Liofilchem MIC Test Strip

Rx only IVD

INTENDED USE

The Liofilchem® MIC Test Strip (MTS) is a quantitative method intended for the in vitro determination of antimicrobial susceptibility of non-fastidious Gram negative and Gram positive aerobic bacteria (for example, *Enterobacteriaceae*, *Pseudomonas*, *Enterococcus* and *Staphylococcus* species) and fastidious bacteria (for example, anaerobes, *Haemophilus* and *Streptococcus* species and *N. gonorrhoeae*). MTS consists of specialized paper impregnated with a pre-defined concentration gradient of an antimicrobial agent, which is used to determine the minimum inhibitory concentration (MIC) in µg/mL of antimicrobial agents against bacteria as tested on agar media using overnight incubation and manual reading procedures. Refer to the drug-specific MTS supplement for microbe applications cleared by FDA.

SUMMARY AND EXPLANATION OF THE TEST

The Liofilchem MTS are used to determine the minimum inhibitory concentration (MIC) of select bacteria to indicate appropriate patient treatment and for identifying resistance patterns. The MIC is the minimum inhibitory concentration of an antibiotic that will inhibit the growth of bacteria under standardized in vitro conditions. Broth and agar dilution MIC procedures based on two-fold serial dilutions of antibiotics are the reference methodologies; expected reproducibility of which is within ± 1 two-fold dilution ([1]).

PRINCIPLE OF THE METHOD

MTS are made of special high quality paper impregnated with a predefined concentration gradient of antibiotic, across 15 two-fold dilutions like those of a conventional MIC method. When the MIC Test Strip is applied onto an inoculated agar surface, the preformed exponential gradient of antimicrobial agent diffuses into the agar for over an hour. After 16-20 hours incubation, a symmetrical inhibition ellipse centered along the strip is formed. The MIC is read directly from the scale in terms of µg/mL at the point where the edge of the inhibition ellipse intersects the strip MIC Test Strip.

REAGENTS

MTS is supplied in 3 different packaging options (no additional reagents are included):

- The 10-test box contains 10 strips individually packed in desiccant envelops and an instruction sheet.
- The 30-test box contains 30 strips individually packed in desiccant envelops and an instruction sheet.
- The 100-test box contains 10 desiccant envelops, each containing 10 strips, and an instruction sheet. The 100-test pack also contains a storage tube.

DIRECTIONS FOR USE

Storage

Check the drug-specific storage temperature on the product label, for storing at either up to −20°C or up to +8°C until the given expiry date. Leftover MIC Test Strip from an opened package (valid for 100 strip pack only, as the 10 and 30 strip packs contain individually packed strips) must be stored at 2-8°C in the airtight tube, containing desiccant, provided in the pack for no more than 7 days. Do not store near sources of heat and do not expose to excessive temperature variations.

Handling

Before using the MTS from an unopened package, visually inspect to ensure the package is intact. Do not use the strips if the package has been damaged. When removed from the refrigerator, allow the package or storage container to reach room temperature for about 30 minutes. Moisture condensing on the outer surface must evaporate completely before opening the package.

Precautions

The MTS is not classified as being hazardous according to current regulations but fall within the specific field of application where a safety data sheet must be supplied because they can cause phenomena of sensitization in sensitive subjects if they come into contact with the skin. The MTS is a disposable product. The MTS 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.

Materials Required but Not Provided:

- Agar plate medium (validated by the media manufacturer for use with antimicrobial susceptibility testing, 90 or 150 mm plates)
- Suspension medium
- McFarland turbidity standard

  (The medium to be used as well as the inoculum suspension will depend on the organism under investigation, see the MTS Supplement for more information)
- Sterile loops, swabs (not too tightly spun), test tubes, pipettes and scissors
- Forceps
- Incubator (35 ± 2°C)
- Quality control organisms
- Additional technical information from www.liofilchem.net

Inoculum Preparation

Suspend well-isolated colonies from an overnight agar plate into the suspension medium to achieve the recommended McFarland standard. A confluent or almost confluent lawn of growth will be obtained after incubation, if the inoculum is correct, and if insufficient growth occurs, the testing should be repeated. In order to verify that your procedure gives the correct inoculum density in terms of CFU/mL (a 0.5 McFarland approximately corresponds to 1-2 x 10^8 CFU/mL for *E. coli*) performing regular colony counts is recommended.

