDPA Overall Results

		Site-to-Site			Lot-to-Lot		
		HN MRSA	**LP MRSA**	**MP MRSA**	**HN MRSA**	**LP MRSA**	**MP MRSA**
MREJ[1] (MREJ types pooled, FAM Channel)	N	33	174	90	35	174	90
	Mean	33.5	31.1	30.7	33.4	31.0	30.8
	SD	0.72	1.05	0.71	0.72	0.94	0.37
	%CV	2.2%	3.4%	2.3%	2.2%	3.0%	1.2%
mecA or *mecC*[2] (MREJ types pooled, ROX Channel)	N	33	174	90	35	174	90
	Mean	35.1	31.8	31.1	35.0	31.7	31.1
	SD	1.16	1.42	0.78	1.15	1.36	0.54
	%CV	3.3%	4.5%	2.5%	3.3%	4.3%	1.7%
		HN MREJ Type ii	**HN MSSA**	**LP MSSA**	**HN MREJ Type ii**	**HN MSSA**	**LP MSSA**
nuc[3] (VIC Channel)	N	24	63	88	19	50	87
	Mean	34.9	34.8	32.0	35.2	34.8	32.0
	SD	1.78	1.69	1.12	1.85	1.57	0.78
	%CV	5.1%	4.9%	3.5%	5.2%	4.5%	2.4%
		HN MREJ Type ii	**HN MSSA**	**TN**	**HN MREJ Type ii**	**HN MSSA**	**TN**
SPC[4] (Cy5.5 Channel)	N	33	27	90	36	40	90
	Mean	30.0	30.3	30.2	29.9	30.0	30.0
	SD	0.79	0.68	0.63	0.49	0.43	0.45
	%CV	2.6%	2.2%	2.1%	1.7%	1.4%	1.5%

[1]Values shown are those obtained for the MREJ target in the samples that gave a SA POS, MRSA POS result
[2]Values shown are those obtained for the *mec*A or *mec*C target in the samples that gave a SA POS, MRSA POS result
[3]Values shown are those obtained for the *nuc* target in the samples that gave a SA POS, MRSA NEG result
[4]Calculated for the Specimen Processing Control of the samples that gave a SA NEG, MRSA NEG result

Sample Storage

Specimens can be stored at25 ±2°C for a maximum of 48 hours or at 2-8 °C for a maximum of 120 hours (5 days) before testing. In case of repeat testing from the Sample Buffer Tube, the following storage conditions apply:

- within 36 hours of the steps covered in the Specimen Preparation section of the package insert, when stored at 25 ±2°C or
- up to 120h (5 days) after the end of the initial run when stored at 2-8°C.

Controls

External Control materials are not provided by BD. Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program:

– Commercially available control materials [*e.g.* a reference MRSA strain (ATCC 43300), and Methicillin-susceptible *Staphylococcus aureus* strain (*e.g.* ATCC 29213) can be used as positive controls. *Staphylococcus epidermidis* strain (*e.g.* ATCC 12228) can be used as negative control.].

- Previously characterized specimens known to be positive or negative for *S. aureus* or MRSA.

The assay includes a Sample Processing Control (SPC) that is present in the Extraction Tube. The SPC monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances.

Analytical Sensitivity

The analytical sensitivity (Limit of Detection or LoD) for the BD MAX™ StaphSR assay was determined as follows: positive specimens were prepared by soaking swabs in a wide range of MRSA or MSSA bacterial suspensions prepared and quantified from cultures. The tested strains included 11 MRSA strains representing 11 MREJ genotypes (i, ii, iii, iv, v, vi, vii, ix, xiii, xiv and xxi) corresponding to 5 SCC*mec* types (I, II, III, IV and XI) as well as 2 MSSA strains. The swabs were then eluted in simulated nasal matrix. Each MRSA and MSSA strain was tested in replicates of 24 per concentration by 2 different operators using 3 different production lots of the BD MAX™ StaphSR assay. Analytical sensitivity (LoD), defined as the lowest concentration at which at least 95% of all replicates tested positive, ranged from 64 to 343 CFU/swab (Table 5) for the detection of MRSA strains and from 174 to 211 CFU/swab (Table 6) for the detection of MSSA strains.

