Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

SHIONOGI

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the US Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please see the accompanying Full Prescribing Information for Fetroja.**

Cleared AST Devices

There are several antimicrobial susceptibility testing (AST) devices available for cefiderocol that have been cleared by the FDA:

Disks

- HardyDisks™
- Thermo Scientific™ Oxoid™ Discs
- BD BBLTM Sensi-Disc™

Plates/Panels

- Thermo Scientific™ Sensititre™ MIC Plates
- Liofilchem® ComASP® Cefiderocol 0.008-128

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HardyDisks™

- HardyDisks™ have been cleared by the FDA
- To order HardyDisks™ for cefiderocol or request additional information, please contact Hardy Diagnostics at 800.266.2222 or visit their website at www.hardydiagnostics.com.
- The catalog numbers are Z9431 (1 cartridge of 50 disks) and Z9435 (5 cartridges of 50 disks)
- See more about the product here: HardyDisks™ Cefiderocol, FDC30, Fetroja

Figure 1: HardyDisks™

For illustration purpose only

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Thermo Scientific™ Oxoid™ Discs

- Thermo Scientific™ Oxoid™ Discs have been cleared by the FDA
- To order Oxoid™ Cefiderocol Antimicrobial Susceptibility Discs, please contact your local Thermo Fisher Scientific Microbiology representative at microbiology@thermofisher.com or 800.255.6730 or visit www.thermofisher.com/AST
- The catalog number is CT1964B. See more about the product here: Cefiderocol Antimicrobial Susceptibility Discs

Figure 2: Thermo Scientific™ Oxoid™ Discs

For illustration purpose only

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BD BBL™ Sensi-Disc™

- BD BBL™ Sensi-Disc™ cefiderocol discs have been cleared by the FDA
- To order cefiderocol discs, please contact BD at 844.823.5433
- The reference number is 232255 (50 discs)

Figure 3: BD BBL™ Sensi-Disc™

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Thermo Scientific™ Sensititre™ MIC Plates

- Thermo Scientific™ Sensititre™ MIC Plates have been cleared by the FDA
- To order Thermo Scientific™ Sensititre™ MIC Plates with cefiderocol, please contact your local Thermo Fisher Scientific Microbiology representative at microbiology@thermofisher.com or 800.255.6730 or visit www.thermofisher.com/AST
- The catalog number is MDRGN2F (Please note that this item continues to remain unavailable as of January 2025).

See more about the product here:

- Sensititre™ Gram Negative Susceptibility Testing Plate, IVD format

Figure 4: Thermo Scientific™ Sensititre™ MIC Plates

For illustration purpose only

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Liofilchem® ComASP® Panels

- Liofilchem® ComASP® Cefiderocol 0.008-128 broth microdilution panels have been cleared by the FDA. In the US, these panels may be ordered from either of these companies:

Liofilchem, Inc.
781.902.0312 or orders@liofilchem.us

- The reference number is 75009U for 4 panels (8 tests). See more about the product here: ComASP® Cefiderocol 0.008-128
- The reading guide for ComASP® Cefiderocol 75009U (FDA-cleared) is available

Fisher Scientific
800.766.7000 or https://www.fishersci.com/

- The catalog number is 22-778-086 for 4 panels (8 tests).

Figure 5: Liofilchem® ComASP® Panels

For illustration purpose only

Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

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Research Use Only Devices

AST devices available for cefiderocol that are for RUO include:

- Liofilchem® Cefiderocol MTS™ (MIC Test Strip) 0.016-256
- Liofilchem® Discs
- Thermo Scientific™ Sensititre™ MIC Plates with Cefiderocol, Colistin, and Fosfomycin

It should be noted that results from RUO devices are not to be used in determining therapeutic options for patient treatment.

Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

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Liofilchem® Cefiderocol MTS™

- Liofilchem® has made MTS™ Cefiderocol (MIC Test Strip) 0.016-256 available for purchase. MTS™ Cefiderocol strips are for RUO in the US and should only be used to determine the MIC of *Pseudomonas aeruginosa*

See more about the product here: MTS™ Cefiderocol 0.016-256

In the US, these strips may be ordered from either of these companies:

Liofilchem, Inc.

