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Instructions for Use

Thermo Scientific Sensititre 20-24 hour Haemophilus influenzae/ Streptococcus pneumoniae MIC Susceptibility Plates

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Sensititre 20-24 hour

Haemophilus influenzae/ Streptococcus pneumoniae

MIC Susceptibility Plates

Rx only -Caution: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.(USA only)

Sensititre 20-24 hour

For in vitro Diagnostic use

For full plate information, including plate layout, QC information, Interpretative criteria, performance data and references please refer to www.trekds.com/techinfo. The plate code and batch number will be required.

INTENDED USE

The Sensititre *Haemophilus influenzae*/ *Streptococcus pneumoniae* plates are *in vitro* diagnostic products for clinical susceptibility testing of *Haemophilus influenzae, Streptococcus pneumoniae* and *Streptococcus species.*

SUMMARY AND PRINCIPLES OF USE

Each plate is dosed with antimicrobial agents at appropriate dilutions. Results can be read manually by visual reading of growth or automatically on an ARIS/Autoreader/OptiRead using fluorescence. The Sensititre Autoreader/OptiRead system utilizes fluorescence technology. The technology involves 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 plates are prepared with the substrate already added to the plate. Enzymatic action of the bacterial surface enzymes on the specific substrates cleave this bond releasing the fluorophore, which is now capable of fluorescence. The amount of fluorescence detected is directly related to the activity of the bacterial surface enzymes and, therefore, to the bacterial growth.

Only plates which have the format name suffixed with F can be read automatically.

Streptococcus pneumoniae and *Streptococcus* spp plates can either be read manually or automatically on the Sensititre Autoreader /ARIS /OptiRead *H. influenzae* can only be read manually on the Vizion or manual viewer. TREK Diagnostic Systems manufactured broth has only been validated with Sensititre Products

PRECAUTIONS

1. Results should be used as an aid to selecting the drug of choice for treatment.
2. Only personnel trained in susceptibility testing techniques should use the system.
3. Since living micro-organisms used with this product can be infectious to the user, proper handling and disposal methods should be used.
4. In the United States Federal law restricts this device to sale, use and distribution by or on the order of a physician or clinical laboratory.
5. The safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labelling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

Only instruments supported by Sensititre i.e. a simple manual viewer, Sensitouch, Vizion, Sensititre AutoReader, OptiRead and ARIS must be used to report results with CE IVD and FDA cleared Sensititre products, any other system used will not be supported.

STORAGE AND SHELF LIFE

The plates should be stored at room temperature (15-25°C) away from direct sunlight and direct heat. Each plate is packaged in foil with a silica gel desiccant. Do not use the plate or broth if past its expiration date, or the desiccant colour is not orange or the foil pouch is damaged.

Inoculate plate within 5 hours of removal from pouch

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected, transported, stored and then plated on to primary isolation medium according to established microbiological laboratory practice to give isolated colonies.

PROCEDURE

Materials included:

Sensititre™ plate with substrate (format name suffixed with F) or without substrate in wells.
Adhesive seal

Materials not included [TREK Inc. Product code]:

Sensititre™ cation adjusted Mueller-Hinton broth with TES buffer and lysed horse blood (CAMHBT+ LHB) for inoculating plates read manually [CP-112]
Sensititre™ cation adjusted Mueller-Hinton broth with TES buffer and lysed horse blood (CAMHBT+ LHB) for inoculating plates read automatically [CP-114]
Sensititre™ cation adjusted Mueller-Hinton broth with TES buffer (CAMHBT) [T3462-05)
Sensititre™ Haemophilus Test Medium (HTM) [T3470]
Sensititre™ doseheads (for use with AutoInoculator™ / AIM™) [E3010]
Sensititre™ AutoInoculator™ / Sensititre AIM™) [V3020]
Sensititre™ AutoReader™ /ARIS™ [V3090] /OptiRead™ [V3030]
Sensititre™ Vizion™ [V2021]
Sensititre™ Nephelometer™ [V3011]
Manual viewer [V4007]
0.5 McFarland polymer turbidity standard [E1041] or 0.5 McFarland barium sulphate turbidity standard [E1040]
1ul and 10µl calibrated loops
50 or 100µl pipettor and disposable tips
Quality control strains
Agar plates
Incubator 34-36^{0}C, non-CO_2
Vortex mixer
Current CLSI documents

SELECTION OF SUSCEPTIBILITY TEST BROTH

All Sensititre approved broths are performance tested for use in Sensititre susceptibility products.

INOCULATION PROCEDURES FOR SENSITITRE PLATES

Allow all broths to come up to room temperature before use.

1. For all plates and transfer 3 to 5 colonies from an overnight chocolate agar plate (*H. influenzae*) or sheep blood agar plate (*Streptococcus spp*.,) incubated in a 5% CO2 atmosphere, into 5ml CAMHBT and adjust to a 0.5 McFarland standard. Mix well.

2. Transfer 100µl of *Streptococcus spp*., into11ml CAMHBT+LHB or 50µl of *H. influenzae* into 11ml HTM to give an inoculum of 5x105 cfu/ml. Note: A small amount of white sediment may be present in the bottom of CP114-10 tubes.

Steps 1 and 2 should be completed within 30 minutes.

3. Transfer 100µl of the broth suspension into the plate by either:

a. Sensititre AutoInoculator/AIM. Replace the tube cap with a Sensititre single-use dosehead and inoculate the plate according to the AutoInoculator/AIM instructions

b. Manual pipette. Pour the broth into a sterile seed trough and inoculate the plate using an appropriate pipette.

Inoculate broth into the plate within 30 minutes.

Remove the test tube/dosehead combination from the AutoInoculator/AIM within 30 seconds of dosing a plate and store inverted in a rack or discard.

4. Perform a purity check on all final inocula after inoculation

5. A periodic check of the colony count of the positive control well should be done (See Appendix 1).

Streptococcus spp., and *Haemophilus influenzae* should have an inoculum of $5x10^5$cfu/ml (range $2x10^5$ – $7x10^5$).

This check is important for *Streptococcus* spp*.,* as inocula can vary depending on the conditions of incubation of the primary plate.

6. Cover all wells with the adhesive seal. Avoid creases as these can lead to skips.

INCUBATION

All fastidious organisms should be incubated at 34-36^{0}C either in the ARIS or in a non-CO2 incubator for 20-24 hours.

Up to 3 plates can be stacked if not incubated in the ARIS.