Table 5: Limit of Detection of MRSA Genotypes by the BD MAX™ StaphSR Assay

MRSA Strain	MREJ Genotype	SCC*mec* type[1]	LoD Concentration [CFU/swab (95% CI[2])]
1	Type i	I	84 (49, 142)
2	Type ii	II	103 (64, 167)
3	Type iii	III	160 (93, 278)
4	Type iv	III	68 (42, 109)
5	Type v	IV	128 (73, 225)
6	Type vi	ND[3]	343 (186, 632)
7	Type vii	II	219 (110, 439)
8	Type ix	ND[3]	144 (82, 255)
9	Type xiii	ND[3]	64 (36, 114)
10	Type xiv	ND[3]	78 (48, 127)
11	Type xxi[4]	XI	112 (64, 197)

[1]SCC*mec* type does not correlate to the MREJ type as these are two different typing methods.
[2]CI: Confidence Intervals
[3]ND = not determined
[4]*mecC*-containing MRSA strains (Also known as $mecA_{LGA251}$ strain)

Table 6: Limit of Detection of MSSA by the BD MAX™ StaphSR Assay

MSSA Strain	LoD Concentration [CFU/swab (95% CI[1])]
1	174 (89, 341)
2	211 (105, 428)

[1]CI: Confidence Intervals

Analytical Inclusivity

An analytical inclusivity study was performed using a variety of MRSA and MSSA strains, taking into account geographic origin, MREJ genotype (wild type and mutant), SCC*mec* type, Pulsed-Field Gel Electrophoresis (PFGE) type, temporal diversity and susceptibility pattern. Seventy-seven (77) MRSA strains from 27 countries (see Table 7) and 51 MSSA strains from 16 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™ StaphSR assay detected MREJ types i, ii, iii, iv, v, vi, vii, ix, xiii, xiv and xxi when tested at low bacterial load (2-3 x LoD). The BD MAX™ StaphSR assay detected MRSA SCC*mec* types I, II, III, IV, V, VI, VII, VIII and XI as well as MRSA PFGE types USA 100 to 800, 1000 and 1100 at 2-3 x LoD. All MRSA strains displaying additional resistance to vancomycin (VRSA and VISA) were also detected. The BD MAX™ StaphSR assay detected all 51 MSSA strains tested including *mecA* empty cassette variants.

Table 7: MRSA Strains Tested in the Inclusivity Study of the BD MAX™ StaphSR Assay.

Collection	Reference Number	MREJ Type	SCCmec typing / *PFGE type*
ATCC	ATCC BAA-1770	iii	USA1000
	ATCC BAA-42[1]	ii	VI
	ATCC BAA-38	i	I
	ATCC BAA-41	ii	II
	ATCC BAA-39	iii	III
	ATCC BAA-40	iv	III
	ATCC 43300	ii	II
	ATCC 33592	iv	III
Harmony collection of European epidemic MRSA	62305	ii mut36	IV
	97S99	ii mut45	IV
	3717	iii	III
	9805-01937	iii mut45	ND
LSPQ	ID-61882	iii	III / CMRSA-3
	ID-61880	vii	II / CMRSA-1
NARSA	NRS383	ii	II / USA200
	NRS385	ii	IV / USA500
	NRS715	ii	II/USA600
	NRS386	ii	IV / USA700
	NRS686	i	IV/IBERIAN
	NRS23[4]	ii	II
	VRS5[3]	ii	ND
	NRS1[4]	ii	II
	NRS4[4]	ii	II
	VRS2[3]	ii	ND
	VRS4[1,3]	ii	ND
	NRS382	ii	II / USA100
	NRS384	ii	IV / USA300
	NRS387	ii	IV / USA800
	NRS484	ii	IV / USA1100
	NRS645	ii	IV/IBERIAN
	NRS123	ii mut36	IV / USA400
NA	NA	ii	II / USA 100
	NA	iii	II / USA 100
	5599	ii	II / USA100

