REF UM-VAN/TEI-040

Instructions for Use

UMIC Vancomycin/Teicoplanin

UMIC Vancomycin/Teicoplanin for manual susceptibility testing of *Staphylococcus* spp. and *Enterococcus* spp. against the critically important antibiotic agents vancomycin and teicoplanin

For *in vitro* diagnostic use

CE IVD

Language: en

Revision A (December 2021)

Document history

Title:	Instructions for Use UMIC Vancomycin/Teicoplanin
Revision:	Revision A (December 2021)
First revision:	December 2021

The following table describes important changes from the previous revision of this document.

Section	**Changes**
–	No changes: first revision

Table of contents

1 Intended use

The UMIC Vancomycin/Teicoplanin is an *in vitro* diagnostic medical device for the quantitative susceptibility testing of clinically relevant fast-growing aerobic Gram-positive bacteria (*Enterococcus* spp. and *Staphylococcus* spp.) against vancomycin and teicoplanin using Mueller Hinton Broth, cation adjusted (CAMHB) . Susceptibility is detected by determining minimum inhibitory concentration according to EUCAST or CLSI guidelines. Only pure cultures obtained from human test material can be used.

The test is not automated. The device is intended for laboratory professional use only. The results of the test are intended solely as an aid to diagnosis for targeted antibacterial therapy and must not be used as single source for diagnosis, treatment or patient management decision.

2 Product description / materials

Contents

Each pack is sufficient for 40 susceptibility tests and contains:

- 5 UMIC Vancomycin/Teicoplanin plates, each containing 8 test strips with 12 wells
- Lid and frame
- Instructions for Use
- Certificate of Analysis
- Results Sheet

Additionally required reagents and materials

- Mueller Hinton II (UM-MH-020); manufacturer: Bruker Daltonics GmbH & Co. KG
- NaCl 0.9%
- Humidity chamber, e.g. UMIC Box Vancomycin/Teicoplanin UM-BOX-VAN/TEI
- Adjustable pipette, e.g. 20-200 µL, incl. pipette tips

Additional lab materials

- McFarland standard 0.5 or densitometer
- Blood agar or tryptic soy agar (TSA) plates without additives

  Note *Use of other agar media requires validation by the user.*

- Incubator
- Inoculation loops
- Marker pen

3 Media composition

Media	Ingredients
NaCl 0.9%	Sodium chloride
Mueller Hinton II (UM-MH-020)	Beef extract Acid hydrolysate of casein Starch

Note *Determination of valid MIC values using the UMIC Vancomycin/Teicoplanin test system requires the usage of the Mueller Hinton II manufactured by Bruker Daltonics GmbH & Co. KG only. Please contact your local distributor for catalog numbers of reagents and media.*

4 Shelf life / storage / disposal

UMIC Vancomycin/Teicoplanin test plates remain usable until the indicated expiry date when stored in their original packaging at 15-25 °C. Unused UMIC Vancomycin/Teicoplanin strips remain usable for up to 2 months after opening when stored in the resealable original packaging.

Store Mueller Hinton II at 2-25 °C. See product label for shelf life of the Mueller Hinton II.

Dispose of transport and secondary packaging of the UMIC Vancomycin/Teicoplanin according to the local waste disposal regulations.

Follow the instructions in section 5 to dispose of used UMIC test strips.

5 Precautions

- For *in vitro* diagnostic use only.
- Do not pipette reagents by mouth.
- Do not use for other purposes than the intended use.
- Samples, bacterial cultures, and inoculated UMIC Vancomycin/Teicoplanin test plates / test strips should be treated as potentially biohazardous and should be handled properly by appropriately qualified and trained staff while observing all relevant precautions. Use aseptic technique throughout the whole test procedure. For more information, see the current version of “BioSafety in Microbiological and Biomedical Laboratories, HHS publication (CDC)” or the relevant national regulations.
- If the primary packaging (aluminum composite foil pouch) is damaged, check the integrity of the sealing foil on the UMIC Vancomycin/Teicoplanin test plates / test strips. If the sealing foil is undamaged, the UMIC Vancomycin/Teicoplanin test plates / test strips can be used. If the sealing foil is damaged, discard the UMIC Vancomycin/Teicoplanin test plates / test strips.
- After reading and evaluation of the test result, all samples and inoculated or contaminated items (pipette tips, UMIC Vancomycin/Teicoplanin test strips) should be autoclaved, incinerated, or treated with a bactericidal disinfectant solution before disposal.
- The Instructions for Use must be strictly adhered to; any deviation can affect the quality of the results.
- The test results should be interpreted by trained staff with experience in microbiology. Clinical background, sample origin, colony and microscopic morphology, serology, and the identification result need to be considered when interpreting the results.

