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

A. 510(k) Number:

K110583

B. Purpose for Submission:

The purpose of the submission is to obtain 510(k) clearance of the OptiRead™ (Autoreader-2) to replace the existing Autoreader-1.

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 Gram negative rods.

D. Type of Test:

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

E. Applicant:

TREK Diagnostic Systems

F. Proprietary and Established Names:

Sensititire® 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 for non-fastidious and fastidious Gram positive cocci and non fastidious Gram negative organisms, through the use of dedicated Sensititre® SWIN software. MIC and BP Susceptibility plates can either be read manually or automatically on the Sensititre OptiRead™, Autoreader® or the ARIS® in combination with the Autoreader® or OptiRead™.

   NOTE: Please refer to the Sensititre® 18-24 hour MIC or Breakpoint Susceptibility System package insert 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 Gram negative organisms.

   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):

   a. For prescription use only.

4. Special instrument requirements:

None

I. Device Description:

J. Substantial Equivalence Information:

1. Predicate device name(s):

Sensititre 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

Similarities		
Item	Device	Predicate
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. Standards/Guidance Documents 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 and automatic plate reader (e.g. OptiRead™).

The Sensititire® 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. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Gram negative isolates, 25 in total, to include *E. coli (6), P. aeruginosa (4), E. cloacae (3), S. marcescens (3), S. maltophilia (2)* and *A. baumannii (2)* were tested. The isolates listed above were tested against the following antibiotics, representative of the major antimicrobial classes: Ampicillin, Ticarcillin, Piperacillin/Tazobactam, Chloramphenicol, Cefazolin, Cefepime, Ceftazidime, Ertapenem, Tetracycline, Levofloxacin, Gentamicin, and Trimethoprim/Sulfamethoxazole.

   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.

Because a number of antibiotic/organism combinations lacked a sufficient number of on-scale MIC results 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 3 different days; using three separate OptiRead™ instruments.. The antibiotics included, Ticarcillin, Cefazolin, Cefepime, Ceftazidime and Trimethoprim/Sulfamethoxazole.

In summary, 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, *E. coli* 25922, *E. coli* 35218, and P. aeruginosa 27853, 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 *E. coli* 25922	Concentration (ug/mL)	Autoreader1	OptiRead™
Ampicillin	2	1	
Expected MIC Range	4	59	60
2-8 ug/mL	8		
Ticarcillin	4	18	16
Expected MIC Range	8	41	43
4-16 ug/mL	16	1	1
Piperacillin/Tazobactam	1/4		1
Expected MIC Range	2/4	60	59
1/4-4/4 ug/mL	4/4		
Chloramphenicol	2		
Expected MIC Range	4	53	56
2-8 ug/mL	8	7	4
Cefazolin	<=1	49	49
Expected MIC Range	2	11	11
1-4 ug/mL	4		
Cefepime	<=0.5	60	60
Expected MIC Range			
.015- 0.12 ug/mL			
Ceftazidime	<=0.25	59	58
Expected MIC Range	0.5	1	2
0.06 – 0.5 ug/mL	1		
Ertapenem	0.004		
Expected MIC Range	0.008	60	59
0.004 – 0.015 ug/mL	0.0015		1
Tetracycline	0.5	1	
Expected MIC Range	1	59	60
0.5 – 2 ug/mL	2		
Levofloxacin	0.008		
Expected MIC Range	0.015	36	55
0.008 – 0.06 ug/mL	0.03	24	5
	0.06		
Gentamicin	0.25	3	3
Expected MIC Range	0.5	57	57
0.25 – 1 ug/mL	1		
Trimethoprim/Sulfamethoxazole	<=0.25/4.75	60	60
Expected MIC Range	0.5/9.5		
<=0.5/9.5 ug/mL	1/19		