Summary of set up and incubation

READING TEST RESULTS

Organism group	McFarland Suspension medium	Final Inoculum	Inoculum transfer	Broth	Plate Reconstitution	Incubation conditions	Incubate Hours
Haemophilus influenzae	MHB	$5x10^5$ cfu/mL	50µL	HTM	100µL	34˚C-36˚C Non-CO_2	20-24
Streptococcus pneumoniae / Streptococcus spp.	MHB	$5x10^5$ cfu/mL	100µL	MHB + LHB	100µL	34˚C-36˚C Non-CO_2	20-24

Check purity test plates. Results are invalid if a mixed culture is present.

1. Automatically

Streptococcus spp., plates may be read automatically on the AutoReader/ARIS/OptiRead according to the instructions in the Software Users Manual.

2. Manually

After incubation, results can be manually read using the Sensititre manual viewer or the Vizion. See User's Manual. It is not necessary to remove the adhesive seal. Growth appears as turbidity or as a deposit of cells at the bottom of a well. The MIC is recorded as the lowest concentration of antimicrobic that inhibits visible growth. Reading faint growth on Vizion can be improved by adjusting the lighting.

When reading *Streptococcus* spp., adjust the lighting as required to look for turbidity, haziness, or a deposit of cells. A small amount of sediment may be present in the bottom of the wells.

Turbidity with *H. influenzae* is slight; adjust the lighting for better contrast.

The positive growth control wells should be read first. If all show no growth, results are invalid.

The following points should be noted:

a. Fading End Points

Most organism / antimicrobic combinations give distinct end points. With some combinations there may be a gradual fading of growth over 2 to 3 wells. The end points should be taken as

the first well that inhibits visible growth, except sulphonamides when the MIC must be read as an 80 - 90% decrease in growth compared to the control well.

b. Contamination

Contamination may result in growth in a well bordered by wells showing no growth. Such a single well contamination can be ignored, but if multiple well contaminants are suspected, the test should be repeated.

c. Skips

Occasionally a “skip” may be seen - a well showing no growth bordered by wells showing growth. There are a variety of explanations including contamination, mutation, creased seal and misaligned dosing. A single skip can be ignored. However, in order to ensure effective antimicrobic therapy NEVER read the skip well as the MIC; always read the lowest well concentration above which there is consistently no growth.

d. Mixed Cultures

Except as referred to in (a) above, if two end points are seen as a distinct “button” of cells followed by several wells of diffuse growth with the “button” no longer visible (or seen as smaller buttons), there may be a mixed bacterial population. Purity can be checked by sub-culturing the growth onto suitable agar. Test results are invalid if a mixed culture is detected.

D Test

The Dtest for broth microdilution test is for manual read detection of inducible Clindamycin resistance in *Streptococcus pyogenes* and *Streptococcus agalactiae* resistant to Erythromycin (MICs ≥ 1µg/mL) and susceptible or intermediate to Clindamycin (MICs ≤ 0.25µg/mL or 0.5µg/mL), and to determine absence of inducible Clindamycin resistance in *Streptococcus pneumonia*e. The performance of this test for the detection of inducible Clindamycin resistance in isolates of *S. pneumoniae* has not been established.
With *S. pyogenes* and *S. agalactiae*, a Dtest (1/0.5 µg/mL) positive (growth) test, determined by manual read, should be reported as inducible Clindamycin resistance.

INTERPRETATION OF RESULTS - Refer to the Interpretation Document in Appendix A (www.trekds.com/techinfo)

There are antimicrobial agents included in this plate that have not been proven to be effective for treating infections for all organisms tested. Refer to the individual FDA approved pharmaceutical antimicrobial agent package insert for interpreting and reporting results of antimicrobial agents that have shown to be active against organism groups both *in vitro* and in clinical infections.

For automatically read results, the software applies interpretive criteria based on FDA guidelines.

QUALITY CONTROL – Refer to the QC range Document in Appendix B (www.trekds.com/techinfo)

Frequency of quality control testing should be set according to standard guidelines. Inoculum should be cultured onto a suitable medium to check for purity. Test results are invalid if a mixed culture is detected.

All Sensititre plates include positive control wells. Tests are invalid unless there is distinct growth in all positive control wells. Some plate formats also include a “negative growth” well. This well is used for calibration of the AutoReader**/** OptiRead system and is not required for manual reading.

A number of factors influence MICs including organism state, inoculum density, temperature and broth. In practice, replicate MICs form a normal distribution with the majority of results lying within one dilution of the modal value.

The control organisms listed in the quality control tables are recommended for monitoring the susceptibility test procedure and checking the potency of antimicrobics. Refer to the quality control tables for expected quality control results. The test procedure can be considered satisfactory if the susceptibility results obtained with the control organisms are within the stated ranges. Results should **not** be reported if QC results are outside the stated ranges.

Contact Sensititre Distributor or Trek Diagnostic Systems for assistance in the event that quality control discrepancies cannot be resolved.

LIMITATIONS

1. Sensititre fastidious plates should not be incubated in a CO2 incubator
2. The ability of the Sensititre system to detect resistance or non-susceptibility to antimicrobics as shown below is unknown because an insufficient number of resistant or non-susceptible strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory.

H. influenzae	***S. pneumoniae***	***S. pyogenes, S. agalactiae, S. anginosus***	***S. pyogenes, S. agalactiae, S. anginosus, S. dysgalactiae***
Amoxicillin / clavulanic acid		Dalbavancin	Oritavancin
Ampicillin / sulbactam		Delafloxacin	
Cefaclor	Cefaclor		
Cefuroxime	Cefuroxime		
Chloramphenicol	Gemifloxacin		
Clarithromycin	Levofloxacin		
Omadacycline	Omadacycline	Omadacycline[a]	
Piperacillin/Tazobactam	Vancomycin		
Rifampin			
Trimethoprim/ sulphamethoxazole		Tedizolid	
	Dtest (manual read)		

[a]Omadacycline is not indicated for *Streptococcus agalactiae*

3. Performance of the Sensititre *Haemophilus influenzae* / *Streptococcus spp*., plates and have not been established for the following antimicrobics. Results should not be reported.