6 Test procedure

This section describes all the steps that are necessary for using the UMIC strips.

6.1 Preparing the samples

Provide a tube with 2-5 mL NaCl 0.9%, pH 5.5-6.5.

Provide a vial of Mueller Hinton II, see section 8.

6.2 Preparing the inoculum

1. Pick several single colonies from an 18-24-hour-old pure culture from blood agar or TSA without additives.
2. Homogenize the colonies well in 2-5 mL NaCl 0.9% until the turbidity matches to a McFarland standard of 0.5.
3. Gram-positive bacteria: Pipette 50 µL of the bacterial suspension into 5 mL Mueller Hinton II and homogenize well.

6.3 Inoculating the strips

Remove the UMIC Vancomycin/Teicoplanin test strips from their resealable packaging max. 30 minutes before use.

1. Cut the sealing foil along the strips to be used and remove the strips from the frame.
2. Put the remaining strips back in the resealable packaging immediately and seal the packaging tightly.
3. Insert the strips into the empty frame that is supplied with the pack. The printed marking “V/T” on each strip must be on the left side of the frame.
4. Remove the sealing foil and note the sample number on the respective strip to prevent mixing up of samples.
5. Inoculate each well of each test strip with 100 µL of the prepared suspension.

Note *After inoculation, check the correct filling of all the wells and take care that no drops of bacterial suspension remain at the edges of the wells. Drops at the well edges may not have contact with the antibiotic. This can result in growth in the respective wells (skipped wells), see section 7.2.*

6.4 Sealing and incubation

1. After inoculation, seal the strips by placing the lid on the frame.
2. Incubate the test strips at 35±1 °C under aerobic conditions for 18±2 hours (*Staphylococcus* spp.) or 24 hours (*Enterococcus* spp.) unless specified otherwise by EUCAST.

Note *To avoid drying of the media in the wells, which is a risk existing in incubators with ventilation system, incubate the system in a humidity chamber, e.g. using the UMIC Box Vancomycin/Teicoplanin UM-BOX-VAN/TEI.*

6.5 Reading

1. Remove the lid.
2. Wipe the bottom of the strips.
3. Visually read the strips with the printed marking “V/T” positioned on the left.

Note *Turbidity = growth/positive. No turbidity = no growth/negative.*

Note *Growth must be visible in the growth control, otherwise the test must be repeated.*

6.6 Analysis

Document the results on the product-specific Results Sheet and interpret the MIC values according to the currently valid international CLSI or EUCAST standards. The Results Sheet is not part of this Instructions for Use.

7 Evaluating results

7.1 MIC value

The minimum inhibitory concentration (MIC) is defined as the lowest concentration of an antibiotic that inhibits visible bacterial growth. Bacterial growth can be observed as turbidity within the medium and/or as a deposit of cells at the bottom of the affected wells of the test strips. MIC determination requires a positive (turbid) growth control. MIC determination is based on the broth microdilution procedure which allows for a quantitative test result regarding susceptibility against vancomycin and teicoplanin for the tested isolate.

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

7.2 Skipped wells

Occasionally, skipped wells can occur within a test strip. A skipped well is characterized by lack of growth in one or more wells of an antibiotic serial dilution while the wells of the next lower/higher concentration show growth. The reasons for skipped wells are diverse: heteroresistance, inhomogeneous inoculum or inhomogeneous inoculation of the wells, etc.

For UMIC Vancomycin/Teicoplanin test strips, a single skipped well in a serial dilution can be ignored. The concentration of the well after which no more visible growth is detectable can be read as the MIC value. If several skipped wells occur in a serial dilution, the sample and test preparation must be repeated.

8 Technical notes

For best results, carefully take into account the following remarks in the Instructions for Use.

