510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K171061

B. Purpose for Submission:

To obtain a substantial equivalence determination from for MRSA*Select* II agar for the qualitative detection of methicillin resistant *Staphylococcus aureus* from anterior nares, and skin and soft tissue wound specimens.

C. Measurand:

Methicillin resistant *Staphylococcus aureus* (MRSA)

D. Type of Test:

Detection of MRSA using a selective and differential chromogenic medium

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

MRSA*Select* II

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1700

2. Classification:

   Class II

3. Product code:

   JSO: Culture media, Antimicrobial susceptibility test, excluding Mueller Hinton Agar

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use(s):

   MRSA*Select* II is a selective and differential chromogenic medium for:

   a) The qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infection in healthcare settings. The test can be performed on anterior nares specimens from patients to screen for MRSA colonization. MRSA*Select* II is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. A negative result does not preclude MRSA nasal colonization. Concomitant cultures are necessary to recover organisms for identification, antimicrobial susceptibility testing, or epidemiological typing. Results can be interpreted after 18 to 28 hours incubation.

   b) The qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from skin and soft tissue wound specimens. The MRSA*Select* II is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and antimicrobial susceptibility testing are necessary for all skin and soft-tissue wound specimens. MRSA*Select* II is not intended to guide, or monitor treatment for MRSA infection, or provide results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hour incubation.

2. Indication(s) for use:

   See Intended Use

3. Special conditions for use statement(s):

   Prescription Use

   Limitations

   The growth requirements of certain MRSA strains can lead to their partial or total inhibition in culture on MRSASelect II.

   Some strains of coagulase-negative Staphylococci, methicillin-susceptible Staphylococcus aureus, and other non-Staphylococcal isolates may grow as pink colonies on MRSASelect II. If in doubt, confirm identification by performing a Gram stain and further testing, and determine the resistance profile if a S. aureus strain is identified.

4. Special instrument requirements:

   None

I. Device Description:

The MRSA*Select* II is a selective and differential chromogenic medium for the qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from anterior nares and detection of MRSA from skin and soft-tissue wound specimens. The selectivity of this medium is due to an antifungal/antibiotic mixture that inhibits the growth of yeast, Gram negative, and Gram positive bacteria, with the exception of methicillin-resistant staphylococci. MRSA will appear as pink colonies on the agar medium. Identification of MRSA is based on the cleavage of a chromogenic substrate by a specific enzymatic activity of *Staphylococcus aureus*, leading to a pink coloration of the MRSA colonies.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bio-Rad MRSA*Select* Extended Incubation
   Bio-Rad MRSA*Select* Wound Specimen

2. Predicate 510(k) number(s):
   K081212
   K100589

3. Comparison with predicate:
   Table 1. Comparison with Predicate Device

Similarities			
Item	**Device (K171061)**	**Predicate for anterior nares specimens (K081212)**	**Predicate for skin and soft-tissue wound specimens (K100589)**
Intended Use	**MRSA***Select* II is a selective and differential chromogenic medium for: A) The qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients to screen for MRSA colonization. **MRSA***Select* II is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. A negative result does	MRSA*Select* is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients and healthcare workers to screen for MRSA colonization.	MRSA*Select* is a selective and differential chromogenic medium for the qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from skin and soft-tissue wound specimens. The medium is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections.

Similarities			
Item	**Device (K171061)**	**Predicate for anterior nares specimens (K081212)**	**Predicate for skin and soft-tissue wound specimens (K100589)**
	not preclude MRSA nasal colonization. Concomitant cultures are necessary to recover organisms for identification, antimicrobial susceptibility testing, or epidemiological typing. Results can be interpreted after 18 to 28 hours incubation. B) The qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from skin and soft tissue wound specimens. The **MRSA***Select* II is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and antimicrobial susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA***Select* II is not intended to guide, or monitor treatment for MRSA infection, or provide results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.	MRSA*Select* is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. Results can be interpreted after 18-28 hours incubation.	Concomitant cultures and susceptibility testing are necessary for all skin and soft-tissue wound specimens. MRSA*Select* is not intended to guide, or monitor treatment for MRSA infection, or provides results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.
Methodology	Selective and differential chromogenic agar	Selective and differential chromogenic agar	Selective and differential chromogenic agar
Incubation	18-28 hours	18-28 hours	18-28 hours
Interpretation	Manual	Manual	Manual