Antimicrobial Agent	**Do not report results for *H. influenzae***	**Do not report results for *Streptococcus* spp., other than *S. pneumoniae***	**Do not report results for *S. pneumoniae***
Ampicillin		X	X
Ampicillin/Sulbactam		X	X
Cefaclor		X	
Cefdinir		X	
Cefixime		X	X
Cefpodoxime		X	X
Ciprofloxacin		X	X
Clarithromycin		X	
Clindamycin	X	X	X
Dalbavancin	X	*	X
Daptomycin	X		X
Delafloxacin	X	*	X

Ertapenem		X	
Erythromycin	X		
Imipenem		X	X
Linezolid	X		
Lomefloxacin		X	X
Meropenem			
Oritavancin	X	**	X
Penicillin	X		
Piperacillin/Tazobactam		X	X
Rifampin		X	X
Tedizolid	X	*	X
Telavancin	X		X
Telithromycin		X	
Tigecycline	X		
Vancomycin	X		

* Tedizolid, Dalbavancin, and Delafloxacin for *Streptococcus pyogenes, S. agalactiae,* and *S. anginosus* only
** Oritavancin for *Streptococcus pyogenes, S. agalactiae, S. dysgalactiae,* and *S. anginosus* only.

4. Beta-lactamase testing *for H. influenzae* may be used to predict resistance to Ampicillin. However, some Ampicillin-resistant strains are Beta-lactamase negative.
5. The interpretation of susceptibility test results requires trained clinical personnel who should use judgement and knowledge prior to accepting test results.
6. Autoread results for *Streptococcus* spp., are only generated for those drugs listed
7. Studies were performed using the AutoInoculator/AIM. When testing Ceftaroline or Telavancin, if an alternative inoculation system is used, validate the performance of the alternate inoculation system with Quality Control testing and perform colony counts.
8. The performance of Tedizolid, Dalbavancin, Delafloxacin with *Streptococcus spp*. (*Streptococcus pyogenes, S. agalactiae,* and *S. anginosus),* and the performance of Oritavancin with *Streptococcus* spp*. (Streptococcus pyogenes, S. agalactiae, S. dysgalactiae, and S. anginosus)* was performed using the AIM/autoinoculator. The use of an alternative inoculation system when testing Tedizolid, Dalbavancin, Delafloxacin and Oritavancin has not been evaluated.
9. Due to the lack of an intermediate and resistant interpretation for Oritavancin, there is a potential very major error rate. There were 13 isolates out of 34 non susceptible isolates that reported one doubling dilution lower than the reference. Use an alternative testing method prior to reporting results for *Streptococcus* spp. with Oritavancin when the Sensititre MIC is 0.25µg/mL (breakpoint) if critical to patient care.
10. The ability of the Sensititre system to detect Dtest positive *S. pneumoniae* isolates is unknown because Dtest positive strains were not tested at the time of comparative testing. Any *S. pneumoniae* isolate determined to be Dtest positive with the Sensititre system should be subjected to additional; testing or submitted to a reference laboratory, if necessary.
11. Dtest results should be interpreted using manual read only. The ability of the Sensititre system to detect a positive Dtest by autoread cannot be confirmed due to the lack of a Dtest positive quality control isolate for Autoread.
12. Studies were performed using the AIM. Performance with other inoculation methods was not determined.

13. Resistance mechanism characterization was not provided for all organisms at the time comparative testing, and therefore the performance of the Sensititre Delafloxacin for fastidious gram positive organisms is unknown for isolates with the following resistance mechanisms: topoisomerase IV and DNA gyrase Quinolone-Resistant Determining Regions (QRDRs), or altered efflux.
14. The performance of Delafloxacin with gram positive organisms was performed using the AutoReader (OptiRead) and VIZION reading methods only. The use of an alternative reading method when testing Delafloxacin has not been evaluated.
15. Only two *S. anginosus* isolates were determined as non-susceptible by the reference method. Although both results were within Essential Agreement, one very major discrepancy was observed when compared to the reference method. If critical to patient care, testing should be repeated using an alternative testing/reference method prior to reporting results for Delafloxacin with organism *S. anginosus* when the Senstitre MIC is 0.06 µg/mL.
16. The performance of Omadacycline with *Haemophilus influenzae* and *Streptococcus* spp. was performed using the AIM autoinoculator. The use of an alternative inoculation system when testing Omadacycline has not been evaluated.
17. The testing of Omadacycline with *Streptococcus* spp. was performed using the AutoReader (OptiRead) and Vizion reading methods and *Haemophilus influenzae* was only read by the Vizion manual method. The use of an alternative reading method when testing omadacycline has not been evaluated.
18. The ability of the Sensititre system to detect resistance to Omadacycline in the following species is unknown because resistant strains were not available at the time of comparative testing: *H. influenzae*, *S. pneumoniae*, *S. pyogenes*, and *S. anginosus*. Isolates yielding Omadacycline MIC results suggestive of a resistant interpretive category should be submitted to a reference laboratory for further testing.
19. Omadacycline MIC values tended to be in exact agreement or at least one dilution lower when testing *S. pyogenes* and *S. pneumoniae* with both OptiRead and VIZION reading methods compared to the CLSI reference broth microdilution. MIC values MIC values tended to be in exact agreement or one dilution higher when testing *S. anginosus* with both OptiRead and VIZION. Omadacycline MIC values tended to be in exact agreement or at least one dilution lower when testing *H. influenzae* with the VIZION only.

PERFORMANCE DATA - Refer to the performance Data document in Appendix C (www.trekds.com/techinfo)

Plates read either manually or automatically are designed to give comparable performance to CLSI reference micro-broth procedure. Comparable performance is defined as ≥ 90% agreement to within a doubling dilution of the reference MIC.
For further information contact TREK Diagnostic Systems or your local distributor

APPENDIX 1: Colony Count Procedure.

1. Immediately following plate inoculation, using a 1µl loop, sample from the positive growth control well and inoculate onto a blood agar.

2. Take another loop (1µl), sample from the same growth well and mix with 50µl sterile deionised water. Inoculate 1µl of this dilution onto a blood agar plate to obtain countable colonies.

3. Incubate both plates at 34 –36^{0}C overnight under appropriate conditions.

4. Read as follows:

Number of colonies

Colony Count	**0.001 plate**	**0.001 of 1/50 dilution**
$<5 \times 10^4 =$	<50	0
$5 \times 10^4 =$	50 – 100	0 –2
$1 \times 10^5 – 5 \times 10^5 =$	>100	≤10
$> 5 \times 10^5 =$	>100	>10

REFERENCES – Refer to www.thermofisher.com **for additional references**

1. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7 Approved Standard. The Clinical and Laboratory Standards Institute.

2. Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement M100 The Clinical and Laboratory Standards Institute.

DISCLAIMER

The information provided in this technical insert is current at the time of printing and may change without notice.

The latest information can be downloaded from the www.TREKDS.com/techinfo or by contacting TREK Technical services.