Collection	Reference Number	MREJ Type	SCCmec typing / *PFGE type*
	7909	ii	IV / USA300
	7916	ii	IV / USA300
	7917	ii	IV / USA300
	7921	ii	IV / USA300
	7922	ii	IV / USA300
	7913	ii mut36	IV / USA400
	NA	ii	IV / USA 800
	1555[5]	xxi	ND
	MAH 30[5]	xxi	ND
	CCRI-11840	i	VIII
	JCSC6082	iii	VII
	92	xiii	ND
	5109	xiv	ND
	CCRI-12480	ii	ND
	CCRI-12496	ii	ND
	CCRI-12640 [2]	ii	ND
	CCRI-9866 [2]	ii mut36	ND
	48	iii	V
	347101	iii	V
	CCRI-12503	iii	ND
	CCRI-12790	iii	ND
	CCRI-12608	iv	ND
	CCRI-8895	iv	III
	CCRI-1263 (R523)	v	IV
	CCRI-12767	v	ND
	571	vi	ND
	MLST 22 HOS 47.3.270206 MJS	vi	ND
	CCRI-12425 [2]	vii	ND
	CCRI-12763	vii	ND
	CCRI-9583	vii	II
	CCRI-9711	vii	ND
	521	vi	ND
	CCRI-9681	ix	ND
	494	xiii	ND
	ST2011 1100[5]	xxi	ND
	126	xiv	ND
	CCRI-8894	i	I
	MAH 20[5]	xxi	ND
	MAH 1[5]	xxi	ND
	CCRI-1262	iii	III
	CCRI-2025	v	IV
	CCRI-9773	vii	II
	CCRI-9624	ii mut36	ND

[1]The initial result was negative for MRSA. Both samples (ATCC BAA-42 and VRS4) were repeated from the SBT and assay results are conforming (SA+, MRSA+).

[2]These are the results for the repeats as the initial run gave an IND result due to a PCR heater warning.

[3]VRSA strains (http://www.narsa.net/control/member/repositories)

[4]VISA strains (http://www.narsa.net/control/member/repositories)

[5]*mecC* variant strains

Evaluation of a Well Characterized Challenge Strain Panel

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

- Seventeen (17) out of 17 MRSA strains with high and low oxacillin minimum inhibitory concentrations (MICs), including PFGE types USA 100 to 800, 1000, PFGE type IV/IBERIAN and *mecC* variant (*mecA*-containing *S. aureus* strain LGA251) tested at a concentration of 2-3 x LoD, exhibited SA POS, MRSA POS results.
- Four (4) out of 4 BORSA strains (Borderline Oxacillin-Resistant *S. aureus*) tested at $\geq 10^6$ CFU/swab, exhibited SA POS, MRSA NEG results.
- Five (5) out of 5 MSSA strains tested at $\geq 10^6$ CFU/swab, exhibited SA POS, MRSA NEG results
- One (1) out of 1 Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) strains tested at $\geq 10^6$ CFU/swab, exhibited a negative result (SA NEG, MRSA NEG).

Analytical Specificity

The BD MAX™ StaphSR assay was performed on samples containing high levels of non-target organisms and MSSA strains (Table 8), using the BD MAX™ System, to demonstrate the specificity of the assay for detection of MRSA and SA.