781.902.0312 or orders@liofilchem.us

The reference numbers are:

- 920671 for 10/pack (individually packed)
- 92067 for 30/pack (individually packed)
- 920670 for 100/pack

Fisher Scientific

800.766.7000 or https://www.fishersci.com/

- The catalog number is 22-778-078 (1 pack of 10 RUO strips)

It should be noted that results from RUO devices are not to be used in determining therapeutic options for patient treatment.

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Liofilchem® Discs

- Liofilchem® discs are available for purchase for RUO in the US. To order Liofilchem® discs, please contact Liofilchem, Inc at 781.902.0312 or orders@liofilchem.us

See more about the product here: Liofilchem® Discs

The reference numbers are:

- 9266 for 5 packs of 50
- 9266/1 for one pack of 50
- 9266/2 for 250 discs

It should be noted that results from RUO devices are not to be used in determining therapeutic options for patient treatment.

Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

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Thermo Scientific™ Sensititre™ MIC Plates

- Thermo Scientific™ Sensititre™ MIC Plates with cefiderocol, colistin, and fosfomycin are available for research use only (RUO)
- To order Thermo Scientific™ Sensititre™ MIC Plates with cefiderocol, colistin, and fosfomycin, please contact your local Thermo Fisher Scientific Microbiology representative at microbiology@thermofisher.com or 800.255.6730 or visit www.thermofisher.com/AST
- The catalog number is MDRGNX2F with cefiderocol, colistin, and fosfomycin (Please note that this item continues to remain unavailable as of January 2025).

See more about the product here:

- Sensititre™ Gram Negative RUO Susceptibility Testing Plate

Figure 7: Thermo Scientific™ Sensititre™ MIC Plates with Cefiderocol, Colistin, and Fosfomycin

For illustration purpose only

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Summary

Shionogi has collaborated with Laboratory Specialists Inc. (LSI) and CDC & FDA AR Isolate Bank to develop a panel of isolates for laboratories to perform verification of cefiderocol susceptibility testing.

A laboratory may use either of the two panels (LSI or CDC & FDA AR Isolate Bank) or a combination of isolates to validate testing in their laboratory.

Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

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Laboratory Specialists Inc.

Shionogi has collaborated with Laboratory Specialists Inc. (LSI) to develop a panel of isolates for laboratories to perform verification of cefiderocol susceptibility testing. This panel is available at no cost to the laboratory.

To request isolates:

- Download the form at the LSI website, http://www.labspec.org/. The form can be found by selecting “AST Method Verification Isolates for New Agents” from the home page. Then, select “request form”
- Fill out the form to request the cefiderocol panel
- Fax the form to (440) 835-5786 or email it to info@labspec.org
- For additional information, contact LSI at info@labspec.org or 440.835.4458

The clinical isolates included in the LSI panel are:[1]

- *Escherichia coli*
- *Enterobacter cloacae*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Acinetobacter baumannii*
- *Stenotrophomonas maltophilia*

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CDC & FDA AR Isolate Bank

Shionogi has collaborated with the CDC & FDA AR Isolate Bank (http://wwwn.cdc.gov/arisolatebank/) to develop a panel of isolates for laboratories to perform verification of cefiderocol susceptibility testing. For a detailed listing of isolates and to order the panel visit http://wwwn.cdc.gov/ARIsolateBank/Panel/PanelDetail?ID=1227.

Isolates are provided at no cost to approved institutions, and customers are charged for shipping costs.

The CDC & FDA AR Isolate Panel includes only the pathogens for which the FDA has determined cefiderocol has demonstrated clinical efficacy and provided breakpoints. The isolates included in the panel are:

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

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Several institutions have antimicrobial susceptibility testing capabilities for cefiderocol and are available to provide testing services (please see below for the List of Reference Laboratories with associated contact information).

List of Reference Laboratories

- Alabama
- Florida
- Georgia
- Maryland
- Minnesota
- Nevada
- New Jersey
- Ohio
- Tennessee
- Utah
- Wisconsin

Thermo Fisher Scientific is able to perform susceptibility testing on isolates. However, it should be noted that Thermo Fisher Scientific is not a CLIA-certified laboratory and there is a fee for testing.