TREK Diagnostic Systems
Units 17-19 Birches Industrial Estate, East Grinstead,
West Sussex, UK. RH19 1XZ,
United Kingdom
Tel: +44-1342-318777

Distributed by:
Remel, Inc., 12076 Santa Fe Trail Drive, Lenexa, Kansas 66215
1-800-255-6730 or 913-888-0939

Appendix A – Interpretation Table

There are antimicrobial agents included in this plate that have not been proven to be effective for treating infections for all organisms tested. Refer to the individual FDA approved pharmaceutical antimicrobial agent package insert for interpreting and reporting results of antimicrobial agents that have shown to be active against organism groups both *in vitro* and in clinical infections

These breakpoints are based on performance evaluations cleared by the FDA

Organism	***Haemophilus influenzae***			***Streptococcus pneumoniae***			***Streptococcus spp.* other than *S. pneumoniae***		
Antimicrobial Agent	**Susceptible**	**Intermediate**	**Resistant**	**Susceptible**	**Intermediate**	**Resistant**	**Susceptible**	**Intermediate**	**Resistant**
AMPICILLIN [A, B]	<1	2	>4						
AMPICILIIN/SULBACTAM [A]	<2/1	-	>4/2						
AMOXICILLIN/ CLAVULANIC ACID [A, E]	<4/2	-	>8/4	<2/1	4/2	>8/4			
AZITHROMYCIN [C,G,K]	<4	-	-	<0.5	1	>2	<0.5	1	>2
CEFACLOR [E]	<8	16	>32	<1	2	>4			
CEFDINIR [C,I]	≤1			<0.5	1	>2			
CEFEPIME [A, C]	<2	-	-						
CEFEPIME (non meningitis) [JE]				<1	2	> 4			
CEFEPIME (beta hemolytic) [C]							<0.5	-	-
CEFIXIME [C]	<1	-	-						
CEFOTAXIME [C]	≤2								
CEFOTAXIME [D, F, H, E] (meningitis)				<0.5	1	>2			
CEFOTAXIME (non meningitis) [D, F, H, E]				<1	2	>4			
CEFOTAXIME (beta haemolytic) [C]							<0.5	-	-
CEFOTAXIME (viridans grp)							<1	2	>4
CEFPODOXIME [C]	<2	-	-						
CEFTAROLINE	<0.5 [C,R]	-	-	<0.5[C]	-	-	<0.5 [C,O,P,Q]		
CEFTRIAXONE [A]	<2	-	-						

Organism	*Haemophilus influenzae*			*Streptococcus pneumoniae*			*Streptococcus spp.* other than *S. pneumoniae*		
Antimicrobial Agent	**Susceptible**	**Intermediate**	**Resistant**	**Susceptible**	**Intermediate**	**Resistant**	**Susceptible**	**Intermediate**	**Resistant**
CEFTRIAXONE (meningitis) [D ,F, H, E]	-	-	-	< 0.5	1	> 2	-	-	-
CEFTRIAXONE (non meningitis) [D, F, H, E]	-	-	-	≤1	2	≥4	-	-	-
CEFTRIAXONE (beta hemolytic) [C]	-	-	-	-	-	-	< 0.5	-	-
CEFTRIAXONE (viridans grp)	-	-	-	-	-	-	< 1	2	>4
CEFUROXIME [A E] sodium (parental)	<4	8	>16	<0.5	1	>2			
CHLORAMPHENICOL	<2	4	>8	<4	-	>8	<4	8	>16
CIPROFLOXACIN [C G K]	<1	-	-	-	-	-	-	-	-
CLARITHROMYCIN [G K]	<8	16	>32	<0.25	0.5	>1	-	-	-
CLINDAMYCIN [I, K]				<0.25	0.5	>1	-	-	-
DALBAVANCIN (viridans group) [C,U,V]	-	-	-	-	-	-	<0.12	-	-
DALBAVANCIN(beta-hemolytic group) [C, L,U,V]	-	-	-	-	-	-	<0.12	-	-
DAPTOMYCIN [O]	-	-	-	-	-	-	≤ 1	See comment A	-
DELAFLOXACIN[O,AA]	-	-	-	-	-	-	≤0.06	-	-
DELAFLOXACIN[P]	-	-	-	-	-	-	≤0.06	0.12	≥0.25
DTEST #	-	-	-	(-) No growth (+) N/A			(-) No Growth (+) Growth *		
ERTAPENEM [C]	≤ 0.5	-	-	≤ 1	2	≥ 4	-	-	-
ERYTHROMYCIN [G, K]	-	-	-	<0.25	0.5	>1	<0.25	0.5	>1
GATIFLOXACIN [C,L]	<1	-	-	<1	2	>4	-	-	-
GEMIFLOXACIN [L]	≤0.12	-	-	≤0.12	0.25	≥0.5	<1	2	>4
IMIPENEM [C]	<4	-	-	-	-	-	<0.12	0.25	>0.5
LEVOFLOXACIN [C]	<2	-	-	<2	4	>8	<2	4	>8
LINEZOLID [L,C]				<2	-	-	<2	-	-

Organism	***Haemophilus influenzae***			***Streptococcus pneumoniae***			***Streptococcus spp* other than *S. pneumoniae***		
Antimicrobial Agent	**Susceptible**	**Intermediate**	**Resistant**	**Susceptible**	**Intermediate**	**Resistant**	**Susceptible**	**Intermediate**	**Resistant**
LOMEFLOXACIN [C]	<2	-	-		-	-			
MEROPENEM [A,C,F,H]	<0.5	-	-	<0.12	-	-	<0.25[O]	-	-
MOXIFLOXACIN [C]	<1	-	-	<1	2	>4	<1	2	>4
OMADACYCLINE[BB]	≤2	4	≥8	≤0.12	0.25	≥0.5	≤0.12	0.25	≥0.5
ORITAVANCIN (viridans group) [C,W,X,Z]	-	-	-	-	-	-	<0.25	-	-
ORITAVANCIN(beta-hemolytic group) [C, L,W,X,Z]	-	-	-	-	-	-	<0.25	-	-
PENICILLIN [E, F, H]	-	-	-	<0.06	0.12-1	>2	-	-	-
PENICILLIN (beta-hemolytic group) [C, L]	-	-	-	-	-	-	<0.12	-	-
PENICILLIN (viridans group) [M]	-	-	-	-	-	-	<0.12	0.25-2	>4
PIPERACILLIN/TAZOBACTAM [A]	<1/4	-	>2/4						
RIFAMPIN	<1	2	>4	-	-	-	-	-	-
TEDIZOLID (viridans group) [c,T]	-	-	-	-	-	-	<0.25	-	-
TEDIZOLID (beta-hemolytic group) [C, L,T]	-	-	-	-	-	-	< 0.5	-	-
Telavancin (viridans group) [c,S]	-	-	-	-	-	-	<0.06	-	-
Telavancin (beta-hemolytic group) [C, L,S]	-	-	-	-	-	-	<0.12	-	-
TELITHROMYCIN	<4	8	>16	<1	2	>4			
TETRACYCLINE	<2	4	>8	<2	4	>8	<2	4	>8
TIGECYCLINE [C]				≤0.06[C]	-	-	<0.25[C]	-	-
TRIMETHOPRIM/ SULPHAMETHOXAZOLE	<0.5/9.5	1/19-2/38	>4/76	<0.5/9.5	1/19-2/38	>4/76			
VANCOMYCIN [C, L,F]				<1	-	-	<1	-	-