Inoculation

Dip a sterile swab in the broth culture or in a diluted form thereof and squeeze it on the wall of the test tube to eliminate excess liquid. Streak the swab over the entire sterile agar surface. Repeat this procedure by streaking 2 more times, rotating the plate approximately 60 degrees each time to ensure an even distribution of inoculum to efficiently streak the inoculum over the entire agar surface. Allow excess moisture to be absorbed so that the surface is completely dry before applying MTS.

Application

Apply the strip to the agar surface with the scale facing upwards and code of the strip to the outside of the plate, pressing it with a sterile forceps on the surface of the agar and ensure that whole length of the antibiotic gradient is in complete contact with the agar surface. The strip can be repositioned within 3 minutes from its application.

Incubation
Incubate the agar plates in an inverted position at the appropriate temperature and atmosphere. See specific drug/organism combinations for any special incubation or atmospheric requirements.

Eliminating Used Material
After use, MIC Test Strip 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
Observe where the relevant inhibition ellipse intersects the strip and read the MIC at complete inhibition. Growth along the entire gradient i.e. no inhibition ellipse indicates that the value is greater than or equal to (≥) the highest value on the scale. An inhibition ellipse that intersects below the lower end of the scale is read as less than (<) the lowest value. An MIC of 0.125 µg/mL is considered the same as 0.12 µg/mL for reporting purposes. See the appropriate MTS product supplements for example specific drug/organism photographs. Also consult the MIC Test Strip Photographic Guide.

Result Interpretation
To categorize the result according to the interpretive criteria, refer to the appropriate MTS product supplement for the specific antimicrobial agent interpretive criteria. Since MTS generates MIC values which fall between two-fold dilutions for interpretation, an MTS MIC value which falls between standard two-fold dilutions must be rounded up to the next standard upper two fold value before categorization. For example a *S. aureus* vancomycin MIC of 1.5 µg/mL is reported as 2 µg/mL.

QUALITY CONTROL
To check the performance of the MTS result, test the quality control strain(s) as shown in the appropriate MTS product supplement. 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. MIC results for a QC strain that fall a half dilution below the lower QC limit should be rounded up to the next upper two-fold value which would establish QC compliance. MIC results that are a half dilution above the upper limit would be rounded up to the next upper two fold value which would result in non-QC compliance.

LIMITATIONS
Refer to the drug-specific MTS Supplement.

EXPECTED VALUES
Expected results for susceptibility tests will vary based on location and institution. Organism resistance patterns will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS
Refer to the drug specific MTS Supplement.

REFERENCES
1. CLSI. 2015. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 10th ed. Approved Standard M07-A10. CLSI, Wayne, PA.

GLOSSARY OF TERMS

Do not reuse


Use by

Batch code

Catalog number


Manufacturer

Contains sufficient for <n> tests

In vitro diagnostic medical device


Temperature limitation


Upper limit of temperature


Consult instructions for use

MIC Test Strip, International Patent

For all inquiries please fill out the form at http://www.liofilchem.net/en/contact.php

Liofilchem Inc., US Distributor and Customer Service
465 Waverley Oaks Rd, Waltham, MA
Phone: 781-902-0312

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

Liofilchem Telavancin MIC Test Strip (MTS)

Rx only IVD

Specifications

Antibiotic code: TLV
MIC range: 0.016-256 µg/mL
Antibiotic group: Lipoglycopeptide

Directions for Use

Follow the MTS package insert instructions.

