ComASP™ Vancomycin / Teicoplanin

System for susceptibility testing of vancomycin and teicoplanin with the broth microdilution method, according to ISO 20776-1.

ENGLISH

DESCRIPTION

Vancomycin and teicoplanin are glycopeptide antibiotics active against most Gram-positive bacteria.

Vancomycin is indicated mainly to treat or prevent infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) or multidrug-resistant (MDR) *Enterococcus* spp. According to EUCAST guideline on detection of resistance mechanisms, the value of minimum inhibitory concentration (MIC) should always be determined when using vancomycin to treat a patient with severe *S. aureus* infection.

Teicoplanin is similar but not identical to vancomycin in its spectrum of activity. Teicoplanin shows an increased potency, particularly against some clinical isolates belonging to *Staphylococcus*, *Streptococcus* and *Enterococcus* genera. However, against some coagulase-negative staphylococci, especially *Staphylococcus haemolyticus*, it may be less active.

Glycopeptide-resistant enterococci (GRE) are recognised as emerging pathogens, particularly in immunocompromised or hospitalised patients, and have been associated with outbreaks in healthcare facilities globally. A rational use of these drugs is necessary to limit the spreading of resistant strains, which implies the need to determine the MIC before the antibiotic is prescribed.

ComASP Vancomycin/Teicoplanin is a single-isolate test panel containing the dried up antibiotics in 15 two-fold dilutions:

- For both vancomycin and teicoplanin concentration ranges from 0.008 to 128 µg/ml;

The system is used to perform the broth microdilution (BMD) method for the antimicrobial susceptibility testing of vancomycin (VA) and teicoplanin (TEC) as recommended by international standards (i.e. CLSI, EUCAST, ISO) but in a simpler and less time-consuming way.

ComASP Vancomycin/Teicoplanin can be used to determine the MIC of vancomycin and teicoplanin against the non-fastidious microorganisms listed below:

- Staphylococci (including heterogeneous methicillin-resistant strains)
- Enterococci (e.g., *Enterococcus faecalis*)

KIT CONTENT

- 4 Systems (panels) of ComASP Vancomycin/Teicoplanin (panels individually packed in foil with silica gel desiccant)
- 4 Tubes of Mueller Hinton II Broth (7.2 ml)
- Instructions Sheet and Test Results Form

ITEMS NECESSARY BUT NOT INCLUDED IN THE KIT

- McFarland 0.5 Barium Sulphate Standard (ref.80400)
- Solution reservoir for multichannel pipette (ref. 96761)
- Physiological Solution (ref. 20095)
- Tips for multichannel pipette (ref. 96758)
- Multichannel pipette 30-300 µl (ref. 96759)

CONFIGURATION

VA	**Vancomycin concentration (µg/ml)**						
Growth	0.008	0.016	0.032	0.064	0.125	0.25	0.5
1	2	4	8	16	32	64	128
TEC	**Teicoplanin concentration (µg/ml)**						
Growth	0.008	0.016	0.032	0.064	0.125	0.25	0.5
1	2	4	8	16	32	64	128

Growth indicates growth control: No antimicrobial agent in the well.

PRINCIPLE OF THE METHOD

Each panel is used for the susceptibility testing of 1 isolate.
Wells are rehydrated with a standardized microbial suspension.
After incubation in thermostat the result is read and interpreted.

COLLECTION AND STORAGE OF THE SAMPLE

ComASP Vancomycin/Teicoplanin is not for use directly with clinical or other specimens. The microorganism to be tested must first be isolated on a suitable non-selective culture medium. In case of mixed culture, selected colonies should be purified by subculturing.

