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A Multicenter Comparison Study of the Sensititre® Automated/Manual Susceptibility Plate to the NCCLS Microdilution Method for *Streptococcus pneumoniae* vs. *Clindamycin*

Authors: T. Kelley[1*], S. B. Killian[1], C.C. Knapp[1], N.Holliday[1], M.R. Jacobs[2], S.Bajaksouzian[2], A.Windau[2], E.S. Moland[3], T.J. Lockhart[3], L.B. Olson[3], J.A. Black[3]

1. TREK Diagnostic Systems, Cleveland, OH 2. University Hospitals, Cleveland, OH
3. Creighton University, Omaha, NE

TREK DIAGNOSTIC SYSTEMS
982 Keynote Circle, Suite 6
Cleveland, OH 44131
800.871.8909 • www.trekds.com

ABSTRACT

Background: A multi-site evaluation was undertaken to compare the performance of the Sensititre susceptibility plate (TREK Diagnostic Systems, Cleveland, OH) for *Streptococcus pneumoniae* with Clindamycin (CLI), testing both automated and manual reading methods, to its performance on the frozen NCCLS broth microdilution reference method. The drug range tested for Clindamycin was (0.015-8 µg/ml).

Methods: The clinical evaluation was conducted at three sites and consisted of 310 fresh clinical *Streptococcus* isolates and 53 CDC challenge *Streptococcus* isolates. The recommended quality control organisms were tested daily and were within the NCCLS expected quality control range.

Results: When the automated reading method was compared to the reference method the clinical isolates' Essential Agreement (EA) and Categorical Agreement (CA) were: 98.7% and 100%, respectively, while the challenge isolates' EA and CA were both 100%, respectively. When the manual reading method was compared to the reference method the clinical isolates' EA and CA was: 98.7% and 99.7%, respectively; for the challenge isolates they were both 100%, respectively. The reproducibility isolates' EA for the automated and manual methods were 98.7% and 98.7%, respectively.

Conclusions: This multi-site evaluation indicates that the performance of the Sensititre susceptibility system with Clindamycin for *Streptococcus pneumoniae,* using either the automated or manual reading method, was equivalent to the performance of the NCCLS microdilution reference method.

*Abstract has been modified

PURPOSE OF THE STUDY

To evaluate the performance of Clindamycin on the Sensititre 18 – 24 hour susceptibility plate compared to the NCCLS microdilution reference method (M7 – A6).

MATERIALS & METHODS

Organisms: The testing at 3 sites consisted of the following:

- 309 Total Clinical isolates
- 53 Total Challenge isolates
- 25 Reproducibility isolates
- 1 Quality Control strain

Susceptibility Testing Methods:

- Each isolate was tested using a Sensititre 18 – 24 susceptibility plate. The plates were set-up and tested according to the manufacturers' instructions.
- The reference plates were tested according to the microdilution methods published by the National Committee for Clinical Laboratory Standards (NCCLS, M7-A6).

Pathogen	Minimal inhibitory concentration (µg/ml)[a]		
Streptococcus pneumoniae	**S**	**I**	**R**
	≤0.25	0.5	≥1

Antibiotics

Antimicrobial	Range Tested	Supplied By
Clindamycin (CLI)	0.15-8	Pfizer Inc.

RESULTS

Clinical Isolates vs. Clindamycin for S. pneumoniae

Read Method	Total Isolates Tested	% Essential Agreement	% Categorical Agreement	Number Resistant	Very Major Errors	Major Errors	Minor Errors
Manual	309	98.7	99.7	76	0	0	1
Automated	309	98.7	100	76	0	0	0

CDC Challenge Isolates vs. Clindamycin for S. pneumoniae

Read Method	Total Isolates Tested	% Essential Agreement	% Categorical Agreement	Number Resistant	Very Major Errors	Major Errors	Minor Errors
Manual	53	100	100	14	0	0	0
Automated	53	100	100	14	0	0	0

Combined (Challenge and Clinical) Isolates vs. Clindamycin for S. pneumoniae

Read Method	Total Isolates Tested	% Essential Agreement	% Categorical Agreement	Number Resistant	Very Major Errors	Major Errors	Minor Errors
Manual	362	98.9	99.7	90	0	0	1
Automated	362	98.9	100	90	0	0	0

Streptococcus pneumoniae - Manual Reading Method
MIC Distribution for Clinical & Challenge Isolates vs. Clindamycin

Test Results \ Reference Results	0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	>8
0.015	2	3	2								
0.03		35	42								
0.06	1	3	178	1							
0.12		1		2							
0.25						1					
0.5						1					
1							1	1			
2								1			
4									1		
8											
>8											86
TOTALS	**3**	**42**	**222**	**3**	**0**	**2**	**1**	**2**	**1**	**0**	**86**

Categorical Interpretations: Susceptible ≤ 0.25, Intermediate = 0.5, Resistant ≥ 8

Streptococcus pneumoniae - Automated Reading Method
MIC Distribution for Clinical & Challenge Isolates vs. Clindamycin

Test Results \ Reference Results	0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	>8
0.015	2	6	1								
0.03	1	30	63								
0.06		5	157	2							
0.12		1		1							
0.25			1								
0.5						2					
1								1			
2							1	1			
4									1		1
8											
>8											85
TOTALS	**3**	**42**	**222**	**3**	**0**	**2**	**1**	**2**	**1**	**0**	**86**

Categorical Interpretations: Susceptible ≤ 0.25, Intermediate = 0.5, Resistant ≥ 8

Reproducibility Isolates vs. Clindamycin
Reference Agreement within ±1 Dilution of Modal MIC

Site	# Agreement Manual	# Agreement Autoread	Total Isolates Tested	Manual %	Autoread %
TREK	25	25	25	100	100
Creighton	24	24	25	96	96
UH	25	25	25	100	100
Combined	74	74	75	98.7	98.7

CONCLUSIONS

This investigation compared the 18 – 24 hour Sensititre susceptibility plate with the NCCLS reference microdilution frozen plate (M7 – A6). The Sensititre plate was equivalent to the performance of the reference method and was very reproducible.

Clinical Isolates:

- The overall essential agreement for Clindamycin, within a +/- one-well dilution range, was 98.7% for the manual method and 98.7% for the autoread method.
- The overall categorical agreement for Clindamycin was 99.7% for the manual method and 100% for the autoread method.

CDC Challenge Organisms:

- The overall essential agreement for Clindamycin, within a +/- one-well dilution range, was 100% for the manual method and 100% for the autoread method.
- The overall categorical agreement for Clindamycin was 100% for the manual method and 100% for the autoread method.

Reproducibility:

- Interlaboratory reproducibility was 98.7% for the manual read method and 98.7% for the autoread method.