Procedures specific to Telavancin MTS:

Organism	*S. aureus* and *E. faecalis*
Medium	Mueller Hinton Agar
Inoculum	Suspension in saline (0.85% NaCl) to 0.5 McFarland
Incubation	Agar plates in inverted position at 35 ± 2°C for 16-20 hours in ambient atmosphere

FDA telavancin interpretive criteria (µg/mL)

Use the following breakpoints to categorize the result according to the interpretive criteria (i.e. susceptible or resistant). An MTS MIC value which falls between standard two-fold dilutions must be rounded up to the next standard upper two fold value before categorization. For example a *S. aureus* telavancin MIC of 0.19 µg/mL is reported as 0.25 µg/mL (see reading guide for example pictures).

Bacterial Species	Susceptible	Intermediate	Resistant
S. aureus (including methicillin-resistant)	≤0.12	-	-
E. faecalis (vancomycin susceptible isolates only)	≤0.25	-	-

FDA Ref: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022110s012lbl.pdf

Quality Control range (µg/mL) (CLSI M100S Performance Standards for Antimicrobial Susceptibility Testing, 27th Edition)

To check the performance of the ceftazidime MTS, media and procedure, test ***Staphylococcus aureus* ATCC 29213** and ***Enterococcus faecalis* ATCC 29212** according to the method as outlined in the MTS package insert. Results are considered satisfactory if they fall within the following ranges:

Quality Control Strain	Acceptable MIC Range (µg/mL)
Staphylococcus aureus, ATCC® 29213	0.03 – 0.12
Enterococcus faecalis, ATCC® 29212	0.03 – 0.12

Performance Characteristics

Correlation to Reference Method[1]

	N[2]	% Essential Agreement	% Category Agreement
S. aureus[3] (including methicillin-resistant)	414[4]	97.6	99.3
E. faecalis[5] (vancomycin-susceptible)	98	95.9	100
All Organisms[6]	540	97.4	99.4

[1] For the plate inoculation procedure, one testing site utilized a plate rotator (Retro C80) to assist even distribution of inoculum. There was no difference in performance for the site using the plate rotator as compared to sites using the manual plate inoculation method.

[2] Total of clinical and challenge isolates.

[3] The telavancin MTS MIC values tended to be in exact agreement or at least one doubling dilution higher when testing *S. aureus* compared to the CLSI reference broth microdilution.

[4] Methicillin susceptible *S. aureus* (203 MSSA) and methicillin resistant *S. aureus* (211 MRSA).

[5] The telavancin MTS MIC values tended to be in exact agreement or at least one doubling dilution lower when testing *E. faecalis* compared to the CLSI reference broth microdilution.

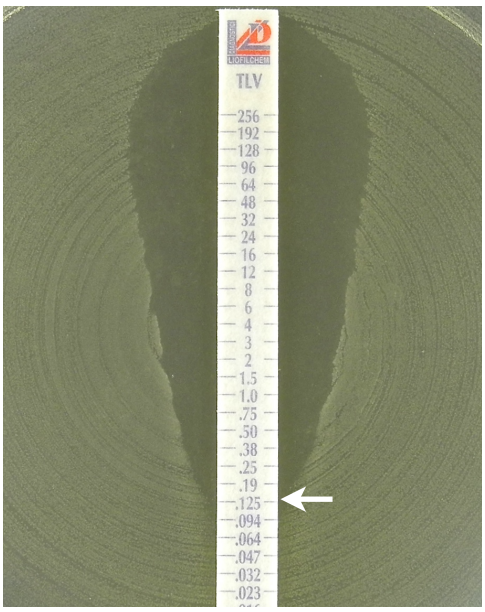
[6] Includes 28 *E. faecium* (challenge set).

