

**INSTRUCTION FOR COMPLETING
510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

K103532

B. Purpose for Submission:

The purpose of the submission is for the 510(k) clearance of the OptiRead™ (Autoreader-2) to replace the existing Autoreader-1. This submission includes performance data specific to the non-fastidious and the fastidious Gram positive cocci.

C. Measurand:

The OptiRead™ (Autoreader2) automatically reads the Sensititre MIC and Breakpoint (BP) Susceptibility test panels and interprets the antimicrobial susceptibility test results for non-fastidious and fastidious Gram positive cocci.

D. Type of Test:

Antimicrobial Susceptibility Test (AST) - Quantitative. The OptiRead™ is an automated fluorescence based growth detection instrument used to read MIC or breakpoint micro-broth dilution susceptibility plates.

E. Applicant:

TREK Diagnostic Systems

F. Proprietary and Established Names:

Sensititre® OptiRead™

G. Regulatory Information:

1. Regulation section:

21 CFR Section 866.1640, Antimicrobial Susceptibility Test Powder

2. Classification:

Class II

3. Product code:

LRG

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use(s):

The Sensititre® OptiRead™ is intended for use with the Sensititre MIC or BP Susceptibility Test System. The Sensititre OptiRead™ is a fluorescence based detection instrument used to read Sensititre MIC or BP Susceptibility plates.

The Sensititre® MIC or Breakpoint Susceptibility System is an in vitro diagnostic product for clinical susceptibility testing of non-fastidious and fastidious Gram positive cocci to include Staphylococcus spp., Enterococcus spp., Streptococcus pneumoniae and other Streptococcus spp.

Note: Please refer to the Sensititre® 18-24 hour MIC or Breakpoint Susceptibility System package insert or operator's manual for additional instructions, limitations and references.

2. Indication(s) for use:

The Sensititre® OptiRead™ is intended for use with the Sensititre MIC or BP Susceptibility Test System. The Sensititre OptiRead™ is a fluorescence based detection instrument used to read Sensititre MIC or BP Susceptibility plates.

The Sensititre® MIC or Breakpoint Susceptibility System is an in vitro diagnostic product for clinical susceptibility testing of non-fastidious and fastidious Gram positive cocci to include Staphylococcus spp., Enterococcus spp., Streptococcus pneumoniae and other Streptococcus spp.

Note: Please refer to the Sensititre® 18-24 hour MIC or Breakpoint Susceptibility System package insert or operator's manual for additional instructions, limitations and references.

3. Special conditions for use statement(s):

Prescription use only.

4. Special instrument requirements:

The OptiRead™ should be used in conjunction with the Sensititre Autoinoculator.

I. Device Description:

The OptiRead™ is a fluorescence based detection system used to read Sensititre MIC or BP Susceptibility plates. The system uses a 360nm wavelength light emitting diode (LED) to excite the sample within each microtitre plate well. The excitation/emission light from each well is then collected using a photodiode. The microtitre plate is held on the OptiRead™ and each well is individually read by the optics positioned beneath the plate. The data of each microtitre plate well is outputted to a personal computer (PC) as comma separated data which is formatted for input into Trek SWIN software.

The OptiRead™ is a replacement to the existing AutoReader1. In comparison the Autoreader1, the OptiRead™ has a reduced footprint and an increased cycle speed.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Autoreader1

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

N50-531

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Fluorescence-based detection device	Same
Isolates	Isolates in pure culture used	Same
Sample Preparation	0.5 McFarland isolate concentration used	Same
Reading Environment	Reading occurs in the dark	Same
Excitation/Detection Optics	360nm excitation source filtering with a 450nm bypass dichroic detection filter	Same
Calibration Method	Self calibration against a solid, non-drifting calibrator material block, before reading each susceptibility plate	Same
Count Range	0-4096 counts	Same
Raw Data Output	Output as a series of microtitre plate well readings along with calibration well readings as comma separated data formatted for input into SWIN software	Same
Result Reported	Results reported as minimum inhibitory concentration (MIC) value and an interpretation of susceptible, intermediate, or resistant (SIR)	Same

Differences		
Item	Device	Predicate
Instrument Size	357.5 mm wide 264 mm deep 188.5 mm high	419 mm wide 470 mm deep 191 mm high
Cycle Speed	15 seconds	45 seconds
Well Indexing Method	Moveable optics reading stationary microtitre plate from underneath.	Microtitre plate moved mechanically over stationary optics underneath
Excitation Source	Flash xenon lamp filtered to a 360 nm wavelength	Light emitting diode, 360 nm wavelength
Method of Signal Detection	Photomultiplier tube	Photodiode tube

K. Standard/Guidance Document(s) referenced (if applicable):

- Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA;
- CLSI M100-S20, Performance Standard for Antimicrobial Susceptibility Testing; Twentieth Informational Supplement;
- CLSI M7-A8, Methods for Dilution Antimicrobial Susceptibility Test for Bacteria that Growth Aerobically; Approved Standard, Eighth Edition.

L. Test Principle:

The Sensititre MIC or Breakpoint Susceptibility System incorporates the use of 96-well microtitre plates which contain doubling dilutions of specific antimicrobial agents in order to achieve drug concentrations over a specified range. Microtitre plates are inoculated with a fixed concentration of microorganism, covered and incubated. After incubation plates can be read either manually or with an automatic plate reader (e.g. OptiRead™).

