K102342

MICROPHAGE

510(k) Summary

As required by 21 CFR Section 807.92(c).

MAY - 5 2011

Submitted by:	MicroPhage, Inc. 2400 Trade Centre Ave Longmont, CO 80503
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Contact:	Drew Smith, PhD
Date of Preparation:	April 29, 2011
Device: Trade name:	KeyPath™ MRSA/MSSA Blood Culture Test – BT
Common name:	Bacterial Identification and Antimicrobial Susceptibility Test (ID/AST); KeyPath™ AST; Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-sensitive *Staphylococcus aureus* (MSSA) from positive blood culture bottles test.
Type of Test:	Bacteriophage amplification, Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-sensitive *Staphylococcus aureus* (MSSA), qualitative
Regulation section:	866.2050 - Staphylococcal typing bacteriophage
Classification:	I
Product code:	OUS
Panel:	83 Microbiology

Predicate Devices:	K071026	BD GeneOhm™ StaphSR Assay
	K851949	Wellcome (Remel) Staphaurex® ZL30
	K011710	Oxoid PBP2' Latex Agglutination
	(preAmendment)	BBL (BD) cefoxitin 30 µg Sensi-Disc
	(preAmendment)	BBL (BD) oxacillin 1 µg Sensi-Disc
	(preAmendment)	Coagulase Test (multiple manufacturers)
	(preAmendment)	Catalase Test (multiple manufacturers)

Device Description:

The KeyPath™ MRSA/MSSA Blood Culture Test – BT uses lytic bacteriophage, specific for *Staphylococcus aureus,* as an amplification technology for detection of *S. aureus* and determination of methicillin resistance or susceptibility in positive blood cultures. To detect *S. aureus* (ID Reaction Tube), the bacteriophage infect the *S. aureus* (if present), replicate within the host (culminating in bacterial lysis) and over the incubation period, produce several cycles of bacteriophage amplification. In a separate Reaction Tube (RS), the Test uses cefoxitin (an oxacillin and methicillin analog) which inhibits bacteriophage amplification for susceptible organisms (MSSA) and fails to inhibit bacteriophage amplification when the organism is resistant to methicillin (MRSA). The Test then uses a self-performing immunoassay (Detector) to detect the increase in concentration of bacteriophage using antibodies specific to the Test bacteriophage, and calibrated such that at above a threshold concentration, it produces a visible signal.

Device Intended Use:

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the timely identification of *Staphylococcus aureus* (*S. aureus*) and determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA) directly from positive blood cultures.

The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance.

The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F and Plus Anaerobic/F).

The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures.

Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing.

Substantial Equivalence:

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent to the BD GeneOhm™ StaphSR Assay (510(k)# K071026). Both assays are indicated for the identification/detection of *S. aureus* from blood culture positives and both are indicated for determination/detection of MRSA. Though each use different technologies (bacteriophage amplification vs. RT – PCR), and the MicroPhage Test is *phenotypic* as opposed to *genotypic*, both perform with high sensitivity and specificity to their intended targets. Table 1 summarizes the major similarities and differences between these two methods.

Table 1 – Similarities and Differences between the KeyPath™ MRSA/MSSA Blood Culture Test – BT and the BD GeneOhm™ StaphSR assay.

SIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**BD GeneOhm™ StaphSR Assay**
Intended Use	The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the **timely identification of *Staphylococcus aureus* (*S. aureus*) and determination of** methicillin susceptibility (MSSA) or **methicillin resistance (MRSA) directly from positive blood cultures.** The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance. **The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain.** The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F and Plus Anaerobic/F). The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures. Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing	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.
Single Use	Yes	Yes
Indication for Use	Professional Use	Professional Use
Interpretation of results	Visual	Visual
Patient population	Clinical patients	Clinical patients
Specimen type	Positive blood culture	Positive blood culture

Assay controls	Pos Control 1: MRSA Pos Control 2: MSSA Neg Control: NSA	Pos Control: MRSA Pos Control: SA Neg Control: NSA

DISSIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test - BT**	**BD GeneOhm™ StaphSR Assay**
Time to result	5 hours	60-75 minutes
Mode of action	The test uses bacteriophage amplification with cefoxitin to quickly determine the presence of MRSA and MSSA in positive blood cultures.	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.
Assay format	Amplification: bacteriophage amplification Detection: Lateral flow immunoassay with colloidal gold particles with monoclonal antibodies specific to assay bacteriophage.	Amplification: polymerase chain reaction (PCR) Detection: Fluorogenic target-specific hybridization probes of the amplified DNA.