Differences			
Item	**Device**	**Predicate for anterior nares specimens (K081212)**	**Predicate for skin and soft tissue wound specimens (K100589)**
Inoculation	Direct	Direct and indirect (saline)	Direct
Specimen Type	Anterior nares Skin and soft-tissue	Anterior nares	Skin and soft-tissue

K. Standard/Guidance Document Referenced (if applicable):

- CLSI M22-A3: Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition
- CLSI M40-A: Quality Control of Microbiological Transport Systems; Approved Standard
- CLSI M100-S23: Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Third Informational Supplement
- CLSI M100-S26: Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Sixth Informational Supplement
- Draft Guidance for Industry and FDA Staff: Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of methicillin-resistant *Staphylococcus aureus* (MRSA) for Culture Based Devices.

L. Test Principle:

The MRSA*Select* II is a selective and differential chromogenic medium for the qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA). The selectivity of this medium is due to an antifungal/antibiotic mixture that inhibits the growth of yeast, Gram negative, and Gram positive bacteria, with the exception of methicillin-resistant staphylococci. Detection is based on the cleavage of a chromogenic substrate by a specific enzyme activity of *Staphylococcus aureus*, leading to a pink coloration of the *Staphylococcus aureus* colonies.

Within 18-28 hours incubation time, methicillin-resistant *Staphylococcus aureus* will produce pink colonies on the MRSA*Select* II. Coagulase negative methicillin-resistant staphylococci do not metabolize the chromogenic substrate and therefore appear as colorless or white colonies. Methicillin-susceptible *Staphylococcus aureus* (MSSA) and methicillin-susceptible coagulase negative *Staphylococcus* are inhibited.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Reproducibility was demonstrated at three study sites over a period of five test days using a blinded panel of 10 ATCC reference strains of *Staphylococcus*. Panel members included MRSA, MSSA, and *S. epidermidis*. Each day of testing, the panel members were prepared, randomized, and blinded to the operators inoculating and reading MRSASelect II plates. Cell suspensions contain approximately $1X10^{2-3}$ CFU/mL for MRSA, $1X10^{3-4}$ CFU/mL of MRSA ATCC BAA-2313™, and $1X10^{6-7}$ for both *S.epidermidis* and MSSA. At each study site, panel members were tested by

two operators using three lots of MRSASelect II. The plates were incubated at 35-37°C, in ambient air. Colonial growth and color were recorded at 18, 24, and 28 hours post incubation. Based on an overall ≥ 95% pass/fail criteria, the18, 24 and 28 hour incubation results were consistent with the expected results with all strains tested using MRSASelect II.

A second study was conducted to evaluate reproducibility using cell suspensions at concentrations close to the device limit of detection (LoD). The study panel included six ATCC reference strains of MRSA prepared in saline suspensions at concentrations that ranged from 80-240 CFU/mL. One of the six MRSA strains (ATCC BAA-2132, *mecC* MRSA) was also tested at a concentration of 800-2400 CFU/mL. Panel members were tested at one site, by three independent operators over the course of five non-consecutive days, using one lot of MRSA*Select* II. The plates were incubated at 35-37°C, in ambient air. Colonial growth and color were recorded at 18, 24, and 28 hours post incubation. Based on an overall ≥ 95% pass/fail criteria, the18, 24 and 28 hour incubations resulted in expected results for all five of the six strains tested. The pass/fail criterion was not met for strain ATCC BAA-2312 (*mecC* MRSA) when tested at a concentration range of 80-240 CFU/mL, however the acceptance criterion was met for this particular strain when tested at a concentration of 800-2400 CFU/mL; this was attributed to inherent characteristics of this *mecC* MRSA strain[1].