- Fifteen (15) out of 15 empty cassette variant MSSA strains tested at $\geq 10^6$ CFU/swab produced SA POS, MRSA NEG results.
- Fifty-seven (57) out of 57 strains of various non-staphylococcal species tested at a concentration of at least $\geq 10^6$ CFU/mL (except for *Cryptococcus neoformans* which was tested at $3x10^5$ CFU/swab) produced negative results (SA NEG, MRSA NEG).
- Forty-five (45) Coagulase-Negative staphylococcal strains (CoNS) and Coagulase-Positive staphylococcal strains (CoPS) representing 28 species were tested at a concentration of 0.5 McFarland with the BD MAX™ StaphSR assay. Forty-five (45) of the 45 strains tested exhibited negative results (SA NEG, MRSA NEG).
- Fifty (50) out of 50 MSSA strains tested at high concentrations $\geq 10^6$ CFU/swab), produced SA POS, MRSA NEG results.
- Seventeen (17) viruses representing 12 different viral species were tested at $\geq 10^5$ PFU/mL. All 17 viruses produced negative results (SA NEG, MRSA NEG).

Table 8: Microorganisms Tested for the Analytical Specificity Study

Non-Staphylococcal Species				
Acinetobater baumannii	*Corynebacterium bovis*	*Escherichia coli* (3 strains)	*Neisseria meningitidis*	*Pasteurella aerogenes*
Acinetobater haemolyticus	*Corynebacterium flavescens*	*Haemophilus influenzae*	*Streptococcus anginosus*	*Proteus mirabilis*
Bacillus cereus	*Corynebacterium genitalium*	*Klebsiella oxytoca*	*Streptococcus agalactiae*	*Proteus vulgaris*
Bordetella pertussis	*Cryptococcus neoformans*	*Klebsiella pneumoniae*	*Streptococcus mitis*	*Providencia stuartii*
Candida albicans (2 strains)	*Enterobacter aerogenes*	*Lactobacillus crispatus*	*Streptococcus mutans*	*Pseudomonas aeruginosa*
Candida guilliermondii	*Enterobacter cloacae*	*Lactobacillus reuteri*	*Streptococcus pneumoniae*	*Pseudomonas fluorescens*
Candida tropicalis	*Enterococcus faecalis*	*Lactobacillus acidophilus*	*Streptococcus pyogenes*	*Salmonella enterica* subsp. Enterica
Candida glabrata	*Enterococcus faecium*	*Listeria monocytogenes*	*Streptococcus salivarius*	*Serratia marcescens*
Citrobacter freundii	*Enterococcus flavescens*	*Micrococcus luteus*	*Streptococcus sanguinis*	*Shigella sonnei*
Citrobacter koseri	*Enterococcus hirae*	*Moraxella catarrhalis*	*Streptococcus suis*	*Yersinia enterocolitica*
Corynebacterium aquaticus	*Enterrococcus gallinarum*	*Neisseria gonorrhoeae*	*Streptococcus* sp.	
Various Coagulase Positive Staphylococcus Species				
Staphylococcus intermedius	*Staphylococcus lutrae* (2 stains)	*Staphylococcus pseudointermedius*	*Staphylococcus schleiferi*	*Staphylococcus schleiferi* subsp. *coagulans*
Staphylococcus delphini				
Various Coagulase Negative Staphylococcus Species				
Staphylococcus arlettae	*Staphylococcus chromogenes*	*Staphylococcus gallinarum*	*Staphylococcus lentus*	*Staphylococcus sciuri*
Staphylococcus auricularis	*Staphylococcus cohnii* subsp. *urealyticum*	*Staphylococcus haemolyticus* (3 strains)	*Staphylococcus lugdunensis*	*Staphylococcus simulans*
Staphylococcus capitis	*Staphylococcus epidermidis* (9 strains)	*Staphylococcus hominis* (3 strains)	*Staphylococcus pasteuri*	*Staphylococcus warneri* (2 strains)
Staphylococcus caprae	*Staphylococcus equorum*	*Staphylococcus hominis* subsp. *hominis*	*Staphylococcus pulvereri*	*Staphylococcus xylosus* (2 strains)
Staphylococcus carnosus	*Staphylococcus felis*	*Staphylococcus kloosii*	*Staphylococcus saprophyticus*	*Staphylococcus xylosus*
Virus				
Adenovirus (type 1 and 7A)	Enterovirus	Human parainfluenza (type 1, 2, 3)	Measles	Respiratory syncytial virus
Human coronavirus (2)	Epstein Barr Virus	Human metapneumovirus	Mumps virus	Rhinovirus
Cytomegalovirus	Human influenza virus (type A and B)			

