



Ceftazidime-avibactam MIC Test Strip Technical Sheet

INTRODUCTION

Liofilchem® MIC Test Strip is a quantitative method intended for the *in vitro* determination of antimicrobial susceptibility of non-fastidious Gram negative and Gram positive aerobic bacteria (for example, Enterobacteriaceae, *Pseudomonas*, *Enterococcus* and *Staphylococcus* species) and fastidious bacteria (for example, anaerobes, *Haemophilus* and *Streptococcus* species and *N. gonorrhoeae*). MIC Test Strip consists of specialized paper impregnated with a pre-defined concentration gradient of an antimicrobial agent, which is used to determine the minimum inhibitory concentration (MIC) in µg/mL of antimicrobial agents against bacteria as tested on agar media using overnight incubation and manual reading procedures.

Ceftazidime-avibactam (Zavicefta) is a combination antibiotic consisting of a cephalosporin-class antibacterial drug and a novel non-β-lactam β-lactamase inhibitor with activity against multidrug-resistant Gram-negative bacteria.

The proposed indication for adults are:

- Complicated Intra-abdominal Infections (cIAI);
- Complicated Urinary Tract Infections (cUTI), including Pyelonephritis;
- Hospital-acquired pneumonia, including ventilator associated pneumonia (VAP);
- Infections due to aerobic Gram-negative organisms in patients with limited treatment options.

Ceftazidime-avibactam MIC Test Strip generates a stable concentration gradient for ceftazidime (0.016-256 µg/mL) in the presence of a fixed concentration of avibactam (4 µg/mL).

TEST PROCEDURE

Before using Ceftazidime-avibactam MIC Test Strip from an unopened package, visually inspect to ensure the package is intact. Do not use the strips if the package has been damaged.

When removed from the refrigerator, allow the package or storage container to reach room temperature for about 30 minutes.

Moisture condensing on the outer surface must evaporate completely before opening the package.

Materials required but not provided:

- Mueller Hinton II Agar, 90 (ref. 10031) or 140 mm (ref. 10231) plates
- Sterile saline (0.85% NaCl) (ref. 20095)
- Sterile loops, swabs (not too tightly spun), test tubes, pipettes and scissors
- Forceps
- 0.5 McFarland turbidity standard (ref. 80400)
- Incubator (35 ± 2°C)
- Quality control organisms
- Additional technical information from www.liofilchem.net

Inoculum preparation

Suspend well-isolated colonies from an overnight agar plate into saline to achieve a 0.5 McFarland standard turbidity.

A confluent or almost confluent lawn of growth will be obtained after incubation, if the inoculum is correct.

In order to verify that your procedure gives the correct inoculum density in terms of CFU/mL, performing regular colony counts is recommended.

Inoculation

Dip a sterile swab in the broth culture or in a diluted form thereof and squeeze it on the wall of the test tube to eliminate excess liquid.

Alternatively, use a rotation plater to efficiently streak the inoculum over the agar surface. Allow excess moisture to be absorbed so that the surface is completely dry before applying MIC Test Strip.

Application

Apply the strip to the agar surface with the scale facing upwards and code of the strip to the outside of the plate, pressing it with a sterile forceps on the surface of the agar and ensure that whole length of the antibiotic gradient is in complete contact with the agar surface. Once applied, do not move the strip.

Incubation

Incubate the agar plates in an inverted position at 35 ± 2°C for 16-20 hours in ambient atmosphere. Extend the incubation for up to 48 hours in case of slow growing organisms.

EVALUATING THE RESULTS

Reading

Observe where the relevant inhibition ellipse intersects the strip and read the MIC at complete inhibition. Growth along the entire gradient i.e. no inhibition ellipse indicates that the value is greater than or equal to (≥) the highest value on the scale. An inhibition ellipse that intersects below the lower end of the scale is read as less than (<) the lowest value.

Interpretation

Use EUCAST breakpoints shown below. Always round up MIC Test Strip half dilution values to the next upper two-fold value before categorization. For example a *P. aeruginosa* ceftazidime-avibactam MIC of 1.5 µg/mL is reported as 2 µg/mL.

See page 2 for example of results. Also consult the MIC Test Strip Photographic Guide.