Table 2. Quality Control *P. aeruginosa 27853*	Concentration (ug/mL)	Autoreader1	OptiRead™
Ticarcillin Expected MIC Range 8-32 ug/mL	8	2	2
	16	57	57
	32	1	1
Piperacillin/Tazobactam Expected MIC Range 1 - 8 ug/mL	1	2	1
	2	34	47
	4	21	10
	8	3	2
Cefepime Expected MIC Range 1-8ug/mL	1	51	51
	2	5	5
	4		
	8		
Ceftazidime Expected MIC Range 1-4 ug/mL	1	56	56
	2	4	4
	4		
Ertapenem Expected MIC Range 2-8 ug/mL	2	24	24
	4	36	36
	8		
Tetracycline Expected MIC Range 8-32 ug/mL	8	21	32
	16	39	28
	32		
Levofloxacin Expected MIC Range 0.5-4ug/mL	0.5	11	12
	1	49	48
	2		
	4		
Gentamicin Expected MIC Range 0.5-2 ug/mL	0.5	22	23
	1	38	37
	2		
Trimethoprim/Sulfamethoxazole Expected MIC Range 8/132-32/608 ug/mL	8/152	22	2
	16/304	37	53
	32/608	1	5

Table 3. Quality Control *E. coli 35218*	Concentration (ug/mL)	Autoreader1	OptiRead™
Ampicillin Expected MIC Range >32 ug/mL	32		
	>32	60	60
Piperacillin/Tazobactam Expected MIC Range 0.5/4 – 2/4 ug/mL	<=0.5/4	20	19
	1/4	9	1
	2/4		

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

The performance of the OptiRead™ was evaluated in 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 35ºC, 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 (222) Gram negative clinical and challenge isolates to include, *E. coli* (40), *P. aeruginosa* (27), *Acinetobacter spp*. other than *A. baumannii* (7), *Klebsiella spp*. (30), *Proteus spp*. (15), *Citrobacter spp*. (10) *Enterobacter spp*. (24), *Serratia spp*. (20), *Burkholderia cepacia* (1), *Morganella morganii* (10), *Providencia spp*. (10), *Pseudomonas species* other than *P. aeruginosa* (13), *S. maltophilia* (1), *A. hydrophila* (2), and *A. baumannii* (12).

The growth rate for the 222 Gram positive clinical and challenge isolates was 99.5%, due to the fact that one of the 27 isolates of P. aeruginosa failed to grow.

The performance evaluations are presented in Table 4.

Table 4 : Non-fastidious Gram Negative Organisms - Autoreader1 versus OptiRead™

Drug	Organism Group	Clinical	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Ampicillin	Enterobacteriaceae	104	57	161	61	100	100	100	109	0	0	0
Ticarcillin	A. baumannii	12	0	12	0	100	na	100	12	0	0	0
	Enterobacteriaceae	104	57	161	57	100	100	100	73	0	0	0
	Non-Enterobacteriaceae	16	6	22	10	100	100	100	15	0	0	0
	P. aeruginosa	14	12	26	20	100	100	100	9	0	0	0
Piperacillin/ Tazobactam	A. baumannii	12	0	12	0	100	na	100	12	0	0	0
	Enterobacteriaceae	104	57	161	111	100	100	100	20	0	0	0
	Non-Enterobacteriaceae	16	6	22	15	100	100	100	3	0	0	0
	P. aeruginosa	14	12	26	21	100	100	100	3	0	0	0
Chloramphenicol	A. baumannii	12	0	12	0	100	na	100	12	0	0	0
	Enterobacteriaceae	104	57	161	125	100	100	98.1	49	3	0	0
	Non-Enterobacteriaceae	16	6	22	13	100	100	100	13	0	0	0
Cefazolin	Enterobacteriaceae	104	57	161	50	100	100	100	82	0	0	0
Ceftazidime	A. baumannii	12	0	12	1	100	100	100	11	0	0	0
	Enterobacteriaceae	104	57	161	34	100	100	100	28	0	0	0
	Non-Enterobacteriaceae	16	6	22	16	100	100	100	4	0	0	0
	P. aeruginosa	14	12	26	18	100	100	100	4	0	0	0
Cefepime	A. baumannii	12	0	12	4	100	100	91.7	8	1	0	0
	Enterobacteriaceae	104	57	161	29	100	100	100	4	0	0	0
	Non-Enterobacteriaceae	16	6	22	11	95.5	90.9	95.5	3	1	0	0
	P. aeruginosa	14	12	26	20	100	100	100	0	0	0	0
Ertapenem	Enterobacteriaceae	104	57	161	155	100	100	100	6	0	0	0
Tetracycline	Enterobacteriaceae	104	57	161	129	100	100	99.4	63	1	0	0
Levofloxacin	Enterobacteriaceae	104	57	161	139	100	100	100	28	0	0	0
Gentamicin	A. baumannii	12	0	12	3	100	100	100	9	0	0	0
	Enterobacteriaceae	104	57	161	146	100	100	100	14	0	0	0
	Non-Enterobacteriaceae	16	6	22	13	100	100	100	5	0	0	0
	P. aeruginosa	14	12	26	18	100	100	100	8	0	0	0