Interfering Substances

Twenty nine (29) microorganisms and chemical substances occasionally used in the nares or found in nasal swab specimens were evaluated for potential interference with the BD MAX™ StaphSR assay (Table 9). MRSA negative samples and MRSA positive samples at 2-3 x LoD were tested with the highest amount of each compound or microorganism likely to be found at the sampling site or on the nasal swab sample. Results demonstrated no reportable interference with any microorganisms or chemical substance except for Tobramycin that showed inhibition in the BD MAX™ StaphSR assay when tested at a concentration of 4.5×10^{-3} g/swab.

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

Substance	Result[1]
Mucin, from bovine submaxillary glands	NI
Dexamethasone Sodium Phosphate Ophtalmic Solution USP, 0.1% Dexamethasone Phosphate Equivalent	NI
Chloraseptic™	NI
Taro-Mupirocin, Mupirocin Ointment USP, 2%	NI
Long Lasting Dristan™ Nasal Mist	NI
Neo-Synephrine™	NI
Equate® Nasal Spray Decongestant	NI
Beconase AQ™	NI
Flunisolide Nasal Solution USP, 0.025%	NI
Nasacort™ AQ	NI
Nasonex™	NI
Relenza™	NI
Tobramycin	I
Blood	NI
Flumist®	NI

Substance	Result
Rhinocort aqua™	NI
Zicam® No-Drip Liquid™ Nasal Gel™ Extreme Congestion Relief	NI
Fluticasone Propionate	NI
Luffeel™	NI
Staphylococcus epidermidis	NI
Micrococcus luteus	NI
Enterococcus faecium	NI
Enterococcus faecalis	NI
Escherichia coli	NI
Corynebacterium flavescens	NI
Moraxella catarrhalis	NI
Staphylococcus hominis subsp *hominis*	NI
Haemophilus influenzae	NI
Streptococcus pneumoniae	NI

[1] NI: No reportable interference with the BD MAX™ StaphSR assay.
I: Reportable interference with the BD MAX™ StaphSR assay.

Microbial Competitive Inhibitory Effect

A study was conducted to determine the potential competitive inhibitory effect of:

- an increasing concentration of MRSE when co-spiked with a low concentration (1-2 x LoD) of MRSA or MSSA, and
- an increasing concentration of MSSA when co-spiked with a low concentration (1-2 x LoD) of MRSA.

Results demonstrated competition from:

- MRSE at an MRSA:MRSE ratio of 1: ≥ $1x10^3$
- MRSE at an MSSA:MRSE ratio of 1: ≥ $1x10^5$
- MSSA at an MRSA:MSSA ratio of 1: ≥ $1x10^4$.

Carryover / Cross-Contamination

A study was conducted to investigate the potential for carry-over/cross-contamination between high MRSA (≥10^7 CFU/swab) specimens and negative specimens throughout the BD MAX™ StaphSR workflow. Twelve (12) replicates of the high

positive sample and 12 replicates of the negative sample were tested in each run by alternating negative and positive replicates. Four (4) operators performed a total of 18 runs of 24 samples. Overall, from 203 reportable results out of 216 expected negative samples, 3 false positive results were obtained (3/203; 1.5%) due to carry-over contamination.

Clinical Performance Studies

Clinical performance characteristics of the BD MAX™ StaphSR assay were determined in a multi-site prospective investigational study. Three (3) investigational centers participated in the study. To be enrolled in the study, patients had to be eligible for MRSA or SA 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 or SA by direct culture. Presumptive *S. aureus* colonies observed on selective (*S. aureus*) chromogenic medium 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 Trypticase Soy Broth with 6.5% NaCl (TSB 6.5% NaCl) was completed in the event that MRSA or SA was not confirmed by the initial direct culture method. Turbid TSB 6.5% NaCl broth was used to inoculate additional chromogenic medium and BA plates; MRSA confirmation was performed as described above.