The Sensititre® System utilized fluorescence technology for the detection of bacterial growth by monitoring the activity of specific surface enzymes produced by the test organism. Growth is determined by generating a fluorescent product from a non-fluorescent (fluorogenic) substrate. The non-fluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond which prevents fluorescence. The fluorophore is then said to be quenched. The substrate can be added to the inoculum broth and dispensed into the test plates at the same time as the test organism or the plates can be prepared with substrate already added to the plate. Enzymatic action of the bacterial surface enzymes on the specific substrates cleaves this bond releasing the fluorophore which is now capable of fluorescing. The amount of fluorescence detected is directly related to the activity of bacterial growth. The MIC is

determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Gram positive isolates, 25 in total, to include *S. aureus* (10), coagulase-negative *Staphylococcus* (5), *Enterococcus faecalis* (5), *Group A Streptococcus* (3), and *Group B Streptococcus* (2) were tested. The isolates listed above were tested against the following antibiotics, representative of the major antimicrobial classes: Oxacillin, Penicillin, Rifampin, Clindamycin, Tetracycline, Erythromycin, Ciprofloxacin, Synercid, Daptomycin, Vancomycin, Linezolid, Chloramphenicol, high level Gentamicin, high level Streptomycin, SXT, Gentamicin, Cefoxitin Screen and D-test.

In addition, *Streptococcal* isolates, 25 in total, to include *S. pneumoniae* (10), *Viridans Streptococcus* (5), *Group A Streptococcus* (6), and *Group B Streptococcus* (4) were tested. The *Streptococcal* isolates listed above were tested against the following antibiotics, representative of the major antimicrobial classes: Clindamycin, Penicillin, Amoxicillin/Clavulanic Acid, Chloramphenicol, Cefepime, Cefotaxime, Meropenem, Tetracycline, Erythromycin, Daptomycin, Linezolid, Levofloxacin, Vancomycin and SXT.

All isolates were tested once at each of three designated study sites. At each site, susceptibility plates were set up using the Autoinoculator and test results were read using Autoreader1 and the OptiRead™. The percent reproducibility was calculated as the number of isolates whose MICs fall within +/- one doubling dilution of the mode, out of the total number of isolates tested across all three study sites.

Review of the reproducibility study data revealed a number of antibiotic/organism combinations that lacked a sufficient number of on-scale MIC results. The antibiotics included the following:

- Gram positive reproducibility study – Oxacillin, Penicillin, Rifampin, Clindamycin, Erythromycin, Synercid and SXT.
- Streptococcal reproducibility study – Tetracycline and Erythromycin

To resolve this issue, an additional modified reproducibility study was conducted which included the testing of 10 isolates (with known on-scale results), in triplicate with three different operators; performed on three different days; using three separate OptiRead™ instruments.

In summary, despite a number of isolates with off-scale MIC results, the percent reproducibility for all antibiotic/organism combinations tested met the acceptance criteria of >95% based on the “best-case” percent calculation.

b. *Linearity/assay reportable range:*

Not Applicable

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

The FDA and CLSI recommended Quality Control (QC) isolates, to include, *S. aureus* BAA-976, *S. aureus* 29213, *S. aureus* BAA-977, *E. faecalis* 29212, *E. faecalis* 51299 and *S. pneumoniae* 49619, were included each day of testing.

All QC susceptibility plates were set up using the Autoinoculator and tested using the existing Autoreader1 and the OptiRead™, at each study site.

All QC results fall within acceptable range. A summary of the QC results are shown in the tables below.

Table 1. Quality Control <i>S. aureus</i> 29213	Concentration (ug/mL)	Autoreader1	OptiRead™
Oxacillin Expected MIC Range 0.12 - 0.5 ug/mL	≤0.25	21	16
	0.5	39	44
	1		
Penicillin Expected MIC Range 0.25 - 2	0.25	8	10
	0.5	39	37
	1	13	13
	2		
Linezolid Expected MIC Range 1 - 4 ug/mL	1		
	2	51	53
	4	9	7
Rifampin Expected MIC Range 0.004 - 0.015 ug/mL	≤ 0.5	60	60
	1		
Chloramphenicol Expected MIC Range 2 - 16 ug/mL	2		
	4		
	8	56	59
	16	4	4
Clindamycin Expected MIC Range 0.06 - 0.25 ug/mL	≤0.12	60	60
	0.25		
Tetracycline Expected MIC Range ≤ 0.12 - 1 ug/mL	≤ 0.12	1	
	0.25	37	38
	0.5	22	22
	1		
Erythromycin Expected MIC Range 0.25 - 1 ug/mL	0.25		5
	0.5	59	55
	1	1	
Ciprofloxacin	≤0.12		

Table 1. Quality Control <i>S. aureus</i> 29213	Concentration (ug/mL)	Autoreader1	OptiRead™
Expected MIC Range ≤0.12 – 0.5 ug/mL	0.25	8	9
	0.5	52	51
Synercid Expected MIC Range 0.25 – 1 ug/mL	≤1	60	60
Daptomycin Expected MIC Range 0.12 – 1 ug/mL	0.25	44	44
	0.5	16	16
	1		
Vancomycin Expected MIC Range ≤0.5 – 2 ug/mL	≤0.5		
	1	58	60
	2	2	
TMP/SXT Expected MIC Range ≤0.5/9.5 ug/mL	≤0.25	60	60
	0.5		
Gentamicin Expected MIC Range ≤0.12 – 1 ug/mL	≤0.12	1	2
	0.25	40	39
	0.5	19	19
	1		

Table 2. Quality Control <i>E. faecalis</i> 29212	Concentration (ug/mL)	Autoreader1	OptiRead™
Oxacillin Expected MIC Range 8 – 32 ug/mL	8	37	27
	16	23	33
	32		
Penicillin Expected MIC Range 1 – 4 ug/mL	1		
	2	60	60
	4		
	8		
Linezolid Expected MIC Range 1 – 4 ug/mL	1	10	6
	2	50	54
	4		
Rifampin Expected MIC Range ≤0.5 – 4 ug/mL	≤0.5	48	42
	1	12	18
	2		
	4		
Chloramphenicol Expected MIC Range 4 – 16 ug/mL	2		
	4	35	36
	8	25	23
	16		1
Clindamycin Expected MIC Range 4 – 16 ug/mL	2		
	4		
	8	2	2
	16	58	58
Tetracycline Expected MIC Range 8-32 ug/mL	4		
	8		
	16	53	51
	32	7	9
Erythromycin Expected MIC Range 1 – 4 ug/mL	0.5		
	1	20	18
	2	40	41
	4		1
Ciprofloxacin Expected MIC Range 0.25 – 2 ug/mL	0.25		
	0.5	52	50
	1	8	10
	2		
Synercid Expected MIC Range	2		
	4	48	48

