



Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

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.**

AST Devices	Isolate Panels for Verification		Available Laboratories to Perform AST	Relevant Prescribing Information	Abbreviations & References
Cleared AST Devices			Research Use Only Devices		
Summary	HardyDisks™	Thermo Scientific™ Oxoid™ Discs	BD BBL™ Sensi-Disc	Thermo Scientific™ Sensititre™ Plates	Liofilchem® ComASP® Panels

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 BBL™ Sensi-Disc™

Plates/Panels

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



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Cleared AST Devices			Research Use Only Devices		
Summary	HardyDisks™	Thermo Scientific™ Oxoid™ Discs	BD BBL™ Sensi-Disc	Thermo Scientific™ Sensititre™ Plates	Liofilchem® ComASP® Panels

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™



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Cleared AST Devices			Research Use Only Devices		
Summary	HardyDisks™	Thermo Scientific™ Oxoid™ Discs	BD BBL™ Sensi-Disc	Thermo Scientific™ Sensititre™ Plates	Liofilchem® ComASP® Panels

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



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Summary	HardyDisks™	Thermo Scientific™ Oxoid™ Discs	BD BBL™ Sensi-Disc	Thermo Scientific™ Sensititre™ Plates Liofilchem® ComASP® Panels

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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Cleared AST Devices			Research Use Only Devices		
Summary	HardyDisks™	Thermo Scientific™ Oxoid™ Discs	BD BBL™ Sensi-Disc	Thermo Scientific™ Sensititre™ Plates	Liofilchem® ComASP® Panels

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



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Cleared AST Devices				Research Use Only Devices				
Summary	HardyDisks™	Thermo Scientific™ Oxoid™ Discs	BD BBL™ Sensi-Disc	Thermo Scientific™ Sensititre™ Plates	Liofilchem® ComASP® Panels			

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



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AST Devices	Isolate Panels for Verification	Available Laboratories to Perform AST	Relevant Prescribing Information	Abbreviations & References
Cleared AST Devices			Research Use Only Devices	
Summary	Liofilchem® Cefiderocol MTS™	Liofilchem® Discs	Thermo Scientific™ Sensititre™ Plates	

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.

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AST Devices	Isolate Panels for Verification	Available Laboratories to Perform AST	Relevant Prescribing Information	Abbreviations & References
Cleared AST Devices		Research Use Only Devices		
Summary	Liofilchem® Cefiderocol MTS™	Liofilchem® Discs	Thermo Scientific™ Sensititre™ Plates	

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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Cleared AST Devices		Research Use Only Devices		
Summary	Liofilchem® Cefiderocol MTS™	Liofilchem® Discs	Thermo Scientific™ Sensititre™ Plates	

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.

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Cleared AST Devices		Research Use Only Devices		
Summary	Liofilchem® Cefiderocol MTS™	Liofilchem® Discs	Thermo Scientific™ Sensititre™ Plates	

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



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AST Devices	Isolate Panels for Verification	Available Laboratories to Perform AST	Relevant Prescribing Information	Abbreviations & References
Summary	LSI	CDC & FDA AR Isolate Bank		

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.

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Summary	LSI	CDC & FDA AR Isolate Bank		

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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Summary	LSI	CDC & FDA AR Isolate Bank		

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*
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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



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

ThermoFisher Scientific

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

ThermoFisher Scientific

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

ThermoFisher Scientific

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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

ThermoFisher Scientific

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

ThermoFisher Scientific

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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

ThermoFisher Scientific

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@atlantichhealth.org

Microbiology Supervisor

Atlantic Consolidated Laboratory - Atlantic Health

100 The American Road Suite 118

Morris Plains, NJ 07950

ThermoFisher Scientific

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

ThermoFisher Scientific

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

ThermoFisher Scientific

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

Thermo Fisher Scientific

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



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List of Reference Laboratories



Wisconsin

Nate Ledebor, 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

ThermoFisher Scientific

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

Fetroja – Availability of Antimicrobial Susceptibility Testing (AST) Resources

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.**

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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.