A. Rare ß-lactamase –negative, ampicillin resistant (BLNAR) strains of *H. influenzae* should be considered resistant to Amoxicillin/Clavulanic acid, Ampicillin/Sulbactam, cefaclor, Cefamandole, Cefonicid, Cefprozil, Loracarbef and Piperacillin/Tazobactam despite apparent in vitro susceptibility of some BLNAR strains to these agents (15).
B. The results of Ampicillin susceptibility tests should be used to predict the activity of Amoxicillin. The majority of isolates of *H. influenzae* that are resistant to ampicillin and Amoxicillin produce a TEM-type ß -lactamase. In most cases, a direct ß -lactamase test can provide a rapid means of detecting Ampicillin and Amoxicillin resistance (15).
C. For some organism/antimicrobial combinations, the absence of resistant strains precludes defining any results categories other than 'susceptible'. For strains yielding results suggestive of a 'non-susceptible' category, organism identification and antimicrobial susceptibility test results should be confirmed. Subsequently, the isolates should be saved and submitted to a reference laboratory that will confirm results using an CLSI reference dilution method.
D. In standard dosages, Cefotaxime or Ceftriaxone is effective in treating pneumococcal pneumonia caused by strains in the intermediate category. However, when recovered from patients with meningitis, strains in the intermediate category may require therapy with maximum dosages of cefotaxime or ceftriaxone.
E. A pneumococcal isolate that is susceptible to penicillin can be considered susceptible to Ampicillin, Amoxicillin, Amoxicillin/Clavulanic acid, Ampicillin/Sulbactam, cefaclor, Cefepime, Cefetamet, Cefixime, Cefotaxime, Cefprozil, Ceftibuten, Ceftriaxone, Cefuroxime, Cefpodoxime, Ceftizoxime, Imipenem and Loracarbef for approved indications. Testing of ampicillin, ampicillin/sulbactam, ceftibuten, cefetamet, ceftizoxime and cefixime against penicillin-intermediate or penicillin-resistant isolates is not recommended, because reliable interpretive criteria for those agents with *S. pneumoniae* are not available. Physicians should be informed that clinical response rates with these agents may be lower than in strains that are not susceptible to Penicillin.
F. Only results of testing with Penicillin, Cefotaxime, Ceftriaxone, Meropenem and Vancomycin should be reported routinely with blood and CSF isolates of *S. pneumoniae* recovered from patients with life threatening infections (i.e meningitis, bacteremia) as per CLSI, M100.
G. Susceptibility and resistance to Azithromycin, Clarithromycin and Dirithromycin can be predicted by testing Erythromycin.
H. If the penicillin result is intermediate or resistant, Cefotaxime, Ceftriaxone and Meropenem should also be reported as per CLSI M100 (15).
I. S. pneumoniae that are susceptible to Penicillin with MIC's of <0.06 µg/ml can be considered susceptible to Cefdinir.
J. Only report interpretations for nonmeningitis and include the nonmeningitis notation on the report. There is not a USA FDA approved indication for the use of Cefepime for meningitis
K. Not routinely reported on isolates from the urinary tract.
L. Breakpoints are for reporting against beta-hemolytic streptococci only
M. Penicillin or Ampicillin intermediate isolates may require combined therapy with an aminoglycoside for bactericidal action
N. Daptomycin breakpoints are for reporting against beta-haemolytic streptococci and Viridans Streptococcus only
O. Reporting *Streptococcus.pyogenes*
P. Reporting *Streptococcus agalactiae*
Q If the non fastidious Sensititre plate is utilised for testing it does not require lysed horse blood in its testing. Therefore, *S pneumoniae* ATCC 49619 cannot be used as a QC organism for the *Streptococcus spp*. The recommended QC organism for this non fastidious Sensititre plate is *S. aureus* ATCC 29213.
R Community acquired bacterial pneumoniae isolates only.
S. Sensititre HP Telavancin MIC values for fastidious gram positive organisms tended to be one doubling dilution higher in *S. agalactiae* and one dilution lower in *S. pyogenes* and S. anginosus compared to reference broth micro-dilution. *Streptococcus spp*. with an interpretation of non-susceptible for Telavancin is uncommon in most institutions or may result from technical errors. Verify AST if this phenotype has not been previously encountered from this patient or institution.
T. Sensititre Tedizolid MIC values for *Streptococcus agalactiae*, *Streptococcus pyogenes* and *Streptococcus anginosus* tended to be one doubling dilution higher than the reference MIC values. At the reference Tedizolid susceptible breakpoint of 0.5µg/mL (*S. agalactiae, S. pyogenes*) or 0.25 µg/mL (*S. anginosus*), Sensititre MIC values tended to be one doubling dilution lower.
U. Dalbavancin should be tested for *Streptococcus agalactiae*, *Streptococcus pyogenes* and *Streptococcus anginosus* isolates only
V. Sensititre Dalbavancin MIC values for Streptococcus species tended to be one doubling dilution higher than the reference method. For one strain each of S. agalactiae (0.6% of susceptible isolates) and S. pyogenes (0.6% of susceptible isolates) and two strains of S. anginosus (5.7% of susceptible isolates) this trending resulted in Sensititre results of non-susceptible while the reference method results were susceptible. Due to the lack of an intermediate interpretation for this drug, this trending could result in a

potential major error, especially for *S. anginosus*. Isolates that yield MIC results other than susceptible for Dalbavancin should be submitted to a reference laboratory for additional testing.
W. Sensititre Oritavancin MIC values for fastidious gram positive organisms tended to be one doubling dilution lower in *Streptococcus spp*. Manual and AutoRead compared to reference broth micro-dilution. *Streptococcus spp*. with an interpretation of non-susceptible for Oritavancin is uncommon in most institutions or may result from technical errors. Verify AST if this phenotype has not been previously encountered from this patient or institution.
X. Use an alternative testing method prior to reporting results for Streptococcus spp. with Oritavancin when the Sensititre MIC is 0.25 µg/mL (breakpoint) if critical to patient care.
Z. Oritavancin should be tested for *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus pyogenes*