Reproducibility

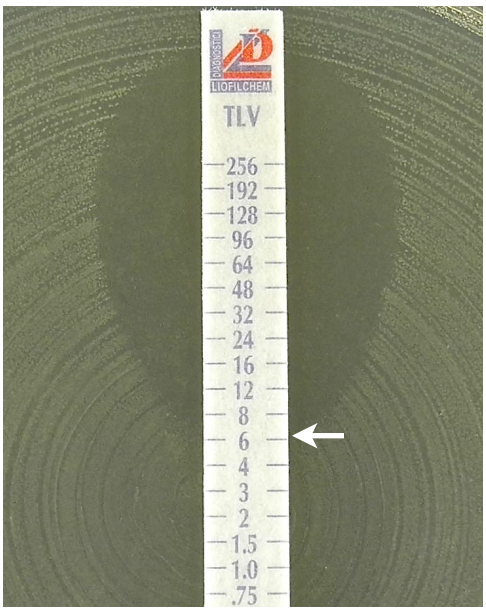
98.1% of telavancin MTS results (7 *S. aureus* made up of Methicillin sensitive *S. aureus* [MSSA], Methicillin resistant *S. aureus* [MRSA], Vancomycin sensitive *S. aureus* [VRSA] and Vancomycin inermediate resistant *S. aureus* [VISA] and 3 *E. faecalis* (vancomycin-susceptible) tested in triplicate at 3 sites on 3 days) were within a doubling dilution of reference broth microdilution results.

Telavancin MIC Test Strip Reading Guide

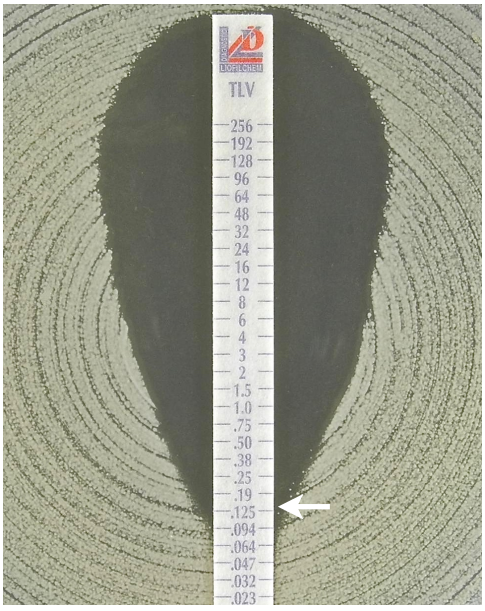
Example 1:
E. faecalis, telavancin MIC = 0.125 µg/mL



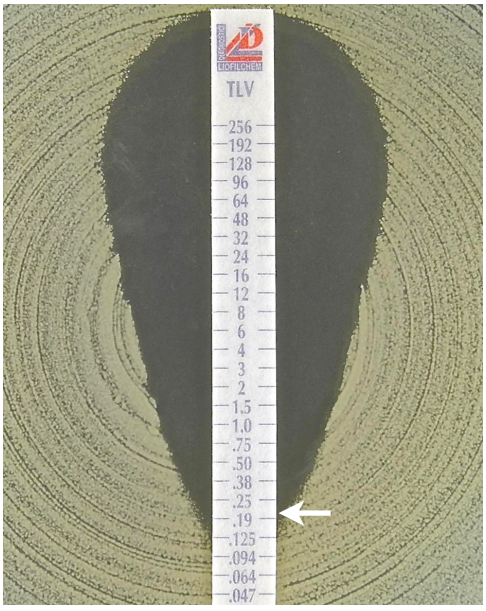
Example 2:
E. faecalis, telavancin MIC = 6 µg/mL,
reported as 8 µg/mL



Example 3:
S. aureus, telavancin MIC = 0.125 µg/mL



Example 4:
S. aureus, telavancin MIC = 0.19 µg/mL,
reported as 0.25 µg/mL



PRESENTATION		µg/mL	Code	Packaging	Ref.
MIC Test Strip	Telavancin	0.016-256	TLV	10 30 100	920531 92053 920530

MIC Test Strip, International Patent

For all inquiries please fill out the form at http://www.liofilchem.net/en/contact.php

Liofilchem Inc., US Distributor and Customer Service
465 Waverley Oaks Rd, Waltham, MA
Phone: 781-902-0312

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

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