Results Obtained with the BD MAX™ StaphSR Assay in Comparison to the Reference Method

A total of 2451 specimens were enrolled in the study. Of those, 94 specimens were regarded as noncompliant per protocol criteria and three (3) fully compliant specimens gave final non-reportable PCR results. A total of 2354 specimen results were used to determine the clinical performance of the BD MAX™ StaphSR assay in comparison to the Reference Method (Tables 10 to 13).

Compared to the Reference Method (Direct/Enriched Culture), the BD MAX™ StaphSR assay identified 93.1% of the MRSA positive specimens and 97.5% of the MRSA negative specimens (Table 10). For the population tested, this resulted in a Negative Predictive Value (NPV) of 99.5% and a Positive Predictive Value (PPV) of 73.2%.

Table 10: Results Obtained for MRSA with the BD MAX™ StaphSR Assay in Comparison to the Reference Method

All Sites	Reference Method		
	MRSA Positive	Negative	Total
BD MAX™ StaphSR Assay	Positive 149	54	203
	Negative 11	2140	2151
	Total 160	2194	2354[1]
Sensitivity: 93.1% (149/160) (95% CI: 88.1%, 96.1%) Specificity: 97.5% (2140/2194) (95% CI:96.8%, 98.1%) PPV: 73.2% (95% CI: 67.8%, 78.3%) NPV: 99.5% (95% CI: 99.1%, 99.7%)			

[1]Further investigation was performed on specimens with discordant results between the Reference Method and the BD MAX™ StaphSR assay.

- 12 of 54 MRSA False Positive BD MAX™ StaphSR specimens were also found to be positive after repeat of Reference Method
- 5 of 11 MRSA False Negative BD MAX™ StaphSR specimens were also found to be negative after repeat of Reference Method

Table 11: Site-by-Site Performance Obtained for MRSA with the BD MAX™ StaphSR Assay in Comparison to the Reference Method

Clinical Sites	Prevalence[a]	Sensitivity (95% CI)[b]	Specificity (95% CI)[b]
Site 1	4.3% (41/960)	92.7% (38/41) (80.6%, 97.5%)	98.9% (908/918) (98.0%, 99.4%)
Site 2	5.8% (38/650)	86.8% (33/38) (72.7%, 94.2%)	98.5% (583/592) (97.1%, 99.2%)
Site 3	10.6% (81/765)	96.3% (78/81) (89.7%, 98.7%)	94.9% (649/684) (93.0%, 96.3%)
Overall	6.7% (160/2375[c])	93.1% (149/160) (88.1%, 96.1%)	97.5% (2140/2194) (96.8%, 98.1%)

[a] Prevalence based on reference method only
[b] Confidence interval
[c] 2375 specimens were reference method compliant

Compared to the Reference Method (Direct/Enriched Culture), the BD MAX™ StaphSR assay identified 92.0% of the SA positive specimens and 93.1% of the SA negative specimens (Tables 12 and 13). For the population tested, this resulted in a NPV of 96.8% and a PPV of 83.4%.

Table 12: Results Obtained for SA with the BD MAX™ StaphSR Assay in Comparison to the Reference Method

All Sites	Reference Method		
	SA Positive	Negative	Total
BD MAX™ StaphSR Assay	Positive 599	118	717
	Negative 52	1585	1637
	Total 651	1703	2354[1]
Sensitivity: 92.0% (599/651) (95% CI: 89.7%, 93.9%) Specificity: 93.1% (1585/1703) (95% CI: 91.8%, 94.2%) PPV: 83.4% (95% CI: 81.9%, 85.8%) NPV: 96.8% (95% CI: 96.0%, 97.6%)			

[1]Further investigation was performed on specimens with discordant results between the Reference Method and the BD MAX™ StaphSR assay.