AA. Reporting *Streptococcus anginosus* Group

BB. Omadacycline should be tested for *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus anginosus* Group, and *Haemophilus influenzae* isolates only

* For *S. pyogenes* and *S. agalactiae* resistant to Erythromycin (MIC > 1 µg/mL) and susceptible or intermediate to Clindamycin (MIC 0.25 or 0.5 µg/mL), growth in the Dtest well indicates inducible Clindamycin resistance. For *S. pneumoniae* , *S. pyogenes* and *S. agalactiae*, no growth in the Dtest well indicates no inducible Clindamycin resistance.
# Interpretations conform to those approved by the CLSI .

Appendix B – Quality Control Tables

TABLE 1: Acceptable quality control MIC ranges (µg/ml) for QC organisms

ORGANISM **ATCC NUMBER**	***S. pneumoniae* 49619**	***H. influenzae*** **49766**	***H. influenzae*** **49247**
ANTIMICROBIC			
AMPICILLIN	-	-	2-8
AMPICILLIN/ SULBACTAM	-	-	2/1-8/4
AMOXILLIN/ CLAVULANIC ACID [A]	0.03/0.015- 0.12/0.06	-	2/1-16/8
AZITHROMYCIN	0.06-0.25	-	1-4
CEFACLOR	1-4	1-4	-
CEFDINIR	0.03-0.25	0.12-0.5	-
CEFEPIME	0.03-0.12[c]	-	0.5-2
CEFIXIME	-	-	0.12-1
CEFOTAXIME	0.03-0.12	-	0.12-0.5
CEFPODOXIME	-	-	0.25-1
CEFTAROLINE	0.008-0.03	-	0.03-0.12
CEFTRIAXONE	0.03-0.12	-	0.06-0.25
CEFUROXIME	0.25-1	0.25-1	-
CHLORAMPHENICOL	2-8	-	0.25-1
CIPROFLOXACIN	-	-	0.004-0.03
CLARITHROMYCIN	0.03-0.12	-	4-16
CLINDAMYCIN	0.03-0.12	-	-
DALBAVANCIN	0.008-0.03	-	-
DAPTOMYCIN [B]	0.06-0.5	-	-
DELAFLOXACIN	0.004-0.015	-	-
D TEST	Negative (no growth)	S. aureus ATCC BAA-977 * is Clindamycin Sensitive Dtest positive (growth)	

ORGANISM **ATCC NUMBER**	***S. pneumoniae* 49619**	***H. influenzae*** **49766**	***H. influenzae*** **49247**
ERTAPENEM	0.03-0.25	0.016-0.06	-
ERYTHROMYCIN	0.03-0.12	-	-
GATIFLOXACIN	0.12-0.5	-	0.004-0.03
GEMIFLOXACIN	0.008-0.03	-	0.002-0.008
IMIPENEM	-	0.25-1	-
LEVOFLOXACIN	0.5-2	-	0.008-0.03
LINEZOLID	0.25-2	-	-
LOMEFOXACIN	-	-	0.03-0.12
MEROPENEM	0.06-0.25	0.03-0.12	-
MOXIFLOXACIN	0.06-0.25	-	0.008-0.03
OMADACYCLINE	0.015-0.12	-	0.5-2
ORITAVANCIN	0.001-0.004	-	-
PENICILLIN G	0.25-1	-	-
PIPERACILLIN/ TAZOBACTAM	-	-	0.06/4-0.5/4
RIFAMPIN	-	-	0.25-1
TEDIZOLID	0.12-0.5	-	-
TELAVANCIN	0.004-0.015	-	-
TELITHROMYCIN	0.004-0.03	-	1-4
TETRACYCLINE	0.06-0.5	-	4-32
TIGECYCLINE	0.015-0.12	-	-
TRIMETHOPRIM/ SULPHAMETHOXAZOLE	0.12/2.4-1/19	-	0.03/0.59-0.25/4.75
VANCOMYCIN	0.12-0.5	-	-

Footnotes

[A] . Quality control range for *E.coli* ATCC 35218 when tested on HTM is 4/2-16/8 µg/ml

[B] *QC ranges reflect MIC`s obtained when Mueller Hinton broth with LHB is supplemented with calcium to a final concentration of 50 µg/ml*

[C] ***CLSI range 0.03-0.25µg/ml***

* *Staphylococcus aureus* ATCC BAA-977 Lot QC, Manual Read only

Appendix C – Performance Tables

Performance characteristics were established at several external study sites by comparing Sensititre *Haemophilus influenzae* / *Streptococcus* species plates with the CLSI recommended reference frozen plates with fresh clinical isolates and a collection of challenge strains. Sensititre *Haemophilus* Test medium was used for the *H. influenzae* and Sensititre Mueller Hinton broth with 2-5 % lysed horse blood for *S. pneumoniae*. MIC values were considered to be in essential agreement when the Sensititre *Haemophilus influenzae* / *Streptococcus* species plate was within +/- one two fold dilution of the reference method. Category agreement was calculated based on the interpretative criteria. The challenge set of 55 isolates for *S, pneumoniae* testing was obtained from the CDC collection augmented with additional appropriate organisms.