Table 2. Quality Control <i>E. faecalis</i> 29212	Concentration (ug/mL)	Autoreader ¹	OptiRead™
2 – 8 ug/mL	8	12	12
	>32		
Daptomycin Expected MIC Range 1 – 4 ug/mL	0.5		
	1	32	33
	2	28	27
	4		
Vancomycin Expected MIC Range 1 – 4 ug/mL	1		
	2	40	32
	4	20	28
TMP/SXT Expected MIC Range ≤ 0.5/9.5	≤ 0.25	60	60
	0.5		
	1		
Gentamicin Expected MIC Range 4 - 16 ug/mL	4	3	2
	8	47	37
	16	10	21
Gentamicin 500 Expected MIC Range ≤ 500 ug/mL	≤ 500	60	60
	≥ 500		
Streptomycin 1000 Expected MIC Range ≤ 1000 ug/mL	≤ 1000	60	60
	≥ 1000		

Table 3. Quality Control <i>E. faecalis</i> 51299	Concentration (ug/mL)	Autoreader ¹	OptiRead™
Gentamicin 500 Expected MIC Range ≥ 500 ug/mL	≤ 500		
	≥ 500	30	30
Streptomycin 1000 Expected MIC Range ≥ 1000 ug/mL	≤ 1000		
	≥ 1000	30	30

Table 4. Quality Control <i>S. pneumoniae</i> 49619	Concentration (ug/mL)	Autoreader ¹	OptiRead™
Clindamycin Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	41	39
	0.12	16	18
Penicillin Expected MIC Range 0.25 – 1 ug/mL	0.25	32	30
	0.5	25	27
	1		
Amox/Clav Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	54	55
	0.12	3	2
Linezolid Expected MIC Range 0.25 – 2 ug/mL	0.25		
	0.5	2	3
	1	55	54
	2		
Chloramphenicol Expected MIC Range 2 – 8 ug/mL	2	2	2
	4	52	52
	8	3	3
Cefepime Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	56	56
	0.12	1	1
Cefotaxime Expected MIC Range 0.03 – 0.12 ug/mL	0.03	1	1
	0.06	55	54
	0.12	1	2
Meropenem Expected MIC Range 0.06 – 0.25 ug/mL	0.06	56	57
	0.12	1	
	0.25		
	0.5		
Tetracycline Expected MIC Range 0.06 – 0.5 ug/mL	0.06		
	0.12	6	8
	0.25	50	48
	0.5	1	1
Erythromycin Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	41	41
	0.12	16	16
Levofloxacin Expected MIC Range 0.5 – 2 ug/mL	0.5	4	5
	1	53	52
	2		
	4		
Daptomycin Expected MIC Range 0.06 – 0.5 ug/mL	0.06		
	0.12	18	17
	0.25	36	36
	0.5	3	4
Vancomycin Expected MIC Range 0.12 – 0.5 ug/mL	0.12		
	0.25	55	55
	0.5	2	2
TMP/SXT Expected MIC Range 0.12 – 1 ug/mL	0.12	1	1
	0.25	43	42
	0.5	10	12
	1	3	2

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Not Applicable

f. *Assay cut-off:*

Not Applicable

2. Comparison studies:

Method comparison with predicate device:

The performance of the OptiRead™ was evaluated by means of a clinical study conducted at three sites. The studies were designed to evaluate the performance of the OptiRead™ compared to the existing Autoreader1 using Sensititre® 18-24 hour susceptibility plates. Specially prepared susceptibility plates containing serial dilutions of select antibiotics representing a range of antimicrobial agent classes were used in the study. Each microorganism suspension was prepared using the Sensititre® Nephelometer. Each plate was inoculated with the prepared microorganism suspension using the Sensititre® Autoinoculator, incubated for 18-24 hours at 35°C, and then read using both the Autoreader1 and the OptiRead™. The MIC results read and interpreted by the Autoreader1 were compared to the MIC results read and interpreted by the OptiRead™. The performance criteria described in the Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems were used to evaluate the performance of the OptiRead™.

Clinical testing was performed on a total of (533) Gram positive clinical and challenge isolates to include, *S. aureus* (89), *Staphylococcus spp.*, coagulase negative (63), *Enterococcus spp.* (56), *Beta-hemolytic Streptococcus Groups C,F and G* (27), *S. pyogenes* (73), *S. agalactiae* (69), *S. pneumoniae* (84), *S. bovis* (2) and *Viridans Streptococcus* (70).

The growth rate for the 533 Gram positive clinical and challenge isolates was 99.8%.

The performance evaluations are illustrated in the tables to follow.