TEST PROCEDURE

1. Take a panel from its envelope and leave it at room temperature for 10 min.
2. Prepare a suspension of the test organism using either the direct colony suspension or growth method.
3. Standardize the suspension to the density of a McFarland 0.5 standard.
4. Optimally within 15 min of preparation, dilute the adjusted suspension 1:20 in saline; this will be the **Solution A**.
5. Add 0.8 ml of Solution A to a tube of MH II Broth* provided in the kit to obtain the **Solution B**.
6. Dispense 100 µl of Solution B in each well of the test.
7. Cover the panel with the lid provided and incubate in ambient air at 36 ± 2°C. The incubation period is 16 to 20 hours for teicoplanin whereas vancomycin testing requires a full 24 h incubation. NOTE: After reading the teicoplanin MIC result continue the panel incubation in the shortest possible time.

* Mueller Hinton II Broth (g/l): Beef Extract 3.0 g; Acid Hydrolysate of Casein 17.5 g; Starch 1.5 g; Distilled Water 1000 ml; pH 7.3 ± 0.1
(adjusted with appropriate salts to provide 20-25 mg/l of calcium and 10-12.5 mg/l of magnesium)

READING THE RESULTS

At the end of the incubation period observe the growth in the wells and establish the MIC, i.e. the lowest concentration of antibiotic that inhibits visible growth.

The result can be read visually or automatically. Reading by the naked eye can be improved by use of bright indirect lighting against a dark background.

Growth appears as turbidity or as a button at the bottom of the well (compare with the amount of growth in the growth-control well).

The growth-control well should be evaluated first. Make sure it is positive for growth. If not, check the viability of the colonies picked and repeat the test using a new panel and a microbial culture of recent growth.

Note the results on the Test Results Form included in the kit (copy as many form as necessary).

INTERPRETATION OF THE RESULTS

The MIC obtained should be interpreted according to current EUCAST or CLSI interpretive criteria.

USER QUALITY CONTROL

Quality control of ComASP Vancomycin/Teicoplanin is performed using the reference strains reported below.

		QC MIC range (µg/ml)	
Strain		**Vancomycin**	**Teicoplanin**
1. *Staphylococcus aureus*	ATCC® 29213, NCTC 12973	0.5 - 2	0.25 - 1
2. *Enterococcus faecalis*	ATCC® 29212, NCTC 12697	1 - 4	0.25 - 1

FACTORS THAT MAY INVALIDATE THE RESULTS

Contaminated culture; poor standardization of the inoculum; non compliance with temperatures and times of incubation.

PRECAUTIONS

The product ComASP Vancomycin/Teicoplanin does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. ComASP Vancomycin/Teicoplanin is a disposable device to be used only for *in vitro* diagnostic use. The product must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store ComASP Vancomycin/Teicoplanin at 2-8°C in the original packaging. Keep away from direct sunlight and direct heat. Do not use the panels beyond the expiry date indicated on the label. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After use, ComASP Vancomycin/Teicoplanin and material that has come into contact with the sample must be decontaminated and disposed of in accordance with guidelines used in the laboratory for decontamination and disposal of potentially infected material.

REFERENCES

1. CLSI. Performance Standards for Antimicrobial Susceptibility Testing; 28th ed. CLSI Supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
2. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 8.1, 2018. http://www.eucast.org.
3. The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST. Version 8.0, 2018. http://www.eucast.org.
4. EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance. Version 2.0, 2017.
5. CLSI. Methods for dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard - Tenth Edition. CLSI document M07-A10. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
6. ISO 20776-1:2006. Clinical laboratory testing and in vitro diagnostic test systems -- Susceptibility testing of infectious 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.

PRESENTATION

Product	µg/ml	Packaging	Ref.
ComASP™ Vancomycin/Teicoplanin	0.008 - 128 (vancomycin) 0.008 - 128 (teicoplanin)	4 test	75005

TABLE OF SYMBOLS

IVD *In Vitro* Diagnostic Medical Device	Do not reuse	Manufacturer	Contains sufficient for <n> tests	Temperature limits
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	**LOT** Batch code

LIOFILCHEM® s.r.l.

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

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