The following limitation was included in the device package insert to address this finding:

The growth requirements of certain MRSA strains can lead to their partial or total inhibition in culture on MRSASelect II.

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

During the clinical study, quality control (QC) testing was performed on the MRSA*Select* II each day of testing using the following QC organisms.

- *Staphylococcus aureus* ATCC 25923 – Negative Control
- *Staphylococcus aureus* (*mec*A positive) ATCC 43300 – Positive Control

[1] "*mecC MRSA typically have lower MICs to oxacillin and cefoxitin that their mecA counterparts and this may affect their recovery on selective agars*". Paterson GK, Harrison EM, Holmes MA. The emergence of *mec*C methicillin resistant *Staphylococcus aureus*. Trends in Microbiology 2014;22(1):42-47. doi:10.1016/j.tim.2013.11.003.

Table 2. Quality Control Expected Results

Quality Control	Test Strains	Inoculum Concentration	Expected results after 24 hours at 35-37°C (ambient air)
Negative Control	ATCC 25923	10^{6-7} CFU/mL	No growth
Positive Control	ATCC 43300	10^{4-5} CFU/mL	Pink Colonial Growth

QC organisms were prepared in saline to achieve a 0.5 McFarland suspension that was further diluted 1:10. A 10 µL aliquot of the negative control strain (ATCC 25923) was inoculated and streaked onto MRSA*Select* II. The positive control strain (ATCC 43300) was further diluted 1:1000 before a 10 µL aliquot was inoculated and streaked onto MRSA*Select* II. After 24 hours of incubation at 35-37°C (ambient air), MRSA*Select* II plates were read and evaluated in accordance with expected results.

QC data was collected across all three study sites during the clinical study and all QC results were acceptable.

d. Recovery/Limit of Detection (LoD):

A recovery (LoD) study was performed using five dilutions each of two well characterized strains of MRSA. Each dilution was plated on three MRSA*Select* II plates and one blood agar plate and incubated at 35-37°C (ambient air) for 18, 24, and 28 hours. The number and color of colonies was recorded after each incubation period. The results of the study revealed that the LoD for growth on MRSA*Select* II was 80 CFU/mL for organism saline suspensions.

A second study was performed to evaluate MRSA*Select* II recovery (LoD) for organisms prepared in saline and also prepared in both human anterior nares and skin and soft tissue wound swab matrices. The study was performed using four well characterized strains of MRSA each prepared in saline suspensions at four concentrations (10^5, 10^4, 10^3, 10^2 CFU/mL). A total of 100 uL of each MRSA-saline suspension was inoculated directly onto each of three MRSA*Select* II plates. In parallel, MRSA-negative swabs with matrix were spiked using 100 µL of MRSA-saline suspension and streaked onto each of three MRSA*Select* II plates. An aliquot of 100 µL of each MRSA-saline suspension was also inoculated onto a blood agar plate to serve as a control and to confirm the inoculum concentration. All plates were incubated at 35-37°C (ambient air). After 18, 24, and 28 hours incubation, plates were examined and the number of pink colonies was counted and recorded. The LoD was determined using plates with an appropriate number of countable colonies. The LoD for each matrix was determined separately and compared to results of samples without matrix. The LoD for nasal and wound matrices was observed to be 1 log higher (800 CFU/mL) than that of saline (80 CFU/mL).

e. Analytical Sensitivity (Inclusivity)

A test panel of 54 well characterized MRSA strains were plated on MRSA*Select* II using saline suspension concentrations of 80-240 CFU/mL (1-3X LoD). The test

panel members consisted of clinically associated strains from the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) and one ATCC strain (ATCC BAA-2312, *mec*C). Serial dilutions of each strain were prepared in saline from a 0.5 McFarland suspension and plated onto MRSA*Select* II and blood agar plates. MRSASelect II plates were incubated at 35-37°C, in ambient air and read at 18, 24, and 28 hours. The color and number of colonies for each strain was recorded. A total of 53/54 MRSA strains grew as pink colonies on MRSASelect II after 18 hours incubation. One strain, NRS 642, was observed as no growth on MRSA*Select* II at 18 hours. After 24 and 28 hours incubation, all 54 strains grew on MRSA*Select* II as pink colonies.

