ComASP® Cefiderocol 0.008-128

Rx only IVD

INDICATIONS FOR USE/INTENDED USE

The ComASP® Cefiderocol 0.008-128 is a quantitative broth microdilution method intended for the in vitro determination of antimicrobial susceptibility of bacteria. ComASP® Cefiderocol consists of polystyrene microtiter panels containing lyophilized concentrations of cefiderocol and tubes of media (iron depleted cation adjusted Mueller Hinton broth), which are used to determine the minimum inhibitory concentration (MIC) in µg/mL using overnight incubation and manual reading procedures. ComASP® Cefiderocol at concentrations of 0.008-128 µg/mL should be interpreted at 16-20 hours of incubation.

ComASP® Cefiderocol can be used to determine the MIC of cefiderocol against the following microorganisms for which cefiderocol has been shown to be active clinically and *in vitro* according to the FDA drug approved label:

Acinetobacter baumannii complex
Escherichia coli
Enterobacter cloacae complex
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens

PRINCIPLE OF THE METHOD

Each ComASP® Cefiderocol panel includes cefiderocol across 15 two-fold dilutions from 0.008-128 µg/mL and a positive control well in lyophilized form in two rows and the same well in the next two rows, allowing for testing of two bacterial isolates/panel. All wells are rehydrated with a standardized microbial suspension made in the iron depleted cation adjusted Mueller Hinton broth provided. After incubation for 16-20 hours the MIC result is read at the lowest concentration that completely inhibits growth.

REAGENTS

- 4 Panels of ComASP® Cefiderocol 0.008-128 (2 isolates can be tested on each panel; panels individually packed in foil with silica gel desiccant)
- 8 Tubes of Iron-Depleted Cation-Adjusted Mueller Hinton Broth (ID-CAMHB) (3.6 ml)
- Instructions Sheet (includes Test Results Form), available from www.liofilchem.com

DIRECTIONS FOR USE

Storage

Store ComASP® Cefiderocol 0.008-128 at 2-8°C in the original packaging. Do not use the panels beyond the expiry date indicated on the label. Eliminate without using it if there are signs of deterioration.

Handling

Before using the ComASP® from an unopened package, visually inspect to ensure the package is intact. Do not use the panels if the package has been damaged.

Precautions

The ComASP® is not classified as being hazardous according to current regulations. The ComASP® is a disposable product. The ComASP® is only for diagnostic *in vitro* use and is intended for professional use. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.

Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

Materials Required but Not Provided:

- Suspension medium (sterile physiological saline)
- McFarland turbidity standard
- non-selective agar plates
- Sterile loops, swabs (not too tightly spun)
- test tubes
- pipettes
- scissors
- Incubator (35 ± 2°C)
- Quality control organisms
- Additional technical information from **www.liofilchem.com**

Panel preparation
Take a panel from its envelope and leave it at room temperature for 10 minutes.

Inoculum Preparation
Suspend well-isolated colonies from an overnight agar plate into physiological saline to achieve the turbidity of the recommended McFarland standard. Optimally, within 15 minutes of preparation, dilute the adjusted suspension 1:20 in physiological saline; this will be the **Solution A**. Add 0.4 mL of Solution A to a tube of ID-CAMHB provided in the kit to obtain the **Solution B**.

Inoculation
Dispense 100 µL of Solution B into each well.

In order to verify that your procedure gives the correct inoculum density in terms of CFU/well (2-8 x 10^5 CFU/mL), performing regular colony counts is recommended.

Incubation
Cover the panel with the lid provided and incubate at 36 ±2°C for 16-20 hours in ambient air. Do not stack panels more than 4 high.

Eliminating Used Material
After use, ComASP® and the material that comes into contact with the sample must be decontaminated and disposed of in accordance with current laboratory techniques for the decontamination and disposal of potentially infected material.

Reading the MIC
At the end of the incubation period observe the growth in the wells and read the MIC as the lowest concentration of antibiotic that completely inhibits organism growth (Clear End Point). The positive control should show strong growth (button of >2 mm or heavy turbidity). The result can be read visually. Reading by the naked eye can be improved by use of bright indirect lighting against a dark background.

