Oritavancin

Antibiotic disc for susceptibility testing of Gram-positive bacteria.

DESCRIPTION

Oritavancin is a lipoglycopeptide with broad-spectrum activity against Gram-positive pathogens, such as staphylococci, including methicillin resistant *Staphylococcus aureus* (MRSA), streptococci and enterococci. This antimicrobial agent causes cell death by inhibiting cell wall synthesis as well as depolarizing and permeabilizing the cellular membrane of susceptible organisms.

Oritavancin has been recently approved by the FDA and EMA for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI) caused by *Staphylococcus aureus* (including methicillin-susceptible and methicillin–resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates only). Afterwards, it has been reported that oritavancin also offers enhanced coverage against vancomycin-susceptible enterococci, vancomycin-resistant enterococci (VRE), and vancomycin-intermediate and vancomycin-resistant staphylococci. Great benefits, compared to other drugs having similar therapeutic indications, derive from its single, once-only dosing regimen administered by intravenous infusion.

As claimed by the drug's Manufacturer as well, to reduce the development of drug-resistant bacteria and maintain the effectiveness of oritavancin and other antibacterial drugs, the antimicrobial agent should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. Therefore, the confirmation of susceptibility of a given isolate to oritavancin becomes of primary importance.

CONTENTS OF THE PACKAGES

Discs in cartridge

The 50-test box contains 1 cartridge with 50 discs packed in a desiccant envelope.
The 250-test box contains 5 cartridges of 50 discs, each cartridge individually packed in a desiccant envelope.
Each package also contains a transparent resealable bag.

Discs in canister

The canister contains 250 discs and a desiccant tablet.

GATHERING AND KEEPING SAMPLES

The colonies that are to be subjected to the susceptibility test are taken up by culture media that have been previously swabbed with the sample under examination. In the case of mixed colonies the bacterial strains must be purified before they are swabbed on the plate for the susceptibility test.

TEST PROCEDURE

1. Suspend well-isolated colonies from an overnight agar plate into saline to achieve a 0.5 McFarland standard turbidity.
2. Using a sterile cotton swab, streak the inoculum over the entire area of a cation-adjusted Mueller Hinton agar plate. Allow excess moisture to be absorbed. Use plates that have a **dry surface** (no visible moisture on the surface) only.
3. Apply Oritavancin discs on the inoculated agar plates.
4. Incubate at 35 ± 2°C for 24 hours in ambient atmosphere.

EVALUATING THE RESULTS

At the end of the incubation period, measure the inhibition zone diameters (mm) with zone edges read as the point showing no obvious growth as detected with the unaided eye. Ignore any internal colonies present in the inhibition halo.

QUALITY CONTROL

The following quality control strains are used as outlined under TEST PROCEDURE:

Microorganism		Zone Range (mm)
Staphylococcus aureus	ATCC® 29213	18-21
Staphylococcus aureus	ATCC® 25923	17-21
Staphylococcus aureus	ATCC® 700698	10-14
Staphylococcus aureus	ATCC® 700699	6-10

LIMITS

Diffusion susceptibility tests use an *in vitro* technique and cannot therefore reproduce the extremely complex *in vivo* conditions. Nevertheless, it is a useful and important tool that helps the clinician choose the correct therapy. Many variable factors influence the final result of the diffusion susceptibility test. The main ones are: the culture medium used, impregnation of the discs, inoculation of the medium, temperature, time and incubation atmosphere of the plates, pre-incubation and pre-diffusion conditions, depth of the medium, etc.

PRECAUTIONS

The discs cannot be classified as being hazardous according to current legislation. Antibiotic Disc are disposable products. Antibiotic Disc are only for diagnostic *in vitro* use and are intended for professional use. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.

STORAGE

Store the unopened package at –20°C till the expiry date. Leftover discs from an opened CARTRIDGE should be stored at 2-8°C for no more than 7 days. The cartridge containing unused discs should be returned into its desiccant envelope and then inserted into the resealable bag. Discs in a CANISTER can be used for up to 2 months from first opening and must be stored at the label storage temperature. Dispose of expired discs.

ELIMINATING USED MATERIAL

After use, the discs 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.

REFERENCES

1. CLSI. Performance Standards for Antimicrobial Susceptibility Testing. 32nd ed. CLSI Supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2022.
2. CLSI. Performance Standards for Antimicrobial Disk Susceptibility Tests. 13th ed. CLSI standard M02. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
3. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 12.0, 2022. http://www.eucast.org.
4. The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST. Version 12.0, 2022. http://www.eucast.org.