Table 5 – Non-Fastidious Gram positives Autoreader₁ versus OptiRead™

Drug	Organism Group	Clinical	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Oxacillin	Coagulase-negative Staph	43	19	62	31	98.4	96.8	100	39	0	0	0
	<i>S. aureus</i>	62	27	89	56	100	100	100	42	0	0	0
Penicillin	Coagulase-negative Staph	43	19	62	38	100	100	96.8	49	0	2	0
	Enterococcus species	40	16	56	41	100	100	100	150	0	0	0
	<i>S. aureus</i>	62	27	89	31	100	100	100	77	0	0	0
	<i>S. agalactiae</i>	0	5	5	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	0	100	na	100	0	0	0	0
Linezolid	Coagulase-negative Staph	43	19	62	33	100	100	100	1	0	0	0
	Enterococcus species	40	16	56	48	100	100	100	5	0	0	0
	<i>S. aureus</i>	62	27	89	89	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	0	5	5	5	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	6	100	100	100	0	0	0	0
Rifampin	Coagulase-negative Staph	43	19	62	3	100	100	100	3	0	0	0
	Enterococcus species	40	16	56	31	100	100	92.9	16	4	0	0
	<i>S. aureus</i>	62	27	89	1	100	100	100	2	0	0	0
Chloramphenicol	Coagulase-negative Staph	43	19	62	59	100	100	100	3	0	0	0
	Enterococcus species	40	16	56	46	98.2	100	98.2	9	1	0	0
	<i>S. aureus</i>	62	27	89	84	100	100	97.8	5	2	0	0
	<i>S. agalactiae</i>	0	5	5	5	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	6	100	100	100	0	0	0	0
Clindamycin	Coagulase-negative Staph	43	19	62	9	100	100	100	22	0	0	0
	<i>S. aureus</i>	62	27	89	3	100	100	100	17	0	0	0
	<i>S. agalactiae</i>	0	5	5	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	0	100	na	100	0	0	0	0
Tetracycline	Coagulase-negative Staph	43	19	62	45	100	100	100	19	0	0	0
	Enterococcus species	40	16	56	22	100	100	100	46	0	0	0
	<i>S. aureus</i>	62	27	89	79	100	100	100	12	0	0	0
	<i>S. agalactiae</i>	0	5	5	4	100	100	100	4	0	0	0
	<i>S. pyogenes</i>	0	6	6	5	100	100	100	1	0	0	0

Table 5. Non-Fastidious Gram Positives Autoreader₁ versus OptiRead™ con't.

Drug	Organism Group	Clinical	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Erythromycin	Coagulase-negative Staph	43	19	62	9	100	100	100	37	0	0	0
	Enterococcus species	40	16	56	18	100	100	100	34	0	0	0
	<i>S. aureus</i>	62	27	89	32	100	100	98.9	58	1	0	0
	<i>S. agalactiae</i>	0	5	5	1	100	100	100	1	0	0	0
	<i>S. pyogenes</i>	0	6	6	0	100	100	100	0	0	0	0
Ciprofloxacin	Coagulase-negative Staph	43	19	62	32	100	100	100	31	0	0	0
	<i>S. aureus</i>	62	27	89	61	100	100	100	30	0	0	0
Synercid (Quinupristin/ Dalfopristin)	Coagulase-negative Staph	43	19	62	0	100	na	100	1	0	0	0
	<i>Enterococcus faecium</i>	12	5	17	4	100	100	100	2	0	0	0
	<i>S. aureus</i>	62	27	89	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	0	100	na	100	0	0	0	0
Daptomycin	Coagulase-negative Staph	43	19	62	56	100	100	100	1	0	0	0
	Enterococcus species	40	16	56	53	100	100	100	2	0	0	0
	<i>S. aureus</i>	62	27	89	87	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	0	5	5	5	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	0	100	na	100	0	0	0	0
Vancomycin	Coagulase-negative Staph	43	19	62	57	100	100	100	0	0	0	0
	Enterococcus species	40	16	56	27	100	100	98.2	25	1	0	0
	<i>S. aureus</i>	62	27	89	84	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	0	5	5	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	0	6	6	0	100	na	100	0	0	0	0
TMP/SXT	<i>S. aureus</i>	62	27	89	2	100	100	100	2	0	0	0
Gentamicin	Coagulase-negative Staph	43	19	62	23	98.4	95.7	100	15	0	0	0
	<i>S. aureus</i>	62	27	89	80	100	100	100	4	0	0	0
Gentamicin (500ug/mL)	Enterococcus species	40	16	56	0	100	na	100	20	0	0	0
Streptomycin (1000ug/mL)	Enterococcus species	40	16	56	0	100	na	100	20	0	0	0
Cefoxitin Screen	<i>S. aureus</i>	62	27	89	na	na	na	100	41	0	0	0
D-test	<i>S. aureus</i>	62	27	89	na	na	na	100	42	0	0	0
D-test	Coagulase-negative Staph	42	19	61	na	na	na	100	30	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Clindamycin	<i>Streptococcus pneumoniae</i>	60	24	84	48	98.8	97.9	98.8	36	0	1	0
Penicillin	Beta-hemolytic Strep Groups C, F, and G	27	0	27	7	100	100	100	0	0	0	0
	Viridans Strep and <i>S. bovis</i>	46	25	71	50	100	100	100	8	0	0	0
	<i>S. agalactiae</i>	53	11	64	54	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	69	100	100	100	51	0	0	0
	<i>S. pyogenes</i>	53	14	67	0	100	na	100	0	0	0	0
Amoxicillin/ Clavulanic Acid	<i>S. pneumoniae</i>	60	24	84	70	100	100	98.8	9	1	0	0
Linezolid	Beta-hemolytic Strep Groups C, F, and G	27	0	27	27	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	64	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	84	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	53	14	67	67	100	100	100	0	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	72	100	100	100	0	0	0	0
Chloramphenicol	Beta-hemolytic Strep Groups C, F, and G	27	0	27	27	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	64	100	100	98.4	0	1	0	0
	<i>S. pneumoniae</i>	60	24	84	55	100	100	100	29	0	0	0
	<i>S. pyogenes</i>	53	14	67	67	100	100	100	0	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	67	100	100	100	0	0	0	0
Cefepime	Beta-hemolytic Strep Groups C, F, and G	27	0	27	27	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	63	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	84	100	100	97.6	3	2	0	0
	<i>S. pyogenes</i>	53	14	67	34	100	100	100	0	0	0	0
Cefotaxime	Beta-hemolytic Strep Groups C, F, and G	27	0	27	19	100	100	100	0	0	0	0
	Viridans Strep + <i>S. bovis</i>	46	25	71	62	100	100	100	4	0	0	0
	<i>S. agalactiae</i>	53	11	64	63	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	73	100	100	100	6	0	0	0
	<i>S. pyogenes</i>	53	14	67	2	100	100	100	0	0	0	0
Meropenem	Beta-hemolytic Strep Groups C, F, and G	27	0	27	7	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	49	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	63	98.8	100	97.6	23	2	0	0
	<i>S. pyogenes</i>	53	14	67	0	100	na	100	0	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	34	100	100	100	7	0	0	0

Table 6. Fastidious Gram Positives (Streptococci) Autoreader¹ versus OptiRead[™] con't.

