MTS™ Rezafungin RZT 0.002-32

Technical Sheet

INDICATIONS FOR USE/INTENDED USE

MTS™ (MIC Test Strip) Rezafungin RZF 0.002-32 µg/mL is a quantitative method for the *in-vitro* susceptibility testing of organisms to the antimicrobial agent.

MTS™ RZF can be used to determine the MIC of Rezafungin against multi-drug resistant *Candida* spp.

MTS™ consists of special porous paper impregnated with a pre-defined concentration gradient of an antimicrobial agent, 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.

DIRECTIONS FOR USE

Storage

Unopened foil packages and canisters: On receipt, store MTS™ RZF 0.002-32 at –20°C until the given expiry date.

Opened canisters: MTS™ in canister can be used for up to 2 months from first opening (record the date on which the canister was open) and must be stored at the label storage temperature. Before using the remaining strips, check the expiry date indicated on the packaging. Do not store near sources of heat and do not expose to excessive temperature variations.

Protect MTS™ from moisture, heat and direct exposure to strong light at all times.

Handling

Before using 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/freezer, 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. Use forceps or a similar device to pick up a strip.

When using MTS™ from a canister, replace the lid immediately after use and store as outlined under STORAGE

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

  (see the guide below for specific instructions)
- 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.com**

Inoculum Preparation

Suspend well-isolated colonies from an overnight agar plate into the suspension medium to achieve the turbidity of the recommended McFarland standard. If the inoculum concentration is correct, a confluent lawn of growth will be obtained after incubation. 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 performing regular colony counts is recommended. An acceptable inoculum should give approximately 1-5 x 10^6 CFU/mL.

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. 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. Once applied, do not move the strip.

Incubation

Incubate the agar plates in an inverted position at the appropriate temperature, atmosphere and time.

Application Guide for MTS™ RZF 0.002-32	
Organism	*Candida* spp.
Medium	RPMI Agar
Inoculum	Suspension in saline (0.85% NaCl) or sterile water to 0.5 McFarland
Incubation	Agar plates in inverted position at 35 ± 2°C for 24-48 hours in ambient atmosphere

Reading the MIC

After the required incubation period observe where the relevant inhibition ellipse intersects the strip.
In case of trailing endpoints, read the MIC at 80% inhibition, i.e. the first visual point of significant inhibition.
Do not read the plate if the culture appears mixed or if the lawn of growth is too light or too heavy.
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. Intersection between

two scale segments should be rounded up to the higher value. An MIC of 0.125 µg/mL is considered the same as 0.12 µg/mL for reporting purposes.

Results Interpretation
To categorize the result, typically as susceptible, intermediate or resistant, refer to current MIC breakpoints published by the CLSI and/or your national reference group (MIC interpretative criteria for defining categories are shown below).
Always round up MTS™ half dilution values to the next upper two-fold value before categorization. For example a *C. albicans* Rezafungin MIC of 0.75 µg/mL is reported as 1 µg/mL (see reading guide section for example pictures).

NOTE: At the date of preparation of this document, there are no MIC breakpoints for Rezafungin.

Eliminating Used Material
After use, MTS™ 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.

QUALITY CONTROL

CLSI-recommended quality control strains are used according to the method as outlined under DIRECTIONS FOR USE.

Control strain	**MIC QC Ranges (µg/mL)**
Candida krusei ATCC 6258	0.015-0.12
Candida parapsilosis ATCC 22019	0.25-2

PERFORMANCE CHARACTERISTICS

The performance of MTS™ RZF 0.002-32 has been established by comparison to the broth microdilution (BMD) reference method following CLSI M07 and ISO 20776-1 standards. Essential Agreement (EA) was calculated to evaluate performance.

Organism	**N**	**% Essential Agreement**
Candida spp.	101	95.2

Essential agreement (EA) was defined as agreement between MTS™ and BMD methods ± 2 doubling dilution.