*Bolded and underlined portions indicates similarities of intended use.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent to combined Coagulase and Catalase Test (both pre-amendment). Both Coag/Cat and MicroPhage Tests are indicated for the identification or detection of *S. aureus* and are phenotypic tests. Table 2 summarizes the major similarities and differences between these two methods.

Table 2 – Similarities and Differences between the KeyPath™ MRSA/MSSA Blood Culture Test – BT and the Coagulase Tube and Catalase Slide Tests.

SIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Coagulase Tube, Catalase Slide Tests (pre-amendment)**
Intended Use	The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the **timely identification of *Staphylococcus aureus* (*S. aureus*)** and determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA) directly from positive blood cultures. The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance. **The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain.** The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F and Plus Anaerobic/F). The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures. Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing	The Coagulase Tube and Catalase Slide Tests (multiple manufacturers) are qualitative *in vitro* diagnostic test for the **identification of *Staphylococcus aureus* (SA)** directly from isolated colonies from a positive blood culture. "Positive" results for both catalase and coagulase are indicative of *S. aureus*. The assays contain rabbit serum with EDTA for Coagulase Test and peroxide (H_2O_2) for Catalase Test substrates which will react with coagulase and catalase enzymes expressed by *S. aureus*. A clumping of rabbit serum confirms the presence of coagulase and production of O_2 bubbles confirms the presence of catalase (i.e. both results indicating presence of *S. aureus*). **The assay is performed on gram positive cocci which have been isolated by streaking on culture plates, identified by Gram stain, from positive blood cultures.** Further subculturing of positive blood cultures are necessary for susceptibility testing.
Single Use	Yes	Yes
Indication for Use	Professional Use	Professional Use
Interpretation of results	Visual	Visual
Patient population	Clinical patients	Clinical patients

Table 2 – Similarities and Differences between the KeyPath™ MRSA/MSSA Blood Culture Test – BT and Coagulase/Catalase Tests for *S. aureus* determination.

DISSIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Coagulase Tube, Catalase Slide Tests (pre-amendment)**
Specimen type	Positive blood culture	Overnight purified plate culture (i.e. isolated colonies) originating from a Positive blood

DISSIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Coagulase Tube, Catalase Slide Tests (pre-amendment)**
		culture
Time to result	5 hours	Catalase: 5 minutes Coagulase: 4-24 hours
Mode of action	The test uses bacteriophage amplification with cefoxitin to quickly determine the presence of MRSA and MSSA in positive blood cultures.	The assays contain rabbit serum with EDTA for the Coagulase Test and peroxide (H_2O_2) for the Catalase Test, substrates which will react with coagulase and catalase enzymes expressed by *S. aureus*. A clumping of rabbit serum confirms the presence of coagulase and production of O_2 bubbles confirms the presence of catalase. Both results indicate the presence of *S. aureus*.
Assay format	Amplification: bacteriophage amplification Detection: Lateral flow immunoassay with colloidal gold particles with monoclonal antibodies specific to assay bacteriophage.	Amplification: none Detection: Clumping of coagulase substrate and O_2 gas production (i.e. bubbles) of catalase substrate when metabolized by the respective enzymes.

*Bolded and underlined portions indicates similarities of intended use.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent to Remel Staphaurex® (510(k)# K851949). Both assays are indicated for the identification or detection of *S. aureus* and are phenotypic tests. Additionally, both use antibody-based detection methods (lateral flow immunoassay vs. latex agglutination). Table 3 summarizes the major similarities and differences between these two methods.

Table 3 – Similarities and Differences between the KeyPath™ MRSA/MSSA Blood Culture Test – BT and Wellcome (Remel) Staphaurex® for *S. aureus* determination.

SIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Remel Staphaurex®**
Intended Use	The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the **timely identification of *Staphylococcus aureus* (*S. aureus*)** and determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA) directly from positive blood cultures. The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance. The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain. The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F	Staphaurex® is a rapid slide agglutination procedure for **differentiating staphylococci which possess clumping factor and/or protein A, particularly *Staphylococcus aureus*, from staphylococci which possess neither of these factors.**

SIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Remel Staphaurex®**
	and Plus Anaerobic/F). The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures. Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing	
Single Use	Yes	Yes
Indication for Use	Professional Use	Professional Use
Interpretation of results	Visual	Visual
Patient populations	Clinical patients	Clinical patients
Assay controls	Pos Control 1: MRSA Pos Control 2: MSSA Neg Control: NSA	Pos Control: SA Neg Control: NSA

DISSIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Remel Staphaurex®**
Specimen type	Positive blood culture	Overnight Purified Culture (16 – 24hr)
Time to result	5 hours	10 - 15 minutes
Mode of action	The test uses bacteriophage amplification with cefoxitin to quickly determine the presence of MRSA and MSSA in positive blood cultures.	The test detects the presence of clumping factor and protein A using coated latex particles which agglutinate in a rapid slide procedure.
Assay format	Amplification: bacteriophage amplification Detection: Lateral flow immunoassay with colloidal gold particles with monoclonal antibodies specific to assay bacteriophage.	Amplification: none Detection: Agglutination of latex particles.

*Bolded and underlined portions indicates similarities of intended use.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent to the Oxoid PBP2' Latex Agglutination test (510(k)# K011710). Both assays are indicated for the determination or identification of MRSA by surrogate markers (bacteriophage amplification vs. penicillin binding protein 2'). Additionally, both use antibody-based detection methods (lateral flow immunoassay vs. latex agglutination) and are phenotypic tests. Table 4 summarizes the major similarities and differences between these two methods.

Table 4 – Similarities and Differences between the KeyPath™ MRSA/MSSA Blood Culture Test – BT and Oxoid PBP2' Latex Agglutination for MRSA determination.

SIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Oxoid PBP2' Latex Agglutination Test**
Intended Use	The KeyPath™ MRSA/MSSA Blood Culture Test – BT is	This test is a rapid latex

SIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Oxoid PBP2' Latex Agglutination Test**
	a qualitative *in vitro* diagnostic test for the timely identification of *Staphylococcus aureus* (*S. aureus*) and **determination of** methicillin susceptibility (MSSA) **or methicillin resistance (MRSA)** directly from positive blood cultures. The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance. The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain. The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F and Plus Anaerobic/F). The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures. Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing	agglutination assay, detecting PBP2' (also called PBP2a), in isolates of *Staphylococcus*, as an aid in **identifying methicillin-resistant *Staphylococcus aureus* (MRSA)** and methicillin-resistant coagulase-negative staphylococci.
Single Use	Yes	Yes
Indication for Use	Professional Use	Professional Use
Interpretation of results	Visual	Visual
Patient populations	Clinical patients	Clinical patients
Assay controls	Pos Control 1: MRSA Pos Control 2: MSSA Neg Control: NSA	Pos Control: MRSA Neg Control: NSA

DISSIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Oxoid PBP2' Latex Agglutination Test**
Specimen	Positive blood culture	Overnight Purified Culture (16 – 24 hrs)
Time to result	5 hours	45 minutes
Mode of action	The test uses bacteriophage amplification with cefoxitin to determine the presence of MRSA and MSSA in positive blood cultures.	Latex particles sensitized with a monoclonal antibody against PBP2' specifically react with methicillin-resistant staphylococci to cause agglutination visible to the unaided eye.
Assay format	Amplification: bacteriophage amplification Detection: lateral flow immunoassay with	Amplification: none

DISSIMILARITIES		
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**Oxoid PBP2' Latex Agglutination Test**
	colloidal gold particles with monoclonal antibodies specific to assay bacteriophage.	Detection: Agglutination of latex particles

*Bolded and underlined portions indicates similarities of intended use.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent to the BD BBL 30 µg cefoxitin Sensi-Disc and BD BBL 1 µg oxacillin Sensi-Disc (both pre-Amendment devices). All three assays are indicated for the phenotypic determination of MRSA and MSSA. Additionally, all use a viable culture of bacteria (e.g., *S. aureus*) to guide interpretation of results, though the MicroPhage Test does not require a subculture of the isolate. All methods produce highly sensitive and specific results for their indicated determinations with low rates of major and very major discrepancies. Table 5 summarizes the major similarities and differences between these two methods.

