APPLICATION NOTE

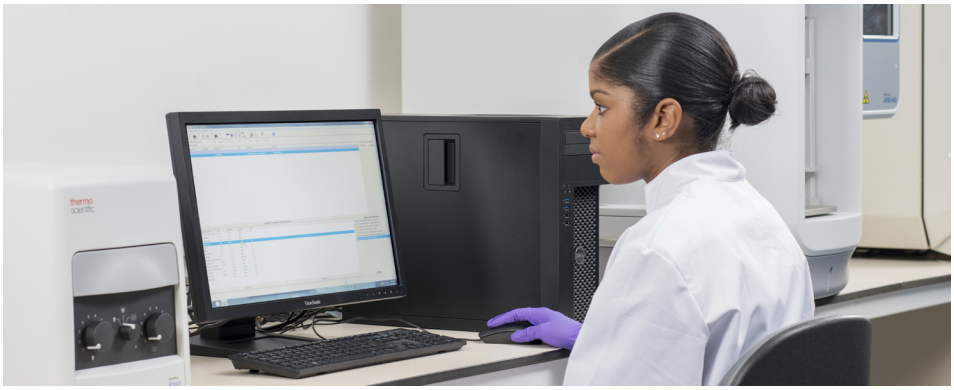
Verification of antimicrobial susceptibility tests

Thermo Scientific Sensititre System – Bringing new drugs onto an existing system or verifying a new system

Prior to implementation in a clinical microbiology laboratory, an initial assessment of a new IVD test must be performed prior to being used for patient testing. This applies to laboratories implementing a new Sensititre System as well as laboratories adding a new antimicrobial to an existing Sensititre System.

In order to demonstrate equivalent performance specifications (accuracy and precision/reproducibility) for an antimicrobial susceptibility testing (AST) device, labs must compare results obtained from a Sensititre System against a reference method (such as CLSI reference method).

CLSI recommends testing at least 10 isolates to verify a new drug on an existing Sensititre System; no less than 30 isolates (preferably 100+) should be tested when a laboratory acquires a new Sensititre System. If a laboratory has never previously tested a specific drug, CLSI guidance is that results from a reference laboratory should be used as the reference method.



Laboratories should be conducting testing to evaluate the following:

Criteria	Definition	Acceptance limits
Accuracy – Essential Agreement	The MIC result is within +/- 1 doubling dilution between the lab and the reference method	Agreement ≥ 90% of test results
Accuracy – Categorical Agreement	The S, I, R interpretations of the MIC results are consistent between the lab and the reference method	Agreement ≥ 90% of test results, with ≤ 3% very major/major discrepancies or errors and <10% minor discrepancies or errors (depending on the reference method used)
Precision - QC strains recommended by manufacturer and clinical Isolates	QC conducted in a 3x5 or a 20/30 day plan. Clinical isolates (at least 5) tested in triplicate over three days	

Always refer to the CLSI M100 for the current recommendations before conducting testing.

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Obtaining isolates for verification studies

Isolates that may be used for verification studies include saved clinical samples, those obtained from colleagues or proficiency samples. At times, laboratories may need to source additional isolates to complete verification studies. One resource is the CDC-FDA Antimicrobial Resistance Isolate Bank (AR Bank).

The AR Bank offers a variety of free-of-charge panels that can be used for in-house verification studies, each containing a collection of isolates with specified MIC results and

Sample plan†

A sample plan for laboratories needing to perform a verification study for a new Gram-negative drug on an existing Sensititre MIC panel.

Day	Accuracy	Precision	QC*
1	5 isolates	2 clinical isolates in triplicate	*P. aeruginosa* ATCC 27853 x 3 *E. coli* ATCC 25922 x 3
2	5 isolates	2 clinical isolates in triplicate	*P. aeruginosa* ATCC 27853 x 3 *E. coli* ATCC 25922 x 3
3		1 clinical isolate in triplicate	*P. aeruginosa* ATCC 27853 X 3 *E. coli* ATCC 25922 x 3
4			*P. aeruginosa* ATCC 27853 X 3 *E. coli* ATCC 25922 x 3
5			*P. aeruginosa* ATCC 27853 X 3 *E. coli* ATCC 25922 x 3

*Allows fulfillment of 3x5 QC plan and conversion to weekly QC; alternatively can perform only on Day 1 and perform daily QC.
†This is a sample plan for illustrative purposes. Laboratories should design their own verification studies.

Sample panels from the CDC-FDA Antimicrobial Resistance Isolate Bank

Ceftazidime/avibactam Panel

A panel of gram-negative bacteria with different susceptibility to ceftazidime/avibactam. This panel can be used for "in-house" validation of ceftazidime/avibactam antimicrobial susceptibility testing methods.

Bank #	Species	Key Resistance Determinants
0431 [PDF – 2 Pages]	Enterobacter aerogenes	ND*
0432 [PDF – 2 Pages]	Enterobacter cloacae	ND*
0433 [PDF – 2 Pages]	Escherichia coli	ND*
0434 [PDF – 2 Pages]	Escherichia coli	ND*

Ceftolozane/tazobactam Panel

A panel of gram-negative bacteria with different susceptibility to ceftolozane/tazobactam. This panel can be used for "in-house" validation of ceftolozane/tazobactam antimicrobial susceptibility testing methods.

Bank #	Species	Key Resistance Determinants
0351 [PDF – 2 Pages]	Pseudomonas aeruginosa	ND*
0352 [PDF – 2 Pages]	Pseudomonas aeruginosa	ND*
0353 [PDF – 2 Pages]	Pseudomonas aeruginosa	ND*
0354 [PDF – 2 Pages]	Pseudomonas aeruginosa	ND*

The Sensititre System is a leader in antimicrobial susceptibility and identification (AST/ID) testing, offering flexible, customizable testing options to accommodate laboratories of all sizes. For further details on our complete range of instrumentation and plates, please visit **thermofisher.com/AST**

For a presentation about conducting verification studies for a new drug on an existing Sensititre System or a new Sensititre System for your lab, please visit our Clinical Microbiology Resource Library at **thermofisher.com/clinicalwebinars**

Contact information:
microbiology@thermofisher.com
USA +1 800 255 6730

Find out more at **thermofisher.com/microbiology**

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