- UMIC Vancomycin/Teicoplanin test strips are for single use only. Do not re-use!
- Use pure cultures from blood agar or TSA without additives that are not older than 24 hours.
- After inoculation, check the correct filling of all the wells and take care that no drops of bacterial suspension remain at the edges of the wells. Drops at the well edges may not have contact with the antibiotic. This can result in growth in the respective wells (skipped wells), see section 7.2.
- Use NaCl 0.9%, pH 5.5-6.5.
- Use only the Mueller Hinton II manufactured by Bruker Daltonics GmbH & Co. KG.
- Pre-heat the Mueller Hinton II before use. Incubate at 35±1 °C for 1 hour.
- Make sure to adjust the NaCl suspension exactly to McFarland standard 0.5. Homogenize the prepared suspension sufficiently.
- Inoculate a blood agar plate or TSA without additives with the bacterial suspension for purity control.
- Do not damage the sealing foil of the adjacent strips. Strips with damaged sealing foil should not be used later because there could be a loss of drug activity.
- Ensure that the test strips are aligned correctly when inserting them into the frame. The printed marking “V/T” on each strip must be on the left side of the frame.
- Follow the specified incubation times. The incubation time must not be less than 16 hours for *Staphylococci* spp. and 24 hours for *Enterococci* spp.
- To avoid drying of the media in the wells, incubate the system in a humidity chamber, e.g. UMIC Box Vancomycin/Teicoplanin UM-BOX-VAN/TEI.

9 Quality control

Strips and reagents are subjected to several quality inspections, systematically executed during various production stages. Bacteriological quality control can be performed using the following strains:

Strains	**ATCC[1] No.**	**DSMZ[2] No.**	**NCTC[3] No.**
Staphylococcus aureus	ATCC 29213	DSM 2569	NCTC 12973
Enterococcus faecalis	ATCC 29212	DSM 2570	NCTC 12697
Enterococcus faecalis (*vanA*)	N/A[4]	DSM 17050	N/A[4]
Enterococcus faecalis (*vanB*)	ATCC 51299	DSM 12956	NCTC 13379

In the evaluation of the control strains, the MIC values of the control strains used should fall within the quality control ranges of the respective drug tested as specified in the relevant standard.

[1] *ATCC=American Type Culture Collection*

[2] *DSMZ=Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (German Collection of Microorganisms and Cell Cultures Ltd.)*

[3] *NCTC=National Collection of Type Cultures*

[4] *N/A =not applicable*

10 Clinical and analytical performance

The general requirements of ISO 20776-1 ff. and/or EUCAST or CLSI apply.

According to the specifications of the standard EN ISO 20776-2, the performance of a product for the antibacterial susceptibility testing is given if, on the one hand, at least 95% of the MIC values of an antibiotic relevant for a test strain lie within the corresponding quality control range or reflect the corresponding resistance phenotype and, on the other hand, the MIC values of an antibiotic deviate from the calculated MIC modal value (or MIC modal range) by a maximum of +/- one dilution level.

11 Warranty

The performance data of the UMIC Vancomycin/Teicoplanin test strips were determined on the basis of these Instructions for Use. Deviations from and changes to the test procedure may impact the quality of the results. Any claims for damages are excluded in such cases.

We would like to point out that all serious incidents related to this product must be reported to the manufacturer and the competent authority of the EU member state in which the user is located.

12 Limitation

To determine valid MIC values using the UMIC Vancomycin/Teicoplanin test system, Mueller Hinton II manufactured by Bruker Daltonics GmbH & Co. KG must be used.