For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Alabama

Derek B. Moates, MS, CT(ASCP)CM – Disks
dmoates@uabmc.edu
Researcher IV, Lab Manager, Fungal Reference Laboratory
The University of Alabama at Birmingham
W287B | 619 E 19th Street South
Birmingham, AL 35249-7331

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Florida

Jose Alexander, MD, D(ABMM), FCCM, SM, MB(ASCP) – Disks, broth microdilution
jose.alexander@adventhealth.com
Medical and Public Health Microbiologist
Director – Clinical Microbiologist | Microbiology/Virology/Immunology
AdventHealth Orlando

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Georgia

Yun "Wayne" Wang, MD, PhD – Disks
yfwang@emory.edu
Professor of Pathology and Laboratory Medicine, School of Medicine
Emory University School of Medicine / Grady Memorial Hospital

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Maryland

Patricia (Trish) J. Simner, PhD, D(ABMM) – Disks
psimner1@jhmi.edu
Associate Professor of Pathology
Director of Bacteriology and Infectious Disease Sequencing Laboratories
Department of Pathology
Johns Hopkins Medicine

Therm hermo Fisher S

For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Minnesota

Mayo Clinical Laboratories - Disks
mcl@mayo.edu
Mayo Clinic
3050 Superior Drive NW
Rochester, MN 55905
Phone: 800.533.1710

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Nevada

Clarinda C. Tagapan, MT (AMT) – Disks
clarinda.tagapan@umcsn.com
Clinical Laboratory Supervisor (Microbiology)
Laboratory Services
University Medical Center of Southern Nevada
1800 W. Charleston Blvd
Las Vegas, NV 89102
Phone: 702.207.8392

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

New Jersey

Mary Fitzgerald, MPH, MLS(ASCP)CM – Disks
mary.fitzgerald@atlantichealth.org
Microbiology Supervisor
Atlantic Consolidated Laboratory - Atlantic Health
100 The American Road Suite 118
Morris Plains, NJ 07950

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Ohio

Laboratory Specialists Inc. – Broth microdilution
26214 Center Ridge Rd
Westlake, Ohio 44145
Phone: 440.835.4458
info@labspec.org

Therm hermo
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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Tennessee

Pamela Foster – Disks, Sensititre™ panels
(Please note Sensititre™ panels remain unavailable as of January 2025)

pamela.j.foster@vumc.org
Vanderbilt University Medical Center
1301 Medical Center Dr, TVC 4526
Nashville, TN 37232
Phone: 615.875.3210

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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List of Reference Laboratories

Utah

Mark Fisher, PhD, D(ABMM) – Broth microdilution
mark.fisher@aruplab.com
Associated Regional and University Pathologists (ARUP), Inc.
Associate Professor of Pathology
Medical Director, Bacteriology and Special Microbiology
University of Utah School of Medicine

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For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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Several institutions have antimicrobial susceptibility testing capabilities for cefiderocol and are available to provide testing services (please see below for the List of Reference Laboratories with associated contact information).

List of Reference Laboratories

Wisconsin

Nate Ledeboer, PhD – Disks, Sensititre™ panels
(Please note Sensititre™ panels remain unavailable as of January 2025)

nledeboe@mcw.edu

Professor, Pathology & Laboratory Medicine

Medical Director, Clinical Microbiology

Medical Director, Molecular Diagnostics

Froedtert & Medical College of Wisconsin

Therm hermo Fisher S

For more information, please email isolatetesting@thermofisher.com or contact technical support at USCLEtechsupport@thermofisher.com.

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Fetroja® is indicated in patients 18 years of age or older for the treatment of:[2]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms:
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Proteus mirabilis*
  - *Pseudomonas aeruginosa*
  - *Enterobacter cloacae* complex

- Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms:
  - *Acinetobacter baumannii* complex
  - *Escherichia coli*
  - *Enterobacter cloacae* complex
  - *Klebsiella pneumoniae*
  - *Pseudomonas aeruginosa*
  - *Serratia marcescens*

Fetroja is contraindicated in:[2]

- Patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of Fetroja

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Abbreviations

AR	antibiotic resistant	HABP	hospital-acquired bacterial pneumonia
AST	antimicrobial susceptibility testing	LSI	Laboratory Specialists Inc.
CDC	Center for Disease Control and Prevention	MIC	minimum inhibitory concentration
cUTI	complicated urinary tract infection	RUO	research use only
CLIA	Clinical Laboratory Improvement Amendments	US	United States
FDA	Food and Drug Administration	VABP	ventilator-associated bacterial pneumonia
FDC	cefiderocol		

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References

1. Data on File 67. Shionogi Inc.
2. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.