Agreement Rates for Manual Read *H. influenzae*, *S. pneumoniae*, and *Streptococcus spp*.[1]

Antimicrobial Agent	*Haemophilus influenzae*		*Streptococcus pneumoniae*		*Streptococcus* spp. other than *S. pneumoniae*	
	% Essential Agreement	% Categorical Agreement	% Essential Agreement	% Categorical Agreement	% Essential Agreement	% Categorical Agreement
Amoxicillin/ Clavulanic Acid	100	100	100	100	100	N/A
Ampicillin	94.0	100	A	A	A	A
Ampicillin/ Sulbactam	100	100	A	A	A	A
Azithromycin	96.9	100	92.7	100	100	98.6
Cefaclor	96.0	97.0	100	98.0	A	A
Cefdinir	98.1	100	98.3	99.0	A	A
Cefepime	96.5	98.9	99.5	100	99.4	98.3
Cefixime	99.0	100	A	A	A	A
Cefpodoxime	95.9	99.0	A	A	A	A
Cefotaxime	94.3	100	100	100	100	98.9
Ceftaroline	99.7[D]	100[D]	100	100	100[E]	100[E]
					100[F]	100[F]
Cefuroxime	96.0	99.0	98.0	100	100	N/A
Ceftriaxone	99.0	100	100	100 [b]	99.4	98.6
Chloramphenicol	99.0	100	98.0 [b]	100 [b]	100	99.4
Ciprofloxacin	99.0	100	A	A	A	A
Clarithromycin	94.9	100	99.3	100	A	A
Clindamycin	A	A	98.9	99.7	A	A
Ertapenem	99.0	100	100	91.0	A	A
Dalbavancin	A	A	A	A	96.7[G]	99.1[G]

Antimicrobial Agent	*Haemophilus influenzae*		*Streptococcus pneumoniae*		*Streptococcus* spp. other than *S. pneumoniae*	
	% Essential Agreement	% Categorical Agreement	% Essential Agreement	% Categorical Agreement	% Essential Agreement	% Categorical Agreement
Daptomycin	A	A	A	A	99.0	100
Delafloxacin[H,I]	A	A	A	A	99.7	100
Dtest	A	A	-	100*	-	100[E] 100[F]
Erythromycin	A	A	100	100	100	98.9
Gatifloxacin	98.1	100	100	100	100	99.4
Gemifloxacin	97.7	100	99.3	100	100	100
Imipenem	99.0	100	A	A	A	A
Levofloxacin	99.5	100	100	100	100	100
Linezolid	A	A	98.0	100	100	99.4
Lomefloxacin	99.5	99.5	A	A	A	A
Meropenem	92.7	99.2	99.5	99.5	100	100
Moxifloxacin	93.3	100	100	99.7	100	100
Omadacycline[J,K]	98.0	98.9	97.2	99.6	95.9	97.0
Oritavancin	A	A	A	A	94.3[G]	95.6[G]
Penicillin	A	A	94.0 [b]	98.0 [b]	99.7	99.1
Piperacillin/ Tazobactam	97.4	100	A	A	A	A
Rifampin	99.0	100	A	A	A	A
Tedizolid	A	A	A	A	100	100
Telavancin	A	A	A	A	99.4	100
Telithromycin	100	98.9	98.9	99.7	A	A
Tetracycline	97.0	100	100 [b]	100 [b]	100	98.6
Tigecycline	A	A	99.6%[C]	100%[C]	99.4	100
Trimethoprim/ Sulphamethoxazole	100	100	100[b]	100 [b]	99.7	N/A
Vancomycin	A	A	99.6	100	100	100

Footnote:
[1] Data was tabulated from testing a total of 362 *S. pneumoniae*, 356 (354 for Telithromycin*) Haemophilus influenzae*, and 349 Streptococcal isolates. Gemifloxacin was tested with 222 Beta Streptococcal isolates only. Daptomycin was tested with 347 isolates.

A Performance not established
B Based on 55 CDC isolates
C227 isolates tested of which 51 isolates manually read on the Sensititre Vizion™
D 348 strains tested and read manually on the Sensititre Vizion™
E Streptococcus pyogenes only
F Streptococcus agalactiae only
G According to the FDA approved pharmaceutical antimicrobial agent package insert, polysorbate-80 should be used for testing freshly prepared or frozen microtiter trays with Dalbavancin and Oritavancin. Dalbavancin and Oritavancin on the Sensititre panel have been developed with an alternative method to provide equivalent performance to the reference method that contained polysorbate-80.
* Dtest positive *S. pneumoniae* isolates not tested
H Only two *S. anginosus* isolates were determined as non-susceptible by the reference method. Although both results were within Essential Agreement, one very major discrepancy was observed when compared to the reference method. If critical to patient care, testing should be repeated using an alternative testing/reference method prior to reporting results for Delafloxacin with organism *S. anginosus* when the Senstitre MIC is 0.06 µg/mL.
I Delafloxacin MIC values for *S. pyogenes* tended to be one doubling dilution higher with the VIZION and OptiRead as compared to the reference microdilution method.
J. Omadacycline should be tested for *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus anginosus* Group, and *Haemophilus influenzae* isolates only. Organisms under the *S.anginosus* group were not speciated during the clinical study.
K. Omadacycline MIC values tended to be in exact agreement or at least one dilution lower when testing *S. pyogenes* and *S. pneumoniae* with both OptiRead and VIZION reading methods compared to the CLSI reference broth microdilution. MIC values MIC values tended to be in exact agreement or one dilution higher when testing *S. anginosus* with both OptiRead and VIZION. Omadacycline MIC values tended to be in exact agreement or at least one dilution lower when testing *H. influenzae* with the VIZION only.

Agreement Rates for Autoread of *S. pneumoniae* and for *Streptococcus spp*. other than *S. pneumoniae*[2]

Antimicrobial Agents	*S. pneumoniae*		*Streptococcus spp.* other than *S. pneumoniae*	
	% Essential Agreement	% Categorical Agreement	% Essential Agreement	% Categorical Agreement
Amoxicillin/ Clavulanic Acid	97.2	97.9	100	N/A
Azithromycin	92.4	100	99.7	97.7
Cefaclor	97.6	100	A	A
Cefdinir	97.9	99.0	A	A
Cefepime	99.7	96.9	99.4	98.6
Cefotaxime	99.7	100	100	98.0
Ceftriaxone	98.3	85.8	98.6	98.6
Ceftaroline	100	100	100[E]	100[E]
			96.9F	100[F]
Cefuroxime	99.7	99.3	100	N/A
Chloramphenicol	97.9	93.4	99.4	98.6
Clarithromycin	97.2	100	A	A
Clindamycin	98.9	100	A	A
Dalbavancin	A	A	96.2[G]	99.0[G]
Daptomycin	A	A	98.7	100[C]
Delafloxacin[H,I,J]	A	A	99.1	99.1
Ertapenem	100	94.0	A	A
Erythromycin	100	100	100	98.6
Gatifloxacin	100	100	100	100
Gemifloxacin	99.7	99.3	100	99.5[B]
Levofloxacin	99.7	99.3	100	100
Linezolid	97.0	100	99.4	99.4
Meropenem	99.0	90.3	100	100
Moxifloxacin	100	99.7	100	100
Omadacycline[K,L]	97.2	99.6	95.4	97.0
Oritavancin	A	A	94.7[G]	95.4[G]
Penicillin	100	97.6	98.6	97.1
Tedizolid	A	A	98.9	99.6
Telavancin	A	A	99	100
Telithromycin	98.6	100	A	A
Tetracycline	99.7	99.0	99.7	98.9
Tigecycline	99.1%[D]	100%[D]	99.0	100
Trimethoprim/ Sulphamethoxazole	97.9	96.9	99.7	A
Vancomycin	99.0	100	100	100

