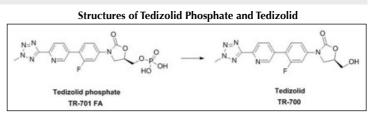


MIC Test Strip Technical Sheet Tedizolid

INTRODUCTION Tedizolid phosphate is a novel oxazolidinone prodrug that is rapidly converted in vivo by phosphatases to the microbiologically active antibiotic tedizolid (Figure) which has potent activity against Grampositive pathogens. In the EU, SIVEXTRO is indicated for the treatment of ABSSSI caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus* spp, β-Haemolytic streptococci of Groups A,B,C,G and Viridans group streptococci (*Streptococcus anginosus* group only).



TEST PROCEDURE

Before using MIC Test Strip Tedizolid 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.

Materials required but not provided:

- Mueller Hinton II Agar, 90 (ref. 10031) or 140 mm (ref. 10231) plates
- Sterile saline (0.85% NaCl) (ref. 20095) or Mueller Hinton Broth (ref. 24107)
- Sterile loops, swabs (not too tightly spun), test tubes, pipettes and scissors
- Forceps
- 0.5 McFarland turbidity standard (ref. 80400)
- Incubator $(35 \pm 2^{\circ}C)$
- Quality control organisms
- Additional technical information from <u>www.liofilchem.net</u>

Inoculum preparation

Suspend well-isolated colonies from an overnight agar plate into saline to achieve a 0.5 McFarland standard turbidity (1 Mc-Farland if mucoid).

A confluent or almost confluent lawn of growth will be obtained after incubation, if the inoculum is correct.

In order to verify that your procedure gives the correct inoculum density in terms of CFU/mL, 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. Alternatively, use a rotation plater to efficiently streak the inoculum over the agar surface. Allow excess moisture to be absorbed so that the surface is completely dry before applying MIC Test Strip.

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. Once applied, do not move the strip.

Incubation

Incubate the agar plates in an inverted position at $35 \pm 2^{\circ}$ C for 16-20 hours in ambient atmosphere. Extend the incubation for up to 48 hours in case of slow growing organisms.

EVALUATING THE RESULTS

Reading

Observe where the relevant inhibition ellipse intersects the strip and read the MIC at almost complete (90%) inhibition. Growth along the entire gradient i.e. no inhibition ellipse indicates that the value is greater than or equal to (\geq) 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.

See page 2 for example of results. Also consult the MIC Test Strip Photographic Guide.

Interpretation

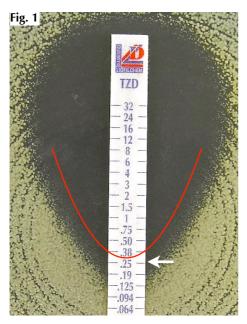
The susceptibility interpretative criteria recommended by the CLSI and EUCAST are shown below. Always round up MIC Test Strip half dilution values to the next upper two-fold value before categorization.

QUALITY CONTROL

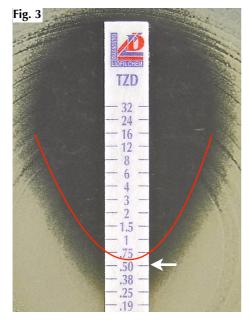
CLSI-recommended quality control strains are used as outlined under TEST PROCEDURE.

| | Breakpoint (µg/mL) | | | | | | | |
|---|--------------------|---|-------------------|------------|------|---|--|--|
| Organism group | CLSI | | | EUCAST | | Quality Control MIC Range (µg/mL) | | |
| | S ≤ | I | $\mathbf{R} \geq$ | S ≤ | R > | | | |
| Staphylococcus spp. | 0.5 | 1 | 2 | 0.5 | 0.5 | S. aureus ATCC® 29213 0.25-1 | | |
| Enterococcus spp. | 0.5 | - | - | | | <i>E. faecalis</i> ATCC® 29212 0.25-1 | | |
| Streptococcus groups A, B, C and G | 0.5 | - | - | 0.5 | 0.5 | <i>S. pneumoniae</i> ATCC® 49619 0.12-0.5 | | |
| Viridans group streptococci (<i>Streptococcus anginosus</i> group only) | 0.25 | - | - | 0.25 | 0.25 | | | |

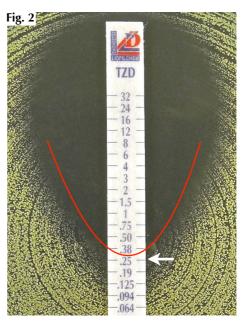
MIC Test Strip Tedizolid Reading Guide



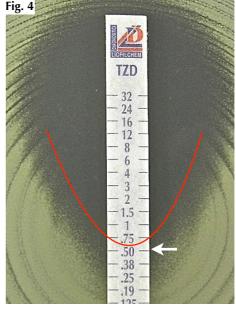
Read at 90% inhibition. MIC 0.25 µg/mL.



Read at 90% inhibition. MIC 0.5 µg/mL.



Read at 90% inhibition. MIC 0.25 µg/mL.



Read at 90% inhibition. MIC 0.5 µg/mL.

REFERENCES

- EUCAST (2016) Clinical Breakpoint Tables. Version 6.0. from www.eucast.org
- CLSI M100S (2016) Performance Standards for Antimicrobial Susceptibility Testing 26th Edition. CLSI M07-A10 (2015) Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically: Approved Standard 10th Edition. Zurenko G. et al (2014) Use of linezolid susceptibility test results as a surrogate for susceptibility of Gram- positive pathogens to tedizolid, a novel
- oxazolidinone. Annals of Clinical Microbiology and Antimicrobials. 13:46.
- Sivextro (tedizolid) Prescribing information. Lexington, MA: Cubist Pharmaceuticals (2014).
- Prokocimer P. et al (2012) In Vitro Activity and Microbiological Efficacy of Tedizolid (TR-700) against Gram-positive Clinical Isolates from a Phase 2 Study of Oral Tedizolid Phosphate (TR-701) in Patient with Complicated Skin and Skin Structure Infections.

| PRESENTATION | µg/mL | Code | Packaging | Ref. |
|--------------------------|----------|------|-----------------|---------------------------|
| MIC Test Strip Tedizolid | 0.002-32 | TZD | 10 30 100 | 921361 92136 921360 |

MIC Test Strip, Patent No. 1395483

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