QUALITY CONTROL

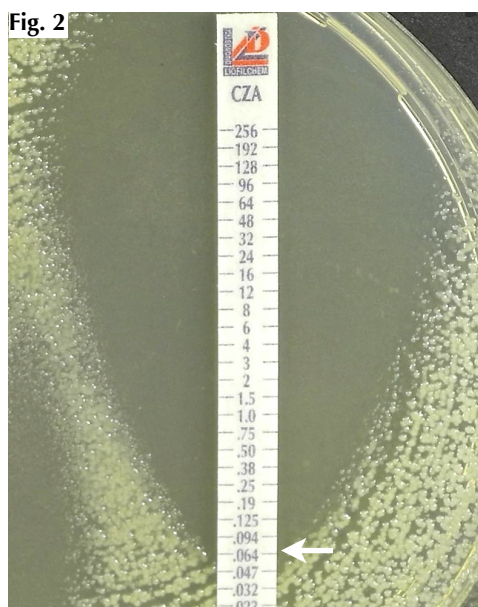
CLSI-recommended quality control strains are used as outlined under TEST PROCEDURE.

Organism	Breakpoint (µg/mL)		Quality Control MIC Range (µg/mL)
	S ≤	R >	
<i>Enterobacteriaceae</i>	8	8	<i>S. aureus</i> ATCC® 29213 4-16
<i>Pseudomonas aeruginosa</i>	8	8	<i>E. coli</i> ATCC® 25922 0.06-0.5
			<i>P. aeruginosa</i> ATCC® 27853 0.5-4
			<i>E. coli</i> ATCC® 35218 0.03-0.12
			<i>K. pneumoniae</i> ATCC® 700603 0.25-2
			<i>H. influenzae</i> ATCC® 49247 0.06-0.5
			<i>H. influenzae</i> ATCC® 49766 0.015-0.06
			<i>S. pneumoniae</i> ATCC® 49619 0.25-2

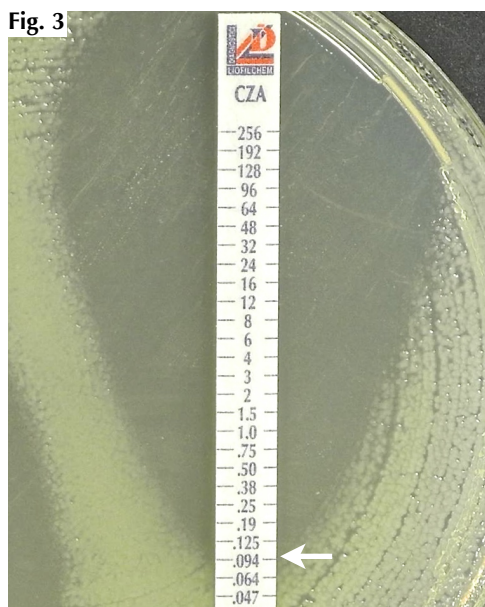
Ceftazidime-avibactam MIC Test Strip Reading Guide



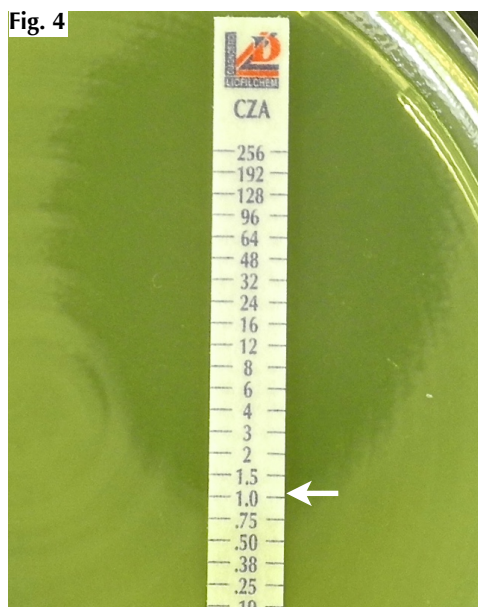
MIC 1 µg/mL



MIC 0.064 µg/mL



MIC 0.094 µg/mL, reported as 0.125 µg/mL



MIC 1 µg/mL

REFERENCES

- CLSI M100-S26 (2016) Performance Standards for Antimicrobial Susceptibility Testing.
- EUCAST (2016) Breakpoint tables for interpretation of MICs and zone diameters, version 6.0 <http://www.eucast.org>
- CLSI M07-A10 (2015) Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically: Approved Standard – Tenth Edition.
- http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004027/WC500210234.pdf

PRESENTATION

	µg/mL	Code	Packaging	Ref.
MIC Test Strip	Ceftazidime*-avibactam (4 µg/mL)	0.016-256*	CZA	10 30 100
				921391 92139 921390

MIC Test Strip, Patent No. 1395483

Liofilchem® and the Liofilchem company logo are registered trademarks of LIOFILCHEM s.r.l.



LIOFILCHEM® s.r.l.

Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy

Tel. +39 0858930745

Fax +39 0858930330

www.liofilchem.net

liofilchem@liofilchem.net