Table 5 – Similarities and Differences between the KeyPath™ MRSA/MSSA Blood Culture Test – BT, the BD BBL 30 µg cefoxitin Sensi-Disc, and the BD BBL 1 µg oxacillin Sensi-Disc for MRSA/MSSA breakpoint determinations.

SIMILARITIES			
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**BD BBL cefoxitin 30 µg Sensi-disc**	**BD BBL oxacillin 1 µg Sensi-disc**
Intended Use	The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the timely identification of *Staphylococcus aureus* (*S. aureus*) and **determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA)** directly from positive blood cultures. The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance. The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain. The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F and Plus Anaerobic/F). The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures.	These discs are used for semi-quantitative ***in vitro* susceptibility testing** by the agar disc diffusion test procedure of common, rapidly growing and certain fastidious bacterial pathogens.	These discs are used for semi-quantitative ***in vitro* susceptibility testing** by the agar disc diffusion test procedure of common, rapidly growing and certain fastidious bacterial pathogens.

SIMILARITIES			
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**BD BBL cefoxitin 30 µg Sensi-disc**	**BD BBL oxacillin 1 µg Sensi-disc**
	Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing		
Single Use	Yes	Yes	Yes
Indication for Use	Professional Use	Professional Use	Professional Use
Interpretation of results	Visual	Visual	Visual
Patient populations	Clinical patients	Clinical patients	Clinical patients
Assay controls	Pos Control 1: MRSA Pos Control 2: MSSA Neg Control: NSA	Pos Control: MRSA Neg Control: MSSA	Pos Control: MRSA Neg Control: MSSA

DISSIMILARITIES			
Item	**KeyPath™ MRSA/MSSA Blood Culture Test – BT**	**BD BBL cefoxitin 30 µg Sensi-disc**	**BD BBL oxacillin 1 µg Sensi-disc**
Specimen	Positive blood culture	Overnight Culture	Overnight Culture
Time to result	5 hours	18-24 hours	18-24 hours
Mode of action	The test uses bacteriophage amplification with cefoxitin to quickly determine the presence of MRSA and MSSA in positive blood cultures.	Diffusion of antibiotic into lawn of *S. aureus*.	Diffusion of antibiotic into lawn of *S. aureus*.
Assay format	Amplification: bacteriophage amplification Detection: lateral flow immunoassay with colloidal gold particles with monoclonal antibodies specific to assay bacteriophage.	Amplification: none Detection: Visual interpretation of zone of inhibition.	Amplification: none Detection: Visual interpretation of zone of inhibition.

*Bolded and underlined portions indicates similarities of intended use.

Clinical Comparison Study

MicroPhage conducted a prospective clinical trial on the KeyPath™ MRSA/MSSA Blood Culture test – BT to assess the performance characteristics across four clinical sites against culture and predicate methods.

Subjects included individuals with positive blood cultures on a BACTEC™ blood culture system (9000 series or F/X). Samples were included if they were from subjects 18 years of age or older and the sample was tested on the KeyPath™ MRSA/MSSA Blood Culture Test – BT within 24 hours of positive determination on BACTEC™ System (i.e. alarm). Aliquots of the blood culture were used to perform a standard culture identification for *S. aureus* (Catalase positive, Tube Coagulase positive, Remel Staphaurex® positive) and antimicrobial susceptibility determination (30 µg cefoxitin disk diffusion) in accordance with CLSI M100-S19.

There were a total of 1116 (366 *S. aureus*) paired samples tested for MRSA/MSSA by the KeyPath™ MRSA/MSSA Blood Culture Test – BT and the standard methods across all study sites.

Sensitivity and specificity of the MRSA/MSSA Blood Culture Test – BT vs. the standard method for detection of *S. aureus* were 91.8% and 98.3%, respectively. The positive predictive value was 96.3%, and the negative predictive value was 96.1%.