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 microbial culture of recent growth.

Note the results on the Test Results Form.

RESULT INTERPRETATION

FDA cefiderocol interpretive criteria (µg/mL)
Use the following breakpoints to categorize the result according to the interpretive criteria (i.e., susceptible, intermediate or resistant).

Organism	MIC Breakpoints (µg/mL)		
	S≤	**I**	**R≥**
Enterobacterales	4	8	16
P. aeruginosa	1	2	4
A. baumannii complex	1	2	4

US FDA Susceptibility Interpretive Criteria (STIC) Ref:
https://www.fda.gov/STIC

QUALITY CONTROL

To check the performance of the ComASP® Cefiderocol result, test the following quality control strain(s). Patient isolate results are considered satisfactory if the quality control result(s) fall within the expected range(s). Patient isolate results should not be reported if the quality control results are outside of this stated QC range.

Quality Control Strain[a]	Acceptable MIC range (µg/mL)
Escherichia coli, ATCC® 25922	0.06–0.5
Pseudomonas aeruginosa, ATCC® 27853	0.06–0.5

[a]Strains recommended for routine QC with cefiderocol by CLSI M100-Ed33.

EXPECTED VALUES

Cefiderocol susceptibility will vary based on epidemiology at the geographic location and institution. Organism resistance patterns will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

Correlation to Reference Method

	N	% Essential Agreement	% Category Agreement
Enterobacterales[1]	210	95.7	92.4
Pseudomonas aeruginosa	126	93.7	92.1
Acinetobacter baumannii	92	96.7	91.3

[1]ComASP® Cefiderocol MIC values tended to be in exact agreement or at least one doubling dilution higher when testing *P. mirabilis*.

Reproducibility

97.4% of ComASP® Cefiderocol results for non-fastidious Gram-negative bacteria (2 *A. baumannii*, 1 *E. coli*, 2 *K. pneumoniae*, 1 *P. mirabilis*, 3 *P. aeruginosa* and 1 *S. marcescens,* tested in triplicate at 3 sites on 3 days) were within a doubling dilution of reference broth microdilution results.

REFERENCES

1. CLSI. Performance Standards for Antimicrobial Susceptibility Testing. 33rd ed. CLSI Supplement M100S. Wayne, PA: Clinical and Laboratory Standards Institute; 2023.
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.

Product	Packaging	Ref.
ComASP® Cefiderocol 0.008-128	4x2 tests	75009U

GLOSSARY OF TERMS

R_x Only	Prescription Use Only
IVD	*In Vitro* Diagnostic medical device
REF	Catalogue number
LOT	Batch code
	Do not reuse
	Fragile, handle with care
	Manufacturer
	Use by
	Contains sufficient for <n> tests
	Consult instructions for use
	Temperature limits

Revision History

Revision	Release Date	Change Summary
0	2023-05	Not applicable (First publication)

Note: Minor typographical, grammar, and formatting changes are not included in revision history.

For all inquiries please fill out the form at https://www.liofilchem.com/en-us/contacts.html

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Microbiology products since 1983

TEST RESULTS FORM

ComASP® Cefiderocol 0.008-128

Patient data
Name
Surname
Age
Gender
Specimen
Notes

Indicate with the sign **+** the microbial growth.

Indicate with the sign **−** the absence of microbial growth.

Read the MIC and interpret the result according to the current US FDA susceptibility interpretive criteria.

Test	**Cefiderocol concentration (µg/ml)**								**MIC value and interpretation**
1	Growth	0.008	0.016	0.032	0.064	0.125	0.25	0.5	.....
									.....
	1	2	4	8	16	32	64	128	.....
2	Growth	0.008	0.016	0.032	0.064	0.125	0.25	0.5	.....
									.....
	1	2	4	8	16	32	64	128	.....

Use a distinct test results form for each sample under investigation. A horizontal line should be drawn on the empty spaces related to an unused test, if any.

Date of Test	**Operator**