f. Analytical specificity:

Cross Reactivity

A cross-reactivity study was performed using a total of 109 strains from organisms that could potentially be encountered in anterior nares or skin and soft tissue wound specimens. Organisms tested included methicillin-susceptible *Staphylococcus aureus* (MSSA), methicillin-resistant coagulase negative *Staphylococcus* (MRCNS), organisms of other genera, and fungi. Testing of 30 additional MSSA strains and seven *Staphylococcus cohnii* strains was conducted to determine potential assay limitations.

For each organisms tested a 0.5 McFarland suspension (~10^8 CFU/mL) was prepared in saline using an 18-24 hour organism culture. A 1:10 dilution of the 0.5 McFarland suspension was prepared and 10 µL was inoculated and streaked on each of two MRSASelect II plates. A blood agar plate was also inoculated and streaked for use in confirming colony counts. All plates were incubated and read after 24, and 28 hours incubation. Cross reactivity was defined as growth of pink colonies on MRSASelect II at 24, and/or 28 hours.

The majority of the organisms tested did not result in growth of pink colonies on MRSASelect II at 24, and/or 28 hours. However, for the following organisms, growth of colonies with a faint pink coloration when in clusters was observed:

- *Corynebacterium imitans*
- *Corynebacterium jeikeium*
- *Aerococcus viridans*
- *Staphylococcus cohnii*
- *Staphylococcus sciuri*

The following limitation was included in the device package insert to address this finding:

Some strains of Corynebacterium imitans, Corynebacterium jeikeium, Aerococcus viridans, Staphylococcus cohnii and Staphylococcus sciuri may develop faint pink

colonies with a more intense coloration when in clusters , but non-pink when colonies are isolated (which enable differentiation from MRSA colonies). If in doubt, confirm the identification of such isolated colonies by Gram stain and further testing.

In addition, a total of 50 MSSA strains were tested, and two strains produced colonies with pink coloration on MRSASelect II. The following limitation was also included in the device package insert to address this finding and false positives observed in the clinical study:

Some strains of coagulase-negative Staphylococci, methicillin-susceptible Staphylococcus aureus, and other non-Staphylococcal isolates may grow as pink colonies on MRSASelect II. If in doubt, confirm identification by performing a Gram stain and further testing, and determine the resistance profile if a S. aureus strain is identified.

Interfering Substances

The following 20 substances were evaluated at physiologically or biologically relevant concentrations for potential interference with the performance of MRSASelect II:

Table 3. Potential Interfering Substances

Saline	Neosynephrine (Nasal Spray)	Dristan 12h (Nasal Spray)
Ayr Saline (Nasal Mist)	Walgreens First Aid Antiseptic Spray	Ocean Premium Saline Nasal Spray
Chloraseptic	Throat lozenges, oral anesthetic and analgesic	Zicam Nasal gel-homeopathic allergy relief medicine
Neosporin	Tecnu first Aid Antiseptic Pain-Relieving Gel	Hydrocortisone (ointment)
Biol Ease	Antibacterial hand sanitizer	70% Isopropyl alcohol
Bactine	Betadine	Hydrogen peroxide
Blood 30% and 50%	Hog gastric mucin 3% and 5%	

A single strain of MRSA (NRS 723) was prepared in saline at a concentration of 10^3 CFU/mL. The MRSA-saline concentration (10^3 CFU/mL) was well above the device LoD determined for saline suspensions (80 CFU/mL), therefore the following limitation was included in the device package insert:

Interference study findings are based on testing conducted using MRSA saline suspensions at concentrations of 10^3 CFU/mL. The effect of potentially interfering endogenous and exogenous substances on the growth and recovery of MRSA at concentrations lower than 10^3 CFU/mL on MRSASelect II after 18-28 hours incubation is unknown.