- 28 of 118 SA False Positive BD MAX™ StaphSR specimens were also found to be positive after repeat of Reference Method
- 23 of 52 SA False Negative BD MAX™ StaphSR specimens were also found to be negative after repeat of Reference Method

Table 13: Site-by-Site Performance Obtained for SA with the BD MAX™ StaphSR Assay in Comparison to the Reference Method

Clinical Sites	Prevalence [a]	Sensitivity with 95% CI [b]	Specificity with 95% CI [b]
Site 1	27.2% (261/960)	90.0% (235/261) (85.8%, 93.1%)	96.3% (672/698) (94.6%, 97.4%)
Site 2	27.5% (179/650)	91.5% (162/177) (86.5%, 94.8%)	90.9% (412/453) (88.0%, 93.3%)
Site 3	27.8% (213/765)	94.8% (202/213) (91.0%, 97.1%)	90.8% (501/552) (88.1%, 92.9%)
Overall	27.5% (653/2375 [c])	92.0% (599/561) (89.7%, 93.9%)	93.1% (1585/1703) (91.8%, 94.2%)

[a] Prevalence based on reference method only
[b] Confidence interval
[c] 2375 specimens were reference method compliant

Results Obtained with the BD MAX™ StaphSR Assay in Comparison to Direct Culture

A total of 2451 specimens were enrolled in the study. Of those, 54 specimens were regarded as noncompliant per protocol criteria and four (4) fully compliant specimens gave non reportable PCR results. A total of 2393 specimen results were used to determine the positive and negative percent agreement of the BD MAX™ StaphSR assay in comparison to Direct Culture (Tables 14 to 17).

Compared to Direct Culture, the BD MAX™ StaphSR assay identified 96.5% of the MRSA positive specimens and 96.9% of the MRSA negative specimens (Tables 14 and 15).

Table 14: Results Obtained for MRSA with the BD MAX™ StaphSR Assay in Comparison to Direct Culture

All Sites		Direct Culture		
		Positive	Negative	Total
BD MAX™ StaphSR Assay	Positive	137	69	*206*
	Negative	5	2182	*2187*
	Total	*142*	*2251*	*2393*
Positive Percent Agreement: 96.5% (137/142) (95% CI: 92.0%, 98.5%) Negative Percent Agreement: 96.9% (2182/2251) (95% CI: 96.1%, 97.6%)				

Table 15: Site-by-Site Performance Obtained for MRSA with the BD MAX™ StaphSR Assay in Comparison to Direct Culture

Clinical Sites	Positive Percent Agreement with 95% CI [a]	Negative Percent Agreement with 95% CI [a]
Site 1	100% (35/35) (90.1%, 100%)	98.6% (911/924) (97.6%, 99.2%)
Site 2	93.5% (29/31) (79.3%, 98.2%)	97.8% (586/599) (96.3%, 98.7%)
Site 3	96.1% (73/76) (89.0%, 98.6%)	94.1% (685/728) (92.1%, 95.6%)
Overall	96.5% (137/142) (92.0%, 98.5%)	96.9% (2182/2251) (96.1%, 97.6%)

[a] Confidence interval

Compared to Direct Culture, the BD MAX™ StaphSR assay identified 95.1% of the SA positive specimens and 90.9% of the SA negative specimens (Tables 16 and 17).