Drug	Organism Group	Clinical	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Tetracycline	Beta-hemolytic Strep Groups C, F, and G	27	0	27	18	100	100	100	9	0	0	0
	<i>S. agalactiae</i>	53	11	64	10	100	100	100	54	0	0	0
	<i>S. pneumoniae</i>	60	24	84	34	100	100	100	50	0	0	0
	<i>S. pyogenes</i>	53	14	67	57	100	100	98.5	10	1	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	51	98.6	98.0	97.2	21	2	0	0
Erythromycin	Beta-hemolytic Strep Groups C, F, and G	27	0	27	17	100	100	100	10	0	0	0
	<i>S. agalactiae</i>	53	11	64	38	100	100	100	26	0	0	0
	<i>S. pneumoniae</i>	60	24	84	40	100	100	98.8	44	1	0	0
	<i>S. pyogenes</i>	53	14	67	58	100	100	100	9	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	34	100	100	98.6	43	1	0	0
Levofloxacin	Beta-hemolytic Strep Groups C, F, and G	27	0	27	25	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	64	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	84	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	53	14	67	66	100	100	100	0	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	69	100	100	100	4	0	0	0
Daptomycin	Beta-hemolytic Strep Groups C, F, and G	27	0	27	27	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	64	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	53	14	67	65	100	100	100	0	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	63	100	100	98.6	8	0	1	0
Vancomycin	Beta-hemolytic Strep Groups C, F, and G	27	0	27	27	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	53	11	64	64	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	60	24	84	84	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	53	14	67	67	100	100	100	0	0	0	0
	<i>Streptococcus</i> species (Viridans Strep + <i>S. bovis</i>)	47	25	72	71	100	100	100	1	0	0	0
TMP/SXT	<i>S. pneumoniae</i>	60	24	84	36	100	100	100	47	0	0	0

EA – Essential Agreement
CA – Category Agreement
R – Resistant isolates
NS – Not Susceptible isolates

maj – major discrepancies
vmj – very major discrepancies
min – minor discrepancies

Essential Agreement (EA) is when there is agreement between the MIC result read/interpreted using the current Autoreader1 and MIC result read/interpreted using the new OptiRead™ within plus or minus one serial two-fold dilution. Category agreement (CA) is when the OptiRead™ MIC result interpretation agrees exactly with the Autoreader1 MIC result interpretation. Evaluable EA is when the MIC result for both the OptiRead™ and the Autoreader1 are on-scale.

The %EA is acceptable when compared to the reference method as described in the FDA guidance document, “*Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) System; Guidance for Industry and FDA*”.

Overall, the MIC results of the Autoreader1 and the OptiRead™ were very similar, for all antibiotics tested. The %EA and %CA for each microorganism group/antibiotic combination were greater than 90%.

In addition the sponsor wished to claim the use of the OptiRead™ in combination with the ARIS® instrument, its automated bench-top incubating and reading system. In the absence of any performance data in support of this claim the sponsor was asked to conduct additional quality control testing, daily over a period of 20 days for a total of 20 repetitions for each representative antibiotic. The sponsor was asked to conduct testing of the following QC isolates, *S. aureus* 29213, *E. faecalis* 29212, and *S. pneumoniae* 49619.

Also, it was agreed that, in addition to the quality control testing, the sponsor would provide challenge isolate testing, for both fastidious and non-fastidious Gram positive isolates, in support of the claim. Non-fastidious Gram positive cocci, 73 in total, to include *S. aureus* (27), Coagulase negative Staphylococcus spp. (19), Enterococcus spp. (16), *S. pyogenes* (6) and *S. agalactiae* (5), were tested. The isolates were tested against the following antibiotics representative of the major antimicrobial classes: Oxacillin, Penicillin, Linezolid, Rifampin, Chloramphenicol, Clindamycin, Tetracycline, Erythromycin, Ciprofloxacin, Synercid, Daptomycin, Vancomycin, Trimethoprim Sulfamethoxazole, Gentamicin, high level Gentamicin, high level Streptomycin.

Fastidious Gram positive cocci, 74 in total, to include *S. agalactiae* (11), *S. pyogenes* (14), *S. pneumoniae* (24), and Viridans Streptococcus spp. (25), were also tested. The isolates were tested against the following antibiotics representative of the major antimicrobial classes: Clindamycin, Penicillin, Amoxicillin/Clavulanic Acid, Linezolid, Chloramphenicol, Meropenem, Tetracycline, Erythromycin, Levofloxacin, Daptomycin, Vancomycin, Trimethoprim Sulfamethoxazole, Cefotaxime, and Cefepime.

The results of the quality control and challenge isolate performance testing are illustrated

in the following tables.