Table 4 : Non-fastidious Gram Negative Organisms - 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
	A. baumannii	12	0	12	6	100	100	100	11	0	0	0
	Fastidious Gram	14	7	21	17	100	100	100	32	0	0	0
SXT	Non-Enterobacteriaceae	16	6	22	9	100	100	100	7	0	0	0

Table 5 : Non-fastidious Gram Negative Organisms - Autoreader1 versus ARIS® - OptiRead™

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%.

To support a claim for the use of the OptiRead™ in combination with the ARIS® instrument, an automated bench-top incubating and reading system, additional quality control testing was conducted, daily over a period of 20 days for a total of 20 repetitions for each representative antibiotic. In addition, testing was conducted using the following QC isolates *E. coli* 25922, *E. coli* 35218 and *P. aeruginosa* 27853.

In addition to the quality control testing, challenge isolate testing, for non-fastidious Gram negative isolates, was conducted in support of the claim. Non-fastidious Gram negative rods, 75 in total, which included *E. coli* (9), *P. aeruginosa* (12), *Acinetobacter spp*. other than *A. baumannii* (6), *Klebsiella spp*. (15), *Proteus spp*. (6), *Enterobacter spp*. (9), *Serratia spp*. (10), *M. morganii* (1), *Providencia spp*. (5), and *Aeromonas hydrophila* (2), were tested. The isolates were tested against the following antibiotics representative of the major antimicrobial classes: Ampicillin, Ticarcillin, Piperacillin/Tazobactam, Chloramphenicol, Ceftazidime, Cefepime, Cefazolin, Ertapenem, Tetracycline, Levofloxacin, Gentamicin, and Trimethoprim/Sulfamethoxazole. The results of the challenge isolate performance testing and quality control are presented in Tables 5-8.

Drug	Organism Group	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
Ampicillin	Enterobacteriaceae	57	57	14	100	100	98.2	47	1	0	0
Ticarcillin	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	17	100	100	100	35	0	0	0
	Non-Enterobacteriaceae	6	6	5	100	100	100	3	0	0	0
	P. aeruginosa	12	12	9	100	100	100	5	0	0	0
Piperacillin/ Tazobactam	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	38	98.2	97.4	98.2	11	1	0	0
	Non-Enterobacteriaceae	6	6	2	100	100	100	1	0	0	0
	P. aeruginosa	12	12	11	100	100	100	0	0	0	0
Chloramphenicol	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	40	100	100	98.2	22	1	0	0
	Non-Enterobacteriaceae	6	6	5	100	100	100	2	0	0	0
Cefazolin	Enterobacteriaceae	57	57	20	100	100	100	33	0	0	0
Ceftazidime	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	16	100	100	100	12	0	0	0
	Non-Enterobacteriaceae	6	6	5	100	100	100	1	0	0	0
	P. aeruginosa	12	12	9	100	100	100	1	0	0	0
Cefepime	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	19	100	100	100	0	0	0	0
	Non-Enterobacteriaceae	6	6	1	100	100	100	1	0	0	0
	P. aeruginosa	12	12	8	100	100	100	0	0	0	0
Ertapenem	Enterobacteriaceae	57	57	56	100	100	100	1	0	0	0
Tetracycline	Enterobacteriaceae	57	57	41	100	100	96.5	30	2	0	0
Levofloxacin	Enterobacteriaceae	57	57	54	100	100	100	6	0	0	0
Gentamicin	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	49	100	100	98.2	6	1	0	0
	Non-Enterobacteriaceae	6	6	4	100	100	100	1	0	0	0
	P. aeruginosa	12	12	7	100	100	100	5	0	0	0

Table 5 : Non-fastidious Gram Negative Organisms - Autoreader1 versus ARIS® - OptiRead™ con't.											
Drug	Organism Group	Challenge	Total	Total Eval	%EA Total	% EA of Evaluable	%CA	R or NS	min	maj	vmj
SXT	A. baumannii	0	0	0	na	na	na	0	0	0	0
	Enterobacteriaceae	57	57	15	100	100	100	6	0	0	0
	Non-Enterobacteriaceae	6	6	0	100	na	100	1	0	0	0