Product	Packaging	Ref.
Oritavancin ORI 5 µg	5 x 50 discs in cartridge	9201
	1 x 50 discs in cartridge	9201/1
	1 x 250 discs in canister	9201/2

TABLE OF SYMBOLS

LOT Batch code	Do not reuse	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Consult instructions for use	

LIOFILCHEM® s.r.l.

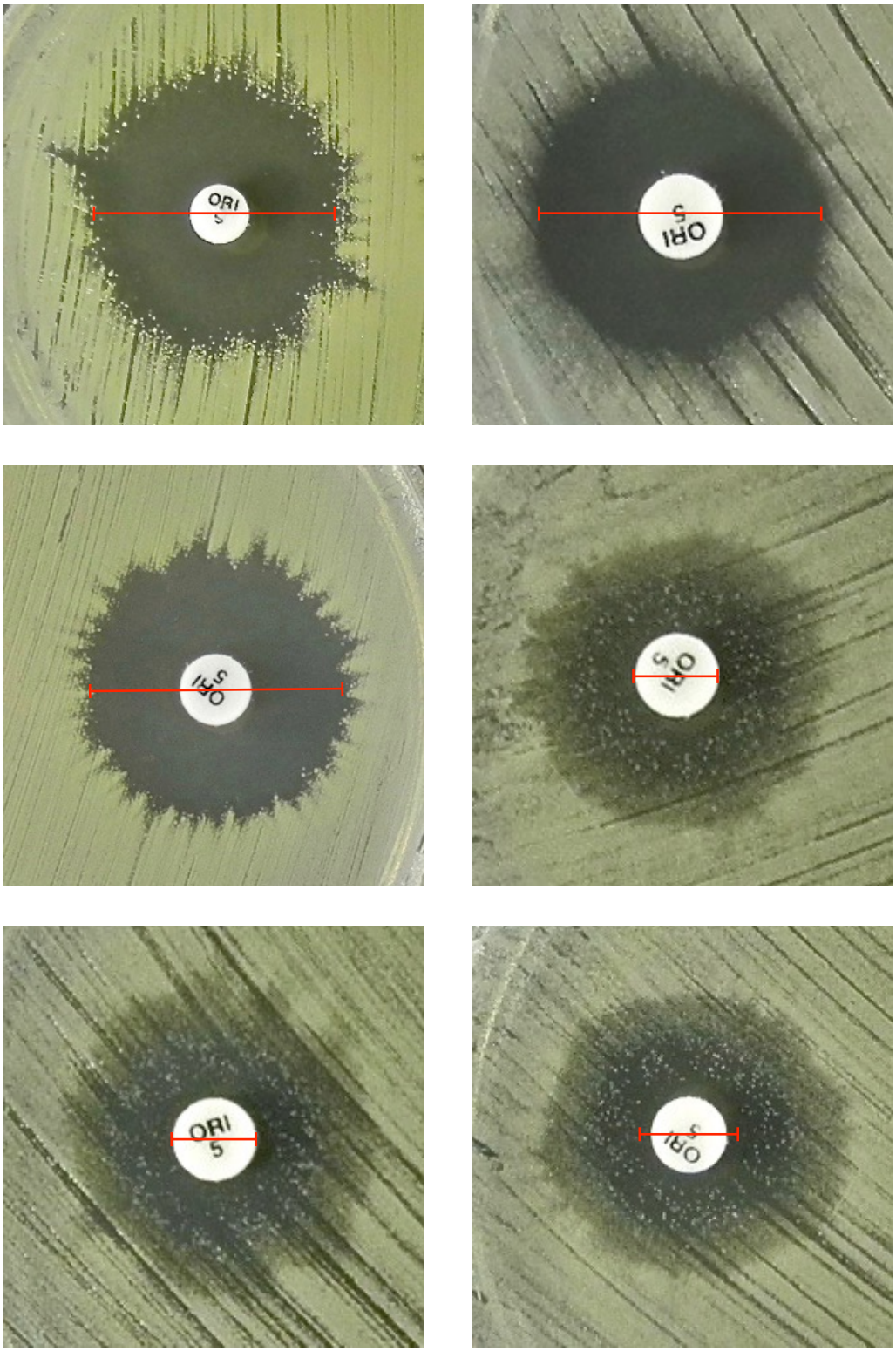
Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.com liofilchem@liofilchem.com