Table 7. Quality Control <i>S. pneumoniae</i> 49619	Concentration (ug/mL)	Autoreader ¹	ARIS®OptiRead™
Clindamycin Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	20	20
	0.12		
Penicillin Expected MIC Range 0.25 – 1 ug/mL	0.25	16	18
	0.5	4	2
	1		
Amox/Clav Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	20	20
	0.12		
Linezolid Expected MIC Range 0.25 – 2 ug/mL	0.25		
	0.5		
	1	20	20
	2		
Chloramphenicol Expected MIC Range 2 – 8 ug/mL	2		
	4	19	14
	8	1	6
Cefepime Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	20	20
	0.12		
Cefotaxime Expected MIC Range 0.03 – 0.12 ug/mL	0.03	2	4
	0.06	18	16
	0.12		
Meropenem Expected MIC Range 0.06 – 0.25 ug/mL	0.06	20	20
	0.12		
	0.25		
	0.5		
Tetracycline Expected MIC Range 0.06 – 0.5 ug/mL	0.06		
	0.12	1	4
	0.25	19	16
	0.5		
Erythromycin Expected MIC Range 0.03 – 0.12 ug/mL	0.03		
	0.06	20	20
	0.12		
Levofloxacin Expected MIC Range 0.5 – 2 ug/mL			
	0.5		
	1	20	20
	2		
Daptomycin Expected MIC Range 0.06 – 0.5 ug/mL	4		
	0.06		
	0.12	19	20
	0.25	1	
Vancomycin Expected MIC Range 0.12 – 0.5 ug/mL	0.5		
	0.12	3	4
	0.25	17	16
TMP/SXT Expected MIC Range 0.12 – 1 ug/mL	0.5		
	0.12		
	0.25	20	20
	0.5		
	1		

Table 8. Quality Control <i>S. aureus</i> 29213	Concentration (ug/mL)	Autoreader1	ARIS®OptiRead™
Oxacillin Expected MIC Range 0.12 - 0.5 ug/mL	≤0.25	17	17
	0.5	3	3
	1		
Penicillin Expected MIC Range 0.25 - 2	0.25	18	18
	0.5	2	2
	1		
	2		
Linezolid Expected MIC Range 1 - 4 ug/mL	1		
	2	20	20
	4		
Rifampin Expected MIC Range 0.004 - 0.015 ug/mL	≤ 0.5	20	20
	1		
Chloramphenicol Expected MIC Range 2 - 16 ug/mL	2		
	4		
	8	20	20
	16		
Clindamycin Expected MIC Range 0.06 - 0.25 ug/mL	≤0.12	20	20
	0.25		
Tetracycline Expected MIC Range ≤ 0.12 - 1 ug/mL	≤ 0.12	1	3
	0.25	19	17
	0.5		
	1		
Erythromycin Expected MIC Range 0.25 - 1 ug/mL	0.25	2	9
	0.5	18	11
	1		
Ciprofloxacin Expected MIC Range ≤0.12 - 0.5 ug/mL	≤0.12		
	0.25	11	11
	0.5	9	9
Synercid Expected MIC Range 0.25 - 1 ug/mL	≤1	20	20
Daptomycin Expected MIC Range 0.12 - 1 ug/mL	0.25	19	19
	0.5	1	1
	1		
Vancomycin Expected MIC Range ≤0.5 - 2 ug/mL	≤0.5		
	1	20	20
	2		
TMP/SXT Expected MIC Range ≤ 0.5/9.5 ug/mL	≤0.25	20	20
	0.5		
Gentamicin Expected MIC Range ≤0.12 - 1 ug/mL	≤0.12	1	1
	0.25	17	17
	0.5	2	2
	1		

Table 9. Quality Control <i>E. faecalis</i> 29212	Concentration (ug/mL)	Autoreader ¹	ARIS® -OptiRead™
Oxacillin Expected MIC Range 8 – 32 ug/mL	8	13	9
	16	7	11
	32		
Penicillin Expected MIC Range 1 – 4 ug/mL	1		
	2	20	20
	4		
	8		
Linezolid Expected MIC Range 1 – 4 ug/mL	1	19	14
	2	1	6
	4		
Rifampin Expected MIC Range ≤0.5 – 4 ug/mL	≤0.5	20	20
	1		
	2		
	4		
Chloramphenicol Expected MIC Range 4 – 16 ug/mL	2		
	4	16	16
	8	4	4
	16		
Clindamycin Expected MIC Range 4 – 16 ug/mL	2		
	4	2	5
	8	18	15
	16		
Tetracycline Expected MIC Range 8-32 ug/mL	4		
	8	6	7
	16	14	13
	32		
Erythromycin Expected MIC Range 1 – 4 ug/mL	0.5		
	1	20	20
	2		
	4		
Ciprofloxacin Expected MIC Range 0.25 – 2 ug/mL	0.25		
	0.5	20	20
	1		
	2		
Synercid Expected MIC Range 2 – 8 ug/mL	2		
	4		
	8	20	20
	>32		
Daptomycin Expected MIC Range 1 – 4 ug/mL	0.5		
	1	14	15
	2	6	5
	4		
Vancomycin Expected MIC Range 1 – 4 ug/mL	1		
	2	17	18
	4	3	2
TMP/SXT Expected MIC Range ≤0.5/9.5	≤0.25	20	20
	0.5		
	1		
Gentamicin Expected MIC Range 4 – 16 ug/mL	4		
	8	20	20
	16		
Gentamicin 500 Expected MIC Range ≤ 500 ug/mL	≤ 500	20	20
	≥ 500		
Streptomycin 1000 Expected MIC Range ≤1000 ug/mL	≤ 1000	20	20
	≥ 1000		