For samples determined to be *S. aureus*, category agreement with the cefoxitin disk diffusion test was 98.9% for determination of methicillin resistance, and 99.4% for determination of methicillin susceptibility.

The initial invalid rate was 0.3%, and all invalids were resolved upon retest.

No significant differences in performance were observed across sites, or between blood culture bottle types.

No significant effect was observed in the performance of the KeyPath™ Test in the presence or absence of antibiotic or antiviral treatments.

Non-clinical Studies

Reproducibility – The KeyPath™ Test was found to be 99.4% reproducible in 648 runs at three sites (2 operators per site) over 6 days, when tested against 2 MRSA, 2 MSSA and 1 *S. epidermidis* strains.

Inclusivity – A panel of 114 *S. aureus* strains representing the phylogenetic diversity of *S. aureus* was tested in duplicate with the KeyPath™ Test. The panel included representatives of 17 clonal complexes and 46 multilocus sequence types. The sensitivity for detection of *S. aureus* was 91.8%. Category agreement was 99% for determination of methicillin-resistance and 100% for determination of methicillin-susceptibility.

Interfering substances – The KeyPath™ Test showed no interference when tested against lipemic, icteric and hemolytic blood samples. A panel of 5 antibiotics, 3 analgesics, an antiviral and an anticoagulant was tested and showed no interference. The immunoassay component (the Detector) was tested against a panel of 20 RF-positive, HAMA-positive and heterophilic antibody sera and showed no cross-reaction to any. The Detector was also tested against a panel of 32 human viruses and showed no cross-reaction.

Mixed culture – MRSA could be reliably detected by the KeyPath™ Test in mixed cultures comprised of ~90% (or greater) Gram negative rods and bacilli, Gram positive cocci in clusters (not *S. aureus*) and Gram positive rods.

Analytical specificity – A panel of 163 isolates comprised of 33 Gram-negative isolates (29 species), 58 Gram-positive not *Staphylococci* (49 species), 5 coagulase-positive *Staphylococci* (5 species), 60 coagulase-negative *Staphylococci* (9 species) and 7 yeast (7 species) was tested and showed 98.8% specificity.

Evaluation of SCCmec Empty Cassette Variants – A panel of 28 strains determined to be *mecA*-positive (MRSA) by commercial and laboratory PCR tests but MSSA by phenotypic culture methods was tested. All 28 strains were determined to be MSSA by the KeyPath™ Test.

We conclude that the performance of the KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent to:

1) Coagulase/catalase and Staphaurex® Test for detection of *S.aureus* from positive BACTEC™ blood cultures,
2) BD BBL Cefoxitin 30µg and BD BBL Oxacillin 1µg Sensi-disc Tests for determination of MRSA and MSSA from *S. aureus* positive Bactec™ blood cultures,
3) Oxoid PBP2' Latex Agglutination Test for determination of MRSA from *S. aureus* positive Bactec™ blood cultures, and
4) BD GeneOhm™ StaphSR Assay for determination of *S. aureus* and MRSA from positive blood cultures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MicroPhage, Inc.
c/o Drew Smith, Ph. D.
Chief Science Officer
2400 Trade Centre Avenue
Longmont, Colorado 80503

MAY - 5 2011

Re: k102342
Trade/Device Name: MicroPhage MRSA/MSSA Blood Culture Test-BT
Regulation Number: 21 CFR 866.2050
Regulation Name: Staphylococcal typing bacteriophage
Regulatory Class: Class I
Product Code: OUS
Dated: May 3, 2011
Received: May 3, 2011

Dear Dr. Smith:

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.

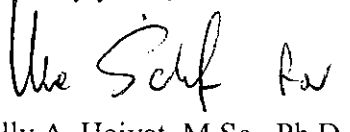
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

MicroPhage, Inc.
2400 Trade Centre Ave.
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510(k) Number: k102342
Device Name: KeyPath™ MRSA/MSSA Blood Culture Test – BT

Indications for Use Statement

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the timely identification of *Staphylococcus aureus* (*S. aureus*) and determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA) directly from positive blood cultures.

The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance.

The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F and Plus Anaerobic/F).

The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures.

Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use ____X____ OR Over-The-Counter-Use _____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K 102342