Footnote:
2 Data was tabulated from testing a total of 288 (362 for Clindamycin, Ertapenem, and Telithromycin*) S. pneumoniae* and 349 Streptococcal isolates. Gemifloxacin was tested with 222 Beta Streptococcal isolates only. Daptomycin was tested with 347 isolates.
A Performance not established

B Beta Streptococci only: Number tested 222

C Beta Streptococci only: Number tested 221

D Number tested 227

E *Streptococcus pyogenes* only

F *Streptococcus agalactiae* only

G According to the FDA approved pharmaceutical antimicrobial agent package insert, polysorbate-80 should be used for testing freshly prepared or frozen microtiter trays with Dalbavancin and Oritavancin. Dalbavancin and Oritavancin on the Sensititre panel have been developed with an alternative method to provide equivalent performance to the reference method that contained polysorbate-80.

H Only two *S. anginosus* isolates were determined as non-susceptible by the reference method. Although both results were within Essential Agreement, one very major discrepancy was observed when compared to the reference method. If critical to patient care, testing should be repeated using an alternative testing/reference method prior to reporting results for Delafloxacin with organism *S. anginosus* when the Senstitre MIC is 0.06 µg/mL.

I Delafloxacin MIC values for *S. pyogenes* tended to be one doubling dilution higher with the VIZION and OptiRead as compared to the reference microdilution method.

J Delafloxacin MIC values for *S. agalactiae* tended to be one doubling dilution lower with the OptiRead as compared to the reference microdilution method. If critical to patient care, *S. agalactiae* isolates with an MIC result of 0.06 µg/mL should be retested with an alternative method or sent to a reference lab.

K Omadacycline should be tested for *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus anginosus* Group, and *Haemophilus influenzae* isolates only. Organisms under the *S.anginosus* group were not speciated during the clinical study.

L Omadacycline MIC values tended to be in exact agreement or at least one dilution lower when testing *S. pyogenes* and *S. pneumoniae* with both OptiRead and VIZION reading methods compared to the CLSI reference broth microdilution. MIC values MIC values tended to be in exact agreement or one dilution higher when testing *S. anginosus* with both OptiRead and VIZION.

Reproducibility

Manual and automated read methods for H*. influenzae, S. pneumoniae* and for *Streptococcus spp.* other than *S. pneumoniae*

The reproducibility of MIC tests was measured against a minimum of ten organisms at several sites. Testing was performed using Sensititre plates read manually. Reproducibility study results for *H. influenzae* were > 97% and for *S. pneumoniae* > 95% for all antimicrobics listed in the tables above.

Tigecycline
The reproducibility of MIC tests was measured against 25 *Streptococcus* spp. at three sites. Testing was performed using Sensititre™ plates read manually and automatically (18-24 hours.); frozen plates were prepared according to CLSI M7-A5 for reference. Sensititre™ manual between site reproducibility was 97%. Sensititre™ autoread between site reproducibility was 97%

Ceftaroline
Reproducibility of MIC tests was measured against 34 *Staphylococcus aureus* and 25 *Streptococcus* spp. (MHB or MHB with LHB) at three sites. Testing was performed using Sensititre plates read manually and automatically (18-24 hours); frozen plates were prepared according to CLSI M7 for reference.

Telavancin
The reproducibility of MIC tests was measured against 25 *Streptococcus* spp. (MHB with LHB) at three sites. Testing was performed using the Sensititre® HP MIC Susceptibility Plates read manually and automatically (20 - 24 hrs).

Tedizolid
The reproducibility of MIC tests was measured against 25 *Streptococcus* spp. (MHB with LHB) at three sites. Testing was performed using the Sensititre® HP MIC Susceptibility Plates read manually and automatically (20 - 24 hrs).

Dalbavancin
The reproducibility of MIC tests was measured against 25 *Streptococcus* spp. (MHB with LHB) at three sites. Testing was performed using the Sensititre® HP MIC Susceptibility Plates read manually and automatically (20 - 24 hrs).

Oritavancin
The reproducibility of MIC tests was measured against 24 gram positive *Streptococcus* spp. tested in MHB w/LHB at three sites. Testing was performed using Sensititre plates only, read manually and automatically. Reproducibility was calculated as the percent of results for the combined sites which were within plus or minus one dilution of the modal value for all sites.

Dtest

Dtest negative *S. pneumoniae*, and Dtest positive and negative *S. pyogenes* and *S. agalactiae*. Testing was performed using Sensititre plates read manually.

	Dtest Manual Read
S. pneumoniae *	100%
S. pyogenes	100%
S. agalactiae	100%

* Dtest positive *S. pneumoniae* isolates not tested

Summary of Reproducibility Data for *Streptococcus* spp. (MHB with LHB):

	Streptococcus spp. Between site reproducibility	
	Manual	Autoread
Ceftaroline	98.7%	98.7%
Dalbavancin	98.7%	100%
Oritavancin	97.2%	95.8%
Tedizolid	100%	98.7%
Telavancin	100%	100%
Tigecycline	97%	97%
Delafloxacin	99.4%	100%
Omadacycline	97.2%	97.2%

	Technical Support email addresses
Austria	microbiology.techsupport.de@thermofisher.com
Belgium	microbiology.techsupport.benelux@thermofisher.com
Czech Republic	mikrobiologie.tech.podpora.cz@thermofisher.com
Denmark	microbiology.techsupport.nordic@thermofisher.com
France	microbiologie.techsupport.fr@thermofisher.com
Finland	mikrobiologia.tekninentuki.fi@thermofisher.com
Germany	microbiology.techsupport.de@thermofisher.com
Italy	microbiologia.supportotecnico.it@thermofisher.com
Netherlands	microbiology.techsupport.benelux@thermofisher.com
Norway	microbiology.techsupport.nordic@thermofisher.com
Spain	microbiologia.soporte.es@thermofisher.com
Sweden	microbiology.techsupport.nordic@thermofisher.com
UK Technical Support	microbiology.techsupport.uk@thermofisher.com
US Technical Support	USCLETechSupport@thermofisher.com