Table 16: Results Obtained for SA with the BD MAX™ StaphSR Assay in Comparison to Direct Culture

All Sites		Direct Culture		
		Positive	Negative	Total
BD MAX™ StaphSR Assay	Positive	564	164	728
	Negative	29	1636	1665
	Total	593	1800	2393
Positive Percent Agreement: 95.1% (564/593) (95% CI: 93.1%, 96.6%) Negative Percent Agreement: 90.9% (1636/1800) (95% CI: 89.5%, 92.1%)				

Table 17: Site-by-Site Performance Obtained for SA with the BD MAX™ StaphSR Assay in Comparison to Direct Culture

Clinical Sites	Positive Percent Agreement with 95% CI[a]	Negative Percent Agreement with 95% CI[a]
Site 1	93.0% (213/229) (89.0%, 95.7%)	93.4% (682/730) (91.4%, 95.0%)
Site 2	94.9% (149/157) (90.3%, 97.4%)	88.6% (419/473) (85.4%, 91.1%)
Site 3	97.6% (202/207) (94.5%, 99.0%)	89.6% (535/597) (86.9, 91.8%)
Overall	95.1% (564/593) (93.1%, 96.6%)	90.9% (1636/1800) (89.5%, 92.1%)

[a] Confidence interval

Out of 2399 nasal swab specimens tested with the BD MAX™ StaphSR assay that were compliant at the specimen and PCR level, 15 (0.6%) were reported as Unresolved after initial testing. The Unresolved Rate after repeat testing is 0.04% (1/2399) (Table 18).

Table 18: Unresolved Rates

Initial Unresolved Rates	Unresolved Rates After Repeat
0.6% (15/2399)* (95% CI: 0.4%, 1.0%)	0.04% (1/2399) (95% CI: 0%, 0.2%)

*Total number based on compliant specimens and BD MAX™ StaphSR assay results

Out of the same 2399 nasal swab specimens tested with the BD MAX™ StaphSR assay, 14 (0.6%) were initially reported as Indeterminate. No result remained Indeterminate upon repeat (two specimens were not retested). Eight (8) (0.3%) were initially reported as Incomplete. No result remained Incomplete upon repeat (one specimen was not retested).

Empty Cassette Variants

Among the 2354 eligible specimens included in the clinical performance determination, a total of 10 specimens fit the empty cassette profile resulting in detection of MREJ, without *mecA* or *mecC* gene detection. All of the 10 specimens were verified true negative MRSA and true positive SA relative to the Reference Method.

Expected Values

In the BD MAX™ StaphSR assay clinical study a total of 2395 reportable results, from specimens compliant at the specimen and PCR levels, were obtained from 3 geographically diverse sites and compared with Direct and Enriched culture. The study population was grouped into in-patient, out-patient and unknown categories. The number and percentage of positive cases, as determined by the BD MAX™ StaphSR assay, are presented in the table below:

		BD MAX™ StaphSR Assay			
Group	Total Number of Specimens[1]	Number of MRSA Positive	Number of SA Positive	Positive MRSA Percentage	Positive SA Percentage
In-patient	1685	178	548	10.6% (178/1685)	32.5% (548/1685)
Out-patient	710	28	182	3.9% (28/710)	25.6% (182/710)
Total[1]	2395	206	730	8.6% (206/2395)	30.5% (730/2395)

[1]Total specimens based on compliant PCR results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GENEOHM SCIENCE CANADA, INC. (BD DIAGNOSTICS)
PATRICIA DIONNE, PH.D, MBA
DIRECTOR, REGULATORY AFFAIRS
2555 BOUL. DU PARC-TECHNOLOGIQUE
QUEBEC, QUEBEC, G1P 4S5
CANADA

November 26, 2013

Re: K132822
Trade/Device Name: BD MAX™ StaphSR
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: II
Product Code: NQX, OOI
Dated: September 16, 2013
Received: September 17, 2013

Dear Dr. Dionne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132822

Device Name
BD MAX™ StaphSR

Indications for Use *(Describe)*

The BD MAX™ StaphSR assay performed on the BD MAX™ System is an automated qualitative in vitro diagnostic test for the direct detection and differentiation of Staphylococcus aureus (SA) and 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/SA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified 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 to recover organisms for epidemiological typing or for further susceptibility testing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ribhi Shawar -S
2013.11.25 08:19:23 -05'00'

FDA