Drug	Organism Group	Challenge	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Oxacillin	Coagulase-negative Staph	19	8	100	100	100	11	0	0	0
	<i>S. aureus</i>	27	17	100	100	100	11	0	0	0
Penicillin	Coagulase-negative Staph	19	8	100	100	100	15	0	0	0
	Enterococcus species	16	11	100	100	100	5	0	0	0
	<i>S. aureus</i>	27	6	100	100	100	21	0	0	0
	<i>S. agalactiae</i>	6	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	5	0	100	na	100	0	0	0	0
Linezolid	Coagulase-negative Staph	19	10	100	100	100	0	0	0	0
	Enterococcus species	16	14	100	100	100	0	0	0	0
	<i>S. aureus</i>	27	27	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	5	5	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	6	6	100	100	100	0	0	0	0
Rifampin	Coagulase-negative Staph	19	1	100	100	100	1	0	0	0
	Enterococcus species	16	8	100	100	87.5	3	0	0	2
	<i>S. aureus</i>	27	0	100	na	100	0	0	0	0
Chloramphenicol	Coagulase-negative Staph	19	17	100	100	100	2	0	0	0
	Enterococcus species	16	13	100	100	100	3	0	0	0
	<i>S. aureus</i>	27	22	100	100	100	5	0	0	0
	<i>S. agalactiae</i>	5	5	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	6	6	100	100	100	0	0	0	0
Clindamycin	Coagulase-negative Staph	19	0	100	0	100	5	0	0	0
	<i>S. aureus</i>	27	0	100	0	100	3	0	0	0
	<i>S. agalactiae</i>	5	0	100	0	100	0	0	0	0
	<i>S. pyogenes</i>	6	0	100	0	100	0	0	0	0
Tetracycline	Coagulase-negative Staph	19	15	100	100	100	2	0	0	0
	Enterococcus species	16	5	100	100	100	12	0	0	0
	<i>S. aureus</i>	27	21	100	100	100	5	0	0	0
	<i>S. agalactiae</i>	5	4	100	100	100	4	0	0	0
	<i>S. pyogenes</i>	6	5	100	100	100	1	0	0	0

Drug	Organism Group	Challenge	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Erythromycin	Coagulase-negative Staph	19	2	100	100	100	7	0	0	0
	Enterococcus species	16	5	100	100	100	8	0	0	0
	<i>S. aureus</i>	27	9	100	100	100	18	0	0	0
	<i>S. agalactiae</i>	5	1	100	100	100	1	0	0	0
	<i>S. pyogenes</i>	6	0	100	na	100	0	0	0	0
Ciprofloxacin	Coagulase-negative Staph	19	17	100	100	100	0	0	0	0
	<i>S. aureus</i>	27	19	100	100	100	9	0	0	0
Synercid (Quinupristin/ Dalfopristin)	Coagulase-negative Staph	19	0	100	na	100	0	0	0	0
	Enterococcus species (does not include E. faecalis)	9	5	100	100	100	3	0	0	0
	<i>S. aureus</i>	27	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	6	0	100	na	100	0	0	0	0
Daptomycin	Coagulase-negative Staph	19	18	94.7	94.4	100	0	0	0	0
	Enterococcus species	16	13	100	100	100	1	0	0	0
	<i>S. aureus</i>	27	25	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	5	5	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	6	0	100	na	100	0	0	0	0
Vancomycin	Coagulase-negative Staph	19	17	100	100	100	0	0	0	0
	Enterococcus species	16	8	100	100	100	5	0	0	0
	<i>S. aureus</i>	27	24	100	100	100	0	0	0	0
	<i>S. agalactiae</i>	5	0	100	na	100	0	0	0	0
	<i>S. pyogenes</i>	6	0	100	na	100	0	0	0	0
TMP/SXT	<i>S. aureus</i>	27	2	100	100	100	0	0	0	0
Gentamicin	Coagulase-negative Staph	19	6	100	100	89.5	4	2	0	0
	<i>S. aureus</i>	27	21	100	100	100	2	0	0	0
Gentamicin (500ug/mL)	Enterococcus species	16	0	100	na	100	7	0	0	0
Streptomycin (1000ug/mL)	Enterococcus species	16	0	100	na	100	6	0	0	0

Table 11. Fastidious Gram Positives (Streptococci) - Autoreader1 versus ARIS® - OptiRead™										
Drug	Organism Group	Challenge	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Clindamycin	Streptococcus pneumoniae	24	16	100	100	100	8	0	0	0
Penicillin	Viridans Strep	25	18	100	100	96.0	13	1	0	0
	<i>S. agalactiae</i>	11	7	100	100	100	11	0	0	0
	<i>S. pneumoniae</i>	24	23	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	14	0	100	na	100	14	0	0	0
Amoxicillin/ Clavulanic Acid	<i>S. pneumoniae</i>	24	23	100	100	95.8	1	1	0	0
Linezolid	<i>S. agalactiae</i>	11	11	100	100	100	11	0	0	0
	<i>S. pneumoniae</i>	24	24	100	100	100	24	0	0	0
	<i>S. pyogenes</i>	14	14	100	100	100	14	0	0	0
	<i>Streptococcus species</i> (Viridans Strep)	25	25	100	100	100	25	0	0	0
Chloramphenicol	<i>S. agalactiae</i>	11	11	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	8	100	100	100	16	0	0	0
	<i>S. pyogenes</i>	14	14	100	100	100	0	0	0	0
	<i>Streptococcus species</i> (Viridans Strep)	25	21	100	100	100	0	0	0	0
Cefepime	<i>S. agalactiae</i>	11	10	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	24	100	100	87.5	0	3	0	0
	<i>S. pyogenes</i>	14	6	100	100	100	0	0	0	0
Cefotaxime	Viridans Strep	25	22	100	100	92.0	2	2	0	0
	<i>S. agalactiae</i>	11	10	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	24	100	100	100	4	0	0	0
	<i>S. pyogenes</i>	14	2	100	100	100	0	0	0	0
Meropenem	<i>S. agalactiae</i>	11	7	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	21	100	100	95.8	5	1	0	0
	<i>S. pyogenes</i>	14	0	100	na	100	0	0	0	0
	<i>Streptococcus species</i> (Viridans Strep)	25	10	100	100	100	5	0	0	0