Ref. 9201

Appendix I

Oritavancin

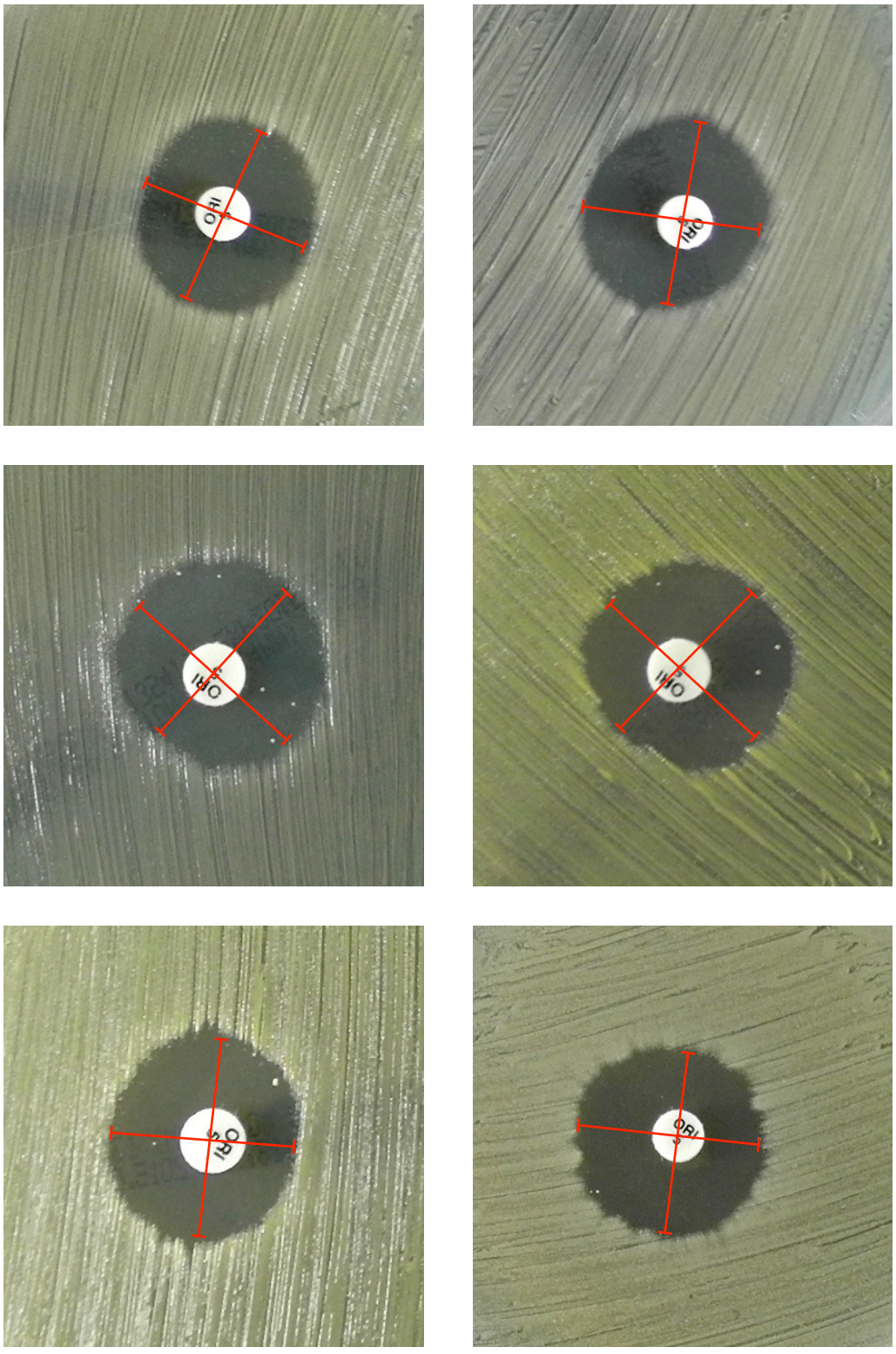
Antibiotic disc for susceptibility testing of Gram-positive bacteria.



(Inhibition zone diameters marked in red)

Troubleshooting

The inhibition zone diameter is the mean value of the longest and shortest diameters.



(Inhibition zone diameters marked in red)

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

CE IVD