ComASP™ Ceftolozane-tazobactam

ENGLISH

System for ceftolozane-tazobactam susceptibility testing with the broth microdilution method, according to ISO 20776-1.

DESCRIPTION

Ceftolozane and tazobactam is a combination antibiotic used for the treatment of multidrug-resistant (MDR) infections caused by Gram-negative pathogens, including *Enterobacteriaceae* and *Pseudomonas aeruginosa*.

A rational use of the drug is necessary to limit the spreading of resistant strains, which implies the need to determine the value of minimum inhibitory concentration (MIC) before the antibiotic is prescribed.

ComASP™ Ceftolozane-tazobactam (C/T)is a double-isolate test panel containing the dried up antibiotics in 15 two-fold dilutions:

- Ceftolozane concentration ranges from 0.008 to 128 µg/ml in the presence of a fixed concentration of tazobactam (4 µg/ml);

The system is used to perform the broth microdilution (BMD) method for the antimicrobial susceptibility testing of ceftolozane-tazobactam as recommended by international standards (i.e. CLSI, EUCAST, ISO) but in a simpler and less time-consuming way.

KIT CONTENT

- 4 Systems (panels) of ComASP C/T
  (panels individually packed in foil with silica gel desiccant)
- 8 Tubes of Mueller Hinton II Broth (3.6 ml)
- Sealing Film
- Instructions Sheet and Test Results Form

ITEMS NECESSARY BUT NOT INCLUDED IN THE KIT

- McFarland 0.5 Barium Sulphate Standard (ref.80400)
- Solution reservoir for multichannel pipette (ref. 96761)
- Physiological Solution (ref. 20095)
- Tips for multichannel pipette (ref.96758)
- Multichannel pipette 30-300 µl (ref.96759)

CONFIGURATION

Test	Ceftolozane*-tazobactam concentration (µg/ml)						
A Growth	0.008	0.016	0.032	0.064	0.125	0.25	0.5
1	2	4	8	16	32	64	128
B Growth	0.008	0.016	0.032	0.064	0.125	0.25	0.5
1	2	4	8	16	32	64	128

*Values on the panel refer to Ceftolozane while Tazobactam is present at a fixed concentration of 4 µg/ml.
Growth indicates growth control: No antimicrobial agent in the well.

PRINCIPLE OF THE METHOD

A panel allows the susceptibility testing of 2 different isolates.
All wells related to either test A, or B are rehydrated with a standardized microbial suspension.
After incubation in thermostat the result is read and interpreted.

COLLECTION AND STORAGE OF THE SAMPLE

ComASP C/T is not for use directly with clinical or other specimens. The microorganism to be tested must first be isolated on a suitable culture medium, either selective or non-selective. In case of mixed culture, selected colonies should be purified by subculturing.

TEST PROCEDURE

1. Take a panel from its envelop and leave it at room temperature for 10 min,
   DO NOT DISCARD THE ENVELOP until both tests have been carried out.
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.
4. Optimally within 15 min of preparation, dilute the adjusted suspension 1:20 in saline; this will be the **Solution A**.
5. Add 0.4 ml of Solution A to a tube of MH II Broth* provided in the kit to obtain the **Solution B**.
6. Dispense 100 µl of Solution B into each well (test A or B).
7. Cover the panel with the lid provided and incubate at 36 ± 2°C for 16-20 hours in ambient air.

* Mueller Hinton II Broth: Beef Extract 3.0 g; Acid Hydrolysate of Casein 17.5 g; Starch 1.5 g;
Distilled Water 1000 ml; pH 7.3 ± 0.1
(adjusted with appropriate salts to provide 20-25 mg/l of calcium and 10-12.5 mg/l of magnesium)

READING THE RESULTS

At the end of the incubation period observe the growth in the wells and establish the MIC, i.e. the lowest concentration of antibiotic that inhibits visible growth.

The result can be read visually or automatically. Reading by the naked eye can be improved by use of bright indirect lighting against a dark background.

Growth appears as turbidity or as a button at the bottom of the well (compare with the amount of growth in the growth-control well).

The growth-control well should be evaluated first. Make sure it is positive for growth. If not, check the viability of the colonies picked and repeat the test using a new row in the same panel or a new panel and a microbial culture of recent growth.

Note the results on the Test Results Form included in the kit (copy as many form as necessary).

INTERPRETATION OF THE RESULTS

The MIC obtained should be interpreted according to current EUCAST or CLSI interpretative criteria.

NOTE: If only one test has been performed in a panel, use the film provided in the kit to seal the inoculated rows so to prevent any leakage of contaminated fluids. Then, return the panel into its own desiccant envelop and into the refrigerator until time of testing (see STORAGE).

USER QUALITY CONTROL

Quality control of ComASP C/T is performed using the reference strains reported below:

Strain		**MIC QC range (µg/ml)**
Escherichia coli	ATCC® 25922	0.12 - 0.5
Pseudomonas aeruginosa	ATCC® 27853	0.25 - 1
Staphylococcus aureus	ATCC® 29231	16 - 64
Escherichia coli	ATCC® 35218	0.06 - 0.25
Klebsiella pneumoniae	ATCC® 700603	0.5 -2

FACTORS THAT MAY INVALIDATE THE RESULTS

Contaminated culture; poor standardization of the inoculum; clinical material unsuitable; use of expired panels or expired supplementary reagents; non compliance with temperatures and times of incubation.

PRECAUTIONS

The product ComASP C/T does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. ComASP C/T is a disposable device to be used for *in vitro* diagnostic use only. The product must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store ComASP C/T at 2-8°C in the original packaging. Once an envelope is opened the panel should be used within 7 days. 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, ComASP C/T 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

1. CLSI. Performance Standards for Antimicrobial Susceptibility Testing; 29th ed. CLSI Supplement M100S. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.
2. 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.
3. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 9.0, 2019. http://www.eucast.org.
4. The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST. Version 9.0, 2019. http://www.eucast.org.
5. ISO 20776-1:2006. 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.

PRESENTATION

Product	µg/ml	Packaging	Ref.
ComASP™ Ceftolozane-tazobactam	0.008 - 128 (ceftolozane) 4 (tazobactam)	4x2 tests	75006

TABLE OF SYMBOLS

IVD *In Vitro* Diagnostic Medical Device	Do not reuse	Manufacturer	Contains sufficient for <n> tests	Temperature limits
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	**LOT** Batch code

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