

ComASP[®] ATM-CZA

DESCRIPTION

ComASP® ATM-CZA is a panel for evaluation of synergistic effect of Aztreonam and Ceftazidime- avibactam of clinical isolates based on growth of the test organism in the presence of various concentrations of Aztreonam and Ceftazidime-avibactam alone and in combination.

Aztreonam (ATM) concentration range

2 µg/mL to 256 µg/Ml

Ceftazidime-avibactam (CZA) concentration range

2 /4 $\mu g/mL$ to 256/4 $\mu g/mL$

Aztreonam + Ceftazidime-avibactam (ACZ) concentration range

0.03 µg/mL to 512 µg/L of Aztreonam + fixed concentration Ceftazidime-avibactam 8/4 µg/mL

CONFIGURATION

Aztreonam (0.03 μg/mL to 512 μg/mL) + Ceftazidime- Avibactam (fixed concentration at 8 μg/mL /4 μg/mL)	Growth	ACZ	ACZ	ACZ	ACZ	ACZ	ACZ	ACZ
		0.03	0.06	0.12	0.25	0.5	1	2
	ACZ	ACZ	ACZ	ACZ	ACZ	ACZ	ACZ	ACZ
	4	8	16	32	64	128	256	512
Ceftazidime-Avibactam (2/4 µg to 256/4 µg)	CZA	CZA	CZA	CZA	CZA	CZA	CZA	CZA
	2/4	4/4	8/4	16/4	32/4	64/4	128/4	256/4
Aztreonam (2 μg/mL to 256 μg/mL)	ATM	ATM	ATM	ATM	ATM	ATM	ATM	ATM
	2	4	8	16	32	64	128	256

Growth indicates growth control: No antimicrobial agent in the well

TEST PROCEDURE

- 1. Take a panel from its envelope and leave it at room temperature for 10 min,
- 2. Prepare a suspension of the test organism using either the direct colony suspension or growth method.
- 3. Standardize the suspension to the density of a McFarland 0.5 standard (1 \times 10⁸ CFU/mL)
- 4. Optimally within 15 min of preparation, dilute the adjusted suspension 1:20 (5 x10⁶ CFU/mL) in saline (Solution A).
- 5. Dilute Solution A 1:10 in CAMH II Broth (5 $x10^5$ CFU/mL) (Solution B).
- 6. Dispense 100 μ l of Solution B into each well of the panel in order to obtain 5 x10⁴ CFU/well.
- 7. Cover the panel with the lid provided and incubate at $36 \pm 2^{\circ}$ C for 16-20 hours in ambient air.

USER QUALITY CONTROL

Quality control of the panel is performed using the following reference strains:

Control strains	Expected Results for MIC range (mg/L) AZTREONAM	Expected Results for MIC range (mg/L) Ceftazidime-avibactam CZA
Staphylococcus aureus ATCC® 29213	-	4 – 16
Escherichia coli ATCC® 25922	0.06-0.25	0.06 - 0.5
Pseudomonas aeruginosa ATCC® 27853	2-8	0.5 - 4
Escherichia coli ATCC® 35218	0.03-0.12	0.03 - 0.12
Klebsiella pneumoniae ATCC® 700603	8-64	0.25 - 2
Klebsiella pneumoniae ATCC® BAA-2814	8-64	-

LIMITATIONS

Invalid results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.

WARNINGS AND PRECAUTIONS

- 1) For research use only.
- 2) Operators must be trained and have certain experience. Please read the instructions carefully before using the kit. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.
- 3) Consult the Safety Data Sheet (SDS) prior to use. SDS available from **liofilchem.com/ifu-sds**
- 4) Do not use if a panel appears to be damaged.
- 5) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- 6) Ensure laboratory equipment is calibrated and maintained in accordance with the laboratory's procedure.

STORAGE

Store at 2-8°C in the original packaging. Keep away from direct sunlight and direct heat. Do not use the panels beyond the expiry date indicated on the label. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After use the panel and material that has come into contact with the sample must be decontaminated and disposed of in accordance with guidelines used in the laboratory for decontamination and disposal of potentially infected material.

REFERENCES

- ISO 20776-1:2019. Clinical laboratory testing and in vitro diagnostic test systems -- Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices -- Part 1:Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases.
- CLSI. Performance Standards for Antimicrobial Susceptibility Testing. 31st ed. CLSI Supplement M100S. Wayne, PA: Clinical and Laboratory Standards Institute; 2021.
- CLSI. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically. 11th ed. CLSI standard M07. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
- The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 11.0, 2021. <u>http://www.eucast.org.</u>
- The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST. Version 11.0, 2021. <u>http://www.eucast.org.</u>

Product	Packaging	Ref.
ComASP® ATM-CZA	40 tests	78001

TABLE OF SYMBOLS

LOT Batch code	Do not reuse	Manufacturer	Σ	Contains sufficient for <pre><n> tests</n></pre>	Temperature limits
REF Catalogue number	Fragile, handle with care	Use by	i	Consult instructions for use	Keep away from heat



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