13 Symbols

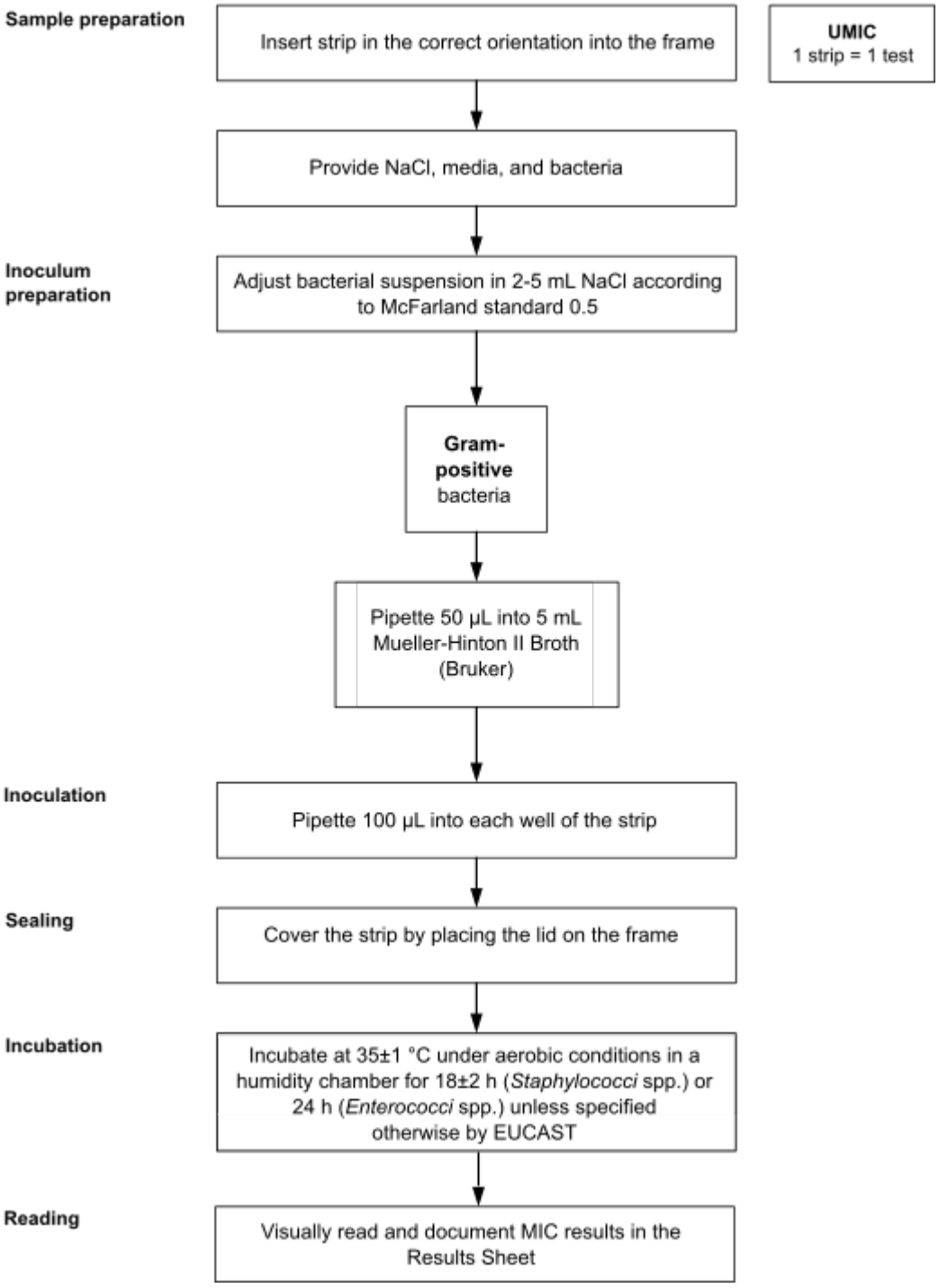
Symbol	Description
	Do not re-use
	Contains sufficient for <n> tests
	Temperature limit
	Consult Instructions for Use
	Caution
	Use-by date
CE	CE marking according to IVDD 98/79/EC
LOT	Batch code
IVD	*In vitro* diagnostic medical device
REF	Catalog number
	Manufacturer

14 References

Note *The standards and guidance documents listed below are subject to update.*

- ISO 20776-1 — 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.
- European Committee on Antimicrobial Susceptibility Testing (EUCAST), Breakpoint tables for interpretation of MICs and zone diameters.
- European Committee on Antimicrobial Susceptibility Testing (EUCAST). EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance.
- Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; CLSI Document M07
- Performance Standards for Antimicrobial Susceptibility Testing; CLSI Document M100.

15 UMIC Vancomycin/Teicoplanin short instruction



16 Manufacturer

Bruker Daltonics GmbH & Co. KG
Fahrenheitstraße 4
28359 Bremen
Germany
Phone: +49 421 2205-0
E-mail: micronaut.support@bruker.com
Web: www.bruker.com/microbiology

For Australian customers:

Bruker Pty. Ltd.
1/28a Albert Street
Preston
Victoria 3072
Australia

Support (hardware and software)
Email: biotyper.anz@bruker.com
Phone: +61 (1800) 171-247

Sales
Email: sales.anz@bruker.com
Phone: +61 (1800) 278-537
Fax: +61 (03) 9474-7070

(Based on *Biocentric Instructions for Use UMIC, Revision 02, April 2020)*

Descriptions and specifications supersede all previous information.