The MRSA-saline suspension was then mixed with 100 µL or 100 mg of the interfering solution or compound to achieve a concentration of 5% (v/v or w/v). An aliquot of this test suspension was inoculated onto two MRSASelect II plates and two

blood agar plates. Plates were incubated at 35-37°C, in ambient air, and evaluated at 18, 24, and 28 hours.

The study findings revealed 12 out of the 20 substances tested showed no notable effect on the ability of MRSASelect II to support growth and recovery of MRSA. The following seven substances demonstrated complete inhibition of growth of MRSA on MRSASelect II:

- Neosynephrine (nasal spray)
- Dristan 12h (nasal spray)
- Ayr Saline (nasal mist)
- Walgreens First Aid (antiseptic spray)
- Tecnu First Aid Antiseptic Pain Relieving Gel
- Bactine
- Betadine

The following substance demonstrated decreased growth and recovery of MRSA on MRSASelect II.

- Ocean Premium Saline (nasal spray)

The following limitations were added to the device package insert in accordance with these study findings.

Use of the following compounds may inhibit growth of MRSA on non-selective media as wells as on MRSASelect II: Neosynephrine®, Dristan 12h®, Ayr Saline®, Walgreens First Aid Antiseptic Spray®, Tecnu First Aid Antiseptic Pain Relieving Gel, Bactine, Betadine.

Use of the antibiotic ointment Ocean Premium Saline Nasal Spray (Phenylcarbinol) may result in decreased growth of MRSA on non-selective media as well as on MRSASelect II.

Validation of Transport Media

A study was conducted to evaluate the effect of three different transport media on the growth of MRSA on MRSASelect II. The transport media evaluated included, LQ Stuart (Becton Dickinson), Amies with Charcoal (Becton Dickinson), and LQ Amies (COPAN). McFarland 0.5 suspensions of four MRSA strains were diluted to achieve $1X10^{7-8}$ and $1X10^{4-5}$ CFU/mL suspensions. Swabs were inoculated with 100 µL of test suspension and incubated for 24 and 48 hours in the transport media at 20°C, 25°C and 30°C. A t=0 swab was also inoculated in the study. After the incubation is transport media was complete, the inoculated swabs were diluted in saline (1:10), and the diluted suspensions were aliquoted onto two blood agar and two MRSASelect II plates. Plates were incubated at 35-37°C (ambient air) for 24 hours, and all growth recorded in CFU/mL. The study findings revealed no notable effect of the three

transport media on the growth and recovery of MRSA on MRSASelect II.

Mixed Infection Study

A mixed infection study was conducted to demonstrate that various levels of *Klebsiella pneumoniae* or methicillin-resistant *Staphylococcus epidermidis* (10^2-10^6 CFU/mL) will not suppress growth of MRSA in concentrations near the device LoD. The study findings revealed that despite the presence of high concentrations of *K. pneumoniae* or methicillin-resistant *Staphylococcus epidermidis*, MRSA colonies were effectively detected on MRSASelect II.

g. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity and Clinical Specificity:*

Anterior Nares Specimen Type

The performance of the MRSASelect II culture medium with anterior nares specimens was evaluated at three clinical sites. A total of 2410 anterior nares specimens were evaluated. All samples were inoculated directly onto media in the following order:

- MRSASelect II plate
- Tryptic Soy Broth (TSB) with 6.5% NaCl

Performance of MRSASelect II was compared to a culture enrichment broth reference method. After inoculation TSB with 6.5% NaCl was incubated in ambient air for up to 48 hours and examined for turbidity. If growth was observed after 24 or 48 hours, TSB broth was subculture to a blood agar plate and incubated. Suspected *Staphylococcus aureus* colonies were identified by Gram stain, catalase, slide agglutination test for detection of *Staphylococcus aureus*, tube coagulase, *mec*A-mediated oxacillin resistance testing using cefoxitin (30ug) disk, and testing for

PBP2a. If not growth was observed after 24 and 48 hours, the broth culture was interpreted as negative.

After inoculation, MRSASelect II plates were incubated in ambient air for up to 28 hours. Pink colonies of any intensity on MRSASelect II plate were interpreted as indicative of the presence of MRSA.