Table 6. Quality Control *E. coli* 25922	Concentration (ug/mL)	Autoreader1	ARIS® - OptiRead™
Ampicillin	2	1	1
Expected MIC Range	4	19	19
2-8 ug/mL	8		
Ticarcillin	4	3	3
Expected MIC Range	8	16	16
4-16 ug/mL	16	1	1
Piperacillin/Tazobactam	1/4		
Expected MIC Range	2/4	20	20
1/4-4/4 ug/mL	4/4		
Chloramphenicol	2		
Expected MIC Range	4	18	18
2-8 ug/mL	8	2	2
Cefazolin	<=1	10	12
Expected MIC Range	2	10	8
1-4 ug/mL	4		
Cefepime Expected MIC Range .015- 0.12 ug/mL	<=0.5	20	20
Ceftazidime	<=0.25	20	20
Expected MIC Range	0.5		
0.06 – 0.5 ug/mL	1		
Ertapenem	0.004		
Expected MIC Range	0.008	20	20
0.004 – 0.015 ug/mL	0.0015		
Tetracycline	0.5		
Expected MIC Range	1	20	20
0.5 – 2 ug/mL	2		
Levofloxacin	0.008		
Expected MIC Range	0.015	18	18
0.008 – 0.06 ug/mL	0.03	2	2
	0.06		
Gentamicin	0.25		
Expected MIC Range	0.5	16	16
0.25 – 1 ug/mL	1	4	4
Trimethoprim/Sulfamethoxazole	<=0.25/4.75	20	20
Expected MIC Range	0.5/9.5		
<=0.5/9.5 ug/mL	1/19		

Table 7. Quality Control *P. aeruginosa 27853*	Concentration (ug/mL)	Autoreader1	ARIS® - OptiRead™
Ticarcillin	8		
Expected MIC Range	16	18	19
8-32 ug/mL	32	2	1
Piperacillin/Tazobactam	1/4		
Expected MIC Range	2/4	9	3
1/4 – 8/4 ug/mL	4/4	9	15
	8/4	2	2
Cefepime	1	18	19
Expected MIC Range	2	2	1
1-8ug/mL	4		
	8		
Ceftazidime	1	19	19
Expected MIC Range	2	1	1
1-4 ug/mL	4		
Ertapenem	2	1	2
Expected MIC Range	4	19	18
2-8 ug/mL	8		
Tetracycline	8	16	20
Expected MIC Range	16	4	
8-32 ug/mL	32		
Levofloxacin	0.5	12	13
Expected MIC Range	1	8	7
0.5-4ug/mL	2		
	4		
Gentamicin	0.5	3	6
Expected MIC Range	1	17	14
0.5-2 ug/mL	2		
Trimethoprim/Sulfamethoxazole	8/152		2
Expected MIC Range	16/304	20	18
8/132-32/608 ug/mL	32/608		

Table 8. Quality Control *E. coli 35218*	Concentration (ug/mL)	Autoreader1	ARIS® - OptiRead™
Ampicillin	32		
Expected MIC Range	>32	20	20
>32 ug/mL			
Piperacillin/Tazobactam	<=0.5/4	13	11
Expected MIC Range	1/4	7	9
0.5/4 – 2/4 ug/mL	2/4		

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 all microorganism group/antibiotic combination were greater than 90%. All QC results fall within acceptable range.

A study was conducted to demonstrate the performance of the OptiRead™ and the OptiRead™ in combination with the ARIS® in reading the Sensititre ESBL Confirmatory Test plates. The study included total of 25 isolates of *E. coli* and *Klebsiella spp*. ESBL producers using the ESBL Confirmatory Test plate. Each ESBL plate was read using the Autoreader1, the OptiRead™ and the OptiRead™ in combination with the ARIS®. The susceptibility results obtained using each reader were compared and found to be identical for all organisms tested. Quality control isolates *E. coli* 25922 and *K. pneumoniae* 700603 were also included in the study. The results were all 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

5. 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 place 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

A full labeling review has been conducted and the requirements as described in 21 CFR 809.10 have been met.

R. Conclusion:

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