Table 11. Fastidious Gram Positives (Streptococci) - Autoreader1 versus ARIS® - OptiRead™ con't.										
Drug	Organism Group	Challenge	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Tetracycline	<i>S. agalactiae</i>	11	2	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	7	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	14	11	100	100	100	0	0	0	0
	<i>Streptococcus species (Viridans Strep)</i>	25	19	100	100	96.0	0	0	0	0
Erythromycin	<i>S. agalactiae</i>	11	7	100	100	100	4	0	0	0
	<i>S. pneumoniae</i>	24	10	100	100	100	14	0	0	0
	<i>S. pyogenes</i>	14	13	100	100	100	1	0	0	0
	<i>Streptococcus species (Viridans Strep)</i>	25	12	100	100	96.0	16	1	0	0
Levofloxacin	<i>S. agalactiae</i>	11	11	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	23	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	14	14	100	100	100	0	0	0	0
	<i>Streptococcus species (Viridans Strep)</i>	25	24	100	100	100	1	0	0	0
Daptomycin	<i>S. agalactiae</i>	11	11	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	14	14	100	100	100	0	0	0	0
	<i>Streptococcus species (Viridans Strep)</i>	25	23	100	100	100	2	0	0	0
Vancomycin	<i>S. agalactiae</i>	11	11	100	100	100	0	0	0	0
	<i>S. pneumoniae</i>	24	24	100	100	100	0	0	0	0
	<i>S. pyogenes</i>	14	14	100	100	100	0	0	0	0
	<i>Streptococcus species (Viridans Strep)</i>	25	25	100	100	100	0	0	0	0
TMP/SXT	<i>S. pneumoniae</i>	24	3	100	100	100	21	0	0	0

EA – Essential Agreement
CA – Category Agreement
R – Resistant isolates
NS – Not Susceptible isolates

maj – major discrepancies
vmj – very major discrepancies
min – minor discrepancies

Essential Agreement (EA) is when there is agreement between the MIC result read/interpreted using the current Autoreader1 and MIC result read/interpreted using the new OptiRead™ in combination with the ARIS® within plus or minus one serial two-fold dilution. Category agreement (CA) is when the ARIS®-OptiRead™ MIC result interpretation agrees exactly with the Autoreader1 MIC result interpretation. Evaluable EA is when the MIC result for both the ARIS®-OptiRead™ and the Autoreader1 are on-scale.

The %EA is acceptable when compared to the reference method as described in the FDA guidance document, “*Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) System; Guidance for Industry and FDA*”.

Overall, the MIC results of the Autoreader1 and the ARIS®-OptiRead™ were very similar, for all antibiotics tested. The %EA and %CA for most microorganism group/antibiotic combination were greater than 90%. In three instances the %CA fell below 90% (*Enterococcus spp.*/Rifampin, Coagulase-negative *Staphylococcus spp.*/Gentamicin, and *S. pneumoniae*/Cefepime) however in each instance the %EA of the evaluable was 100% and all were due to the occurrence of low numbers of minor discrepancies.

All QC results fall within acceptable range.

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. *Clinical Sensitivity:*
Not Applicable

b. *Clinical specificity:*
Not Applicable

c. *Other clinical supportive data (when a. and b. are not applicable):*
Not Applicable

4. Clinical cut-off:

Not Applicable

1. Expected values/Reference range:

Not Applicable

N. Instrument Name:

TREK Diagnostic Systems; Sensititre® OptiRead™

O. System Descriptions:

1. Modes of Operation:

The OptiRead™ is a dedicated microtitre plate reader linked to a computer running the Sensititre® SWIN software. The OptiRead™, a single excitation/detection wavelength fluorimeter, is a fluorescence based detection system used to read Sensititre® MIC or BP Susceptibility plates. The system uses a 360nm wavelength light emitting diode (LED) to excite the sample within each microtitre plate well. The excitation/emission light from each well is then collected using a photodiode. The microtitre plate is held on the OptiRead™ and each well is individually read by the optics positioned beneath the plate. The X-Y movement of the optics is controlled by the OptiRead™ firmware which responds to commands sent by the host computer. The data of each microtitre plate well is outputted to a personal computer (PC) as comma separated data which is formatted for input into the SWIN software.

2. Software:

Sensititre® MIC or BP Susceptibility plate reading is initiated via the SWIN software on an external PC and the data from the OptiRead™ is then transferred back to the SWIN software where the results are generated.

The Hazard Analysis and Software Documentation has been reviewed and determined to be adequate.

3. Specimen Identification:

Sensititre® MIC or BP Susceptibility plates are scanned into SWIN. In addition, the specimen identification is typed into SWIN.

4. Specimen Sampling and Handling:

Sensititre® MIC or BP Susceptibility plates inoculated with pure cultures are manually placed into the panel holder of the OptiRead™ instrument.

5. Calibration and Quality Control:

OptiRead™ is initially calibrated at the factory. The calibration requires that the plate corner well locations are identified using a dedicated calibration software tool which communicates with the OptiRead™ via the instrument's external serial port. The instrument's optics package is driven to automatically locate the corner well locations by identifying the point of peak signal. These corner well locations are then used to calculate the remaining well locations, all of which are recorded as calibration points within the instrument. Further instrument verification and quality control of both the mechanical and reading systems of the OptiRead™ are performed by means of nine tests using a standardized solution.

In addition the OptiRead™ conducts an automatic calibration of the excitation/detection optics and accompanying electronics before every plate read. More specifically, for antimicrobial susceptibility testing the OptiRead™ calibrates against a calibration well included in each microtitre plate panel; for identification, the OptiRead™ calibrates against a solid state calibration block located with the instrument itself.

In support of ongoing quality control management the OptiRead™ is checked annually by a trained Trek field service engineer, in accordance with the instrument preventative maintenance schedule, to ensure maintenance of the device calibration and performance. The field service engineer uses a software tool which calibrates/verifies instrument operation including calibration quality of plate corner locations.

The OptiRead™ is also equipped with a number of error notifications which are designed to pick up problems with the quality of the instrument readings during regular every day use. For example, the OptiRead™ will automatically halt a plate reading and display an error notification when the motion of the drive system used to index the optics package becomes restricted by a foreign object. Additionally, error notifications specific to the reading system calibration are also present, such that if acceptable calibration is not achieved, which could lead to compromised quality of plate read results, the instrument plate read will be halted and an error notification will be displayed.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

Not Applicable

Q. Proposed Labeling

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

R. Conclusion:

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