Cefiderocol 30µg Disc

Antibiotic disc for susceptibility testing of Gram-negative bacteria.

DESCRIPTION

Cefiderocol is a siderophore cephalosporin with a unique mechanism for penetrating efficiently into Gram-negative pathogens. Cefiderocol binds to free iron and is actively transported into bacterial cells through the outer membrane. This Trojan horse strategy allows cefiderocol to enter the space in-between the bacterial cell walls and disrupt cell wall synthesis. In addition, cefiderocol is stable against nearly all beta-lactamases, including both the serine and metallo-carbapenemases.

CONTENT OF THE PACKAGE

Cefiderocol 30µg Disc is available in two packaging formats:

- The 50-test box contains 1 cartridge with 50 discs packed in a desiccant envelop.
- The 250-test box contains 5 cartridges of 50 discs, each cartridge individually packed in a desiccant envelop.

Each package also contains a transparent resealable bag.

GATHERING AND KEEPING SAMPLES

The colonies that are to be subjected to the susceptibility test are taken up by culture media that have been previously swabbed with the sample under examination. In the case of mixed colonies the bacterial strains must be purified before they are swabbed on the plate for the susceptibility test.

TEST PROCEDURE

1. Suspend well-isolated colonies from an overnight agar plate into saline to achieve a 0.5 McFarland standard turbidity.
2. Using a sterile cotton swab, streak the inoculum over the entire area of a Mueller Hinton (MH) agar plate.
3. Apply the disc firmly to the surface of the inoculated agar plate.
4. Invert the plates and incubate in ambient air at 35 ± 2°C for 20-24 hours (CLSI) or at 35 ± 1°C for 16-20 hours (EUCAST).

EVALUATING THE RESULTS

At the end of the incubation period, measure the inhibition zone diameters to the nearest whole mm and interpret according to current reference standards.

Bacterial species	Zone Diameter Breakpoints (mm)							
	CLSI			FDA			EUCAST	
	S ≥	I	R ≤	S ≥	I	R ≤	S ≥	R <
Enterobacterales[1]	16	12-15	11	16	9-15	8	22	22
Pseudomonas aeruginosa	18	13-17	12	22	13-21	12	22	22
Acinetobacter baumannii complex	15	11-14	10	19	12-18	11	Note[2]	Note[2]
Stenotrophomonas maltophila	17	13-16	12	–	–	–	Note[3]	Note[3]

[1] FDA identified breakpoints for *E. coli, K. pneumoniae, P. mirabilis, E. cloacae* complex and *S. marcescens*.

[2] Zone diameters of ≥ 17 mm correspond to MIC values below the PK-PD breakpoint of S ≤ 2 mg/L.

[3] Zone diameters of ≥ 20 mm correspond to MIC values below the PK-PD breakpoint of S ≤ 2 mg/L.

QUALITY CONTROL

Quality control ranges are as follows:

Organisms		Disc Diffusion QC Ranges (mm)	
		CLSI	EUCAST
Escherichia coli	ATCC® 25922	25-31	24-30
Pseudomonas aeruginosa	ATCC® 27853	22-31	23-29

LIMITS

Diffusion susceptibility tests use an *in vitro* technique and cannot therefore reproduce the extremely complex *in vivo* conditions. Nevertheless, it is a useful and important tool that helps the clinician choose the correct therapy. Many variable factors influence the final result of the diffusion susceptibility test. The main ones are: the culture medium used, impregnation of the discs, inoculation of the medium, temperature, time and incubation atmosphere of the plates, pre-incubation and pre-diffusion conditions, depth of the medium, etc.

PRECAUTIONS

Cefiderocol 30µg Disc cannot be classified as being hazardous according to current legislation. The discs are disposable products for *in-vitro* diagnostic use (*). The product must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

* In USA, Cefiderocol 30µg Disc is available for Research Use Only (RUO) and should not be used for diagnostic purposes.

STORAGE

Store the unopened package at -20°C till the expiry date. Leftover discs from an opened cartridge should be stored at 2-8°C for no more than 7 days. Reinsert the cartridge containing unused discs into the desiccant envelop and then into the resealable pouch. Return the cartridge to the refrigerator as soon as the application of the discs has been completed. Dispose of expire discs.

ELIMINATING USED MATERIAL

After use, the discs 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.

REFERENCES

- The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters . Version 11.0, 2021. http://www.eucast.org
- 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. http://www.eucast.org
- EUCAST disk diffusion method. Version 9.0, 2021.
- Clinical and Laboratory Standards Institute. Performance Standards for Antimicrobial Susceptibility Testing. CLSI Supplement M100. 31st Edition, 2021.
- Clinical and Laboratory Standards Institute. Performance Standards for Antimicrobial Disk Susceptibility Tests. CLSI Standard M02. 13th Edition, 2018.
- U.S. Food & Drug Administration. FDA-Identified Interpretive Criteria and/or Exceptions to the Recognized Standard of CLSI M100. https://www.fda.gov/STIC Antibacterial Susceptibility Test Interpretive Criteria - Content current as of: 28 Sep 2020.

Description	Packaging	Ref.
Cefiderocol FDC 30 µg	5 x 50 discs	9266
Cefiderocol FDC 30 µg	1 x 50 discs	9266/1

TABLE OF SYMBOLS

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

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Liofilchem srl

Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (TE) Italy
Tel. +39 0858930745 Fax +39 0858930330
Headquarter, Manufacturing Site, International distribution
www.liofilchem.com

Liofilchem, Inc. In US available as RUO device

465 Waverley Oaks Rd. Suite 317, Waltham, MA 02452, USA
Tel 781-902-0312
US Distribution Center