A summary of the clinical performance of MRSASelect II with anterior nares specimens is illustrated in Table 4 below.

Table 4. Clinical Performance of MRSASelect II versus Enriched Broth Culture Reference Method - Anterior Nares

All Sites (Anterior Nares)		Culture Enrichment Broth (PBP2a)		
		POS	NEG	TOTAL
MRSASelect II (Primary Culture)	POS	232	37[b]	269
	NEG	23[a]	2118	2141
	TOTAL	255	2155	2410
All Sites			95% C.I.	
Sensitivity (%)		91.0%	86.8%	93.9%
Specificity (%)		98.3%	97.6%	98.8%
Pos. Predictive Value		86.2%	81.6%	89.9%
Neg. Predictive Value		98.9%	98.4%	99.3%

[a] No growth on MRSASelect II for all 23 specimens.
[b] A total of 11 isolates were determined to be strains of coagulase-negative Staphylococcus species; nine isolates were determined to be strains of methicillin-susceptible *S. aureus*; and 27 isolates were determined to be non-*S. aureus* species.

Skin and Soft Tissue Wound Specimen Type

The performance of MRSASelect II culture medium with skin and soft tissue wound specimens was evaluated at three clinical sites. A total of 842 wound specimens were evaluated. All the samples were inoculated directly onto the following media in this order:

- 5% Sheep Blood Agar
- MRSASelect II
- Tryptic Soy Broth (TSB) with 6.5% NaCl

Performance of MRSASelect II was compared to an enriched broth culture reference method. After inoculation TSB with 6.5% NaCl was incubated in ambient air for up to 48 hours and examined for turbidity. If growth was observed after 24 and 48 hours, TSB broth was subcultured to a blood agar plate and incubated. Suspected *Staphylococcus aureus* colonies were identified by Gram stain, catalase, slide

agglutination test for detection of *Staphylococcus aureus*, tube coagulase, and *mec*A-mediated oxacillin resistance testing using cefoxitin (30µg) disk. If no growth is observed after 24 and 48 hours, the broth culture was determined to be negative.

After inoculation, MRSASelect II plates were incubated in ambient air for up to 28 hours. Pink colonies of any intensity on the MRSASelect II plate were interpreted as indicative of the presence of MRSA.

A summary of the clinical performance of MRSASelect II with skin and soft tissue wound specimens is illustrated in Table 5 below.

Table 5. Clinical Performance of MRSASelect II versus Enriched Broth Culture Reference Method - Skin and Soft Tissue Wound

All Sites (Skin and Soft Tissue Wound)		**Culture Enrichment Broth (Cefoxitin)**		
		POS	NEG	TOTAL
MRSASelect II (Primary Culture)	POS	147	32[(a)]	179
	NEG	5[(b)]	658	663
	TOTAL	152	690	842
All Sites			95% C.I.	
Sensitivity (%)		96.7%	96.0%	97.5%
Specificity (%)		95.4%	94.5%	96.2%
Pos. Predictive Value		82.1%	80.5%	83.7%
Neg. Predictive Value		99.2%	98.9%	99.6%

[a]Discordant analysis was performed for 27 of the 32 specimens identified as MRSA positive by MRSASelect II and negative by enrichment culture. MRSA was confirmed in 17 of the 27 specimens using a PBP2a test.

[b]Discordant analysis was performed for 5 of 5 specimens identified as MRSA negative by MRSASelect II and positive by enrichment culture. MRSA was confirmed in 3 of 5 specimens using a PBP2a test.

b. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off**:** Not applicable.

5. Expected values/Reference range:

Anterior nares specimens - The overall prevalence of MRSA as determined by the enriched broth culture reference method was 10.6% (255/2410). The overall prevalence of MRSA as determined by MRSASelect II was 11.2% (269/2410).

Skin and soft tissue wound specimens - The overall prevalence of MRSA as determined by the enriched broth culture reference method was 18.0% (152/842). The overall prevalence of MRSA as determined by the MRSASelect II was 21.2% (179/842).

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.