REFERENCES

1. ISO 20776-1:2006. Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infection agents and evaluation of performance of antimicrobial susceptibility test devices—part 1, reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases. ISO, Geneva, Switzerland.
2. Clinical and Laboratory Standards Institute. Performance Standards for Antifungal Susceptibility Testing of Yeasts, latest edition. CLSI supplement M60.
3. Clinical and Laboratory Standards Institute. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; latest edition. CLSI standard M27.
4. Clinical and Laboratory Standards Institute. Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi; latest edition. CLSI supplement M61.
5. Clinical and Laboratory Standards Institute. Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; latest edition. CLSI standard M38.
6. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint Tables for Interpretation of MICs and Zone Diameters; latest version.
7. The European Committee on Antimicrobial Susceptibility Testing. Antifungal Agents. Breakpoint Tables for Interpretation of MICs; latest version. EUCAST documents available at www.eucast.org

TABLE OF SYMBOLS


Do not reuse

Batch code


Manufacturer


Consult instructions for use


Upper limit of temperature


Use by

Catalog number

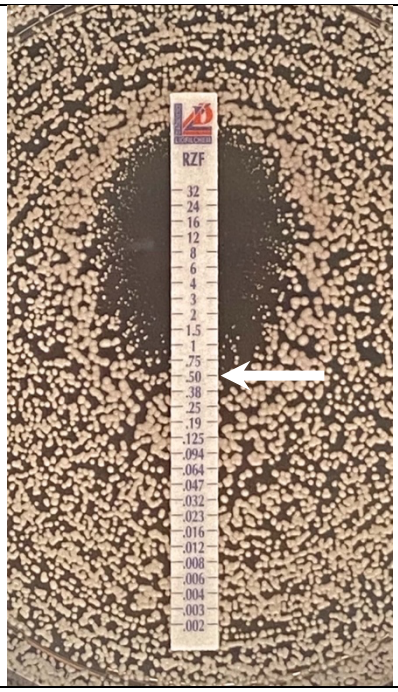

Contains sufficient for <n> tests


Temperature limitation

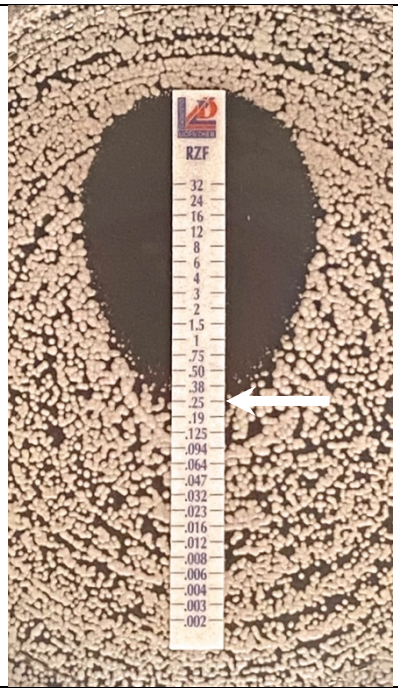
MTS™ Rezafungin Reading Guide

Note: Interpret the MIC as 80% inhibition

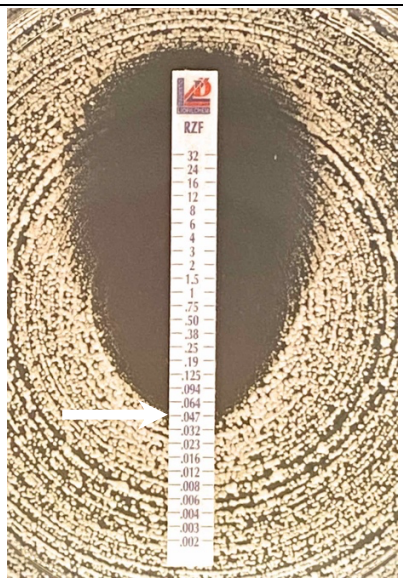
Example 1:
C. parapsilosis, RZF = 0.5 µg/mL



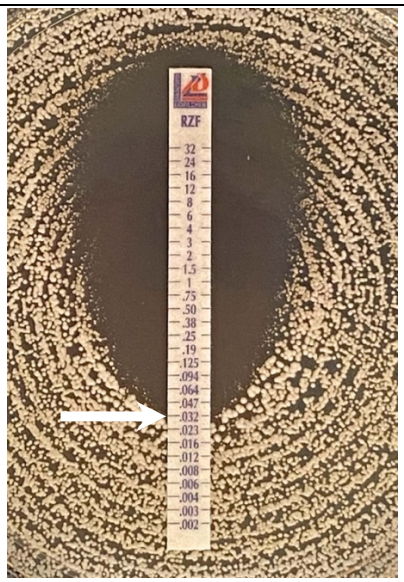
Example 2:
C. krusei, RZF MIC = 0.25 µg/mL



Example 3:
C. albicans, RZF MIC = 0.047 µg/mL, reported as 0.064 µg/mL



Example 4:
C. albicans, RZF MIC = 0.032 µg/mL



Description		µg/mL	Code	Packaging	Ref.
MTS™	Rezafungin	0.002-32	RZF	10 30 100	920911 92091 920910

This document is available from **liofilchem.com/MTS**

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