REF UM-MH-020

Instructions for Use

Mueller Hinton II

CE IVD

Language: en

Revision A (April 2022)

Regulatory notices

Read the Instructions for Use before use and follow the directions that are described in it.

Note If any serious incident occurs in relation to the device, this shall be reported to the manufacturer and to the competent authority of your localization. Use the following e-mail address: micronaut.support@bruker.com

Bruker Daltonics GmbH & Co. KG makes no warranty or guarantee of any kind with respect to the performance of this product, when not used in accordance with this IFU, and/or if used for purposes outside the claimed Intended Use.

Document history

Title:	Instructions for Use Mueller Hinton II
Revision:	Revision A (March 2022)
First revision:	March 2022

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

Section	Changes
–	No changes: first revision

Table of contents

1 Intended purpose

The Mueller Hinton II (cation-adjusted) is an *in vitro* diagnostic medical device for the quantitative detection of bacterial growth of clinically relevant aerobic bacteria in the presence of antimicrobial agents. Only pure cultures obtained from human test material can be used. The device must be used in combination with devices of the UMIC product line. The test is based on the broth microdilution method and is not automated. The results 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. The device is intended for professional laboratory use only.

2 Precautions and warnings

The following safety information apply to the use of this product.

2.1 General precautions

Mueller Hinton II vials are for single use only.

Inspect the product on arrival and do not use in case of damage. Vials with tight caps should be opened carefully to avoid injury due to breakage of glass.

Wear protective clothing and observe federal, state, and local regulations.

2.2 Precautions for handling the product

Do not use tubes if evidence of microbial contamination, evaporation, precipitation, or other signs of deterioration are present.

For additional information, refer to the Safety Data Sheet (s) that can be downloaded from www.bruker.com/msds

2.3 Precautions for handling specimens

Samples, bacterial cultures, inoculated Mueller Hinton II and other materials used must be considered as potentially infectious and must be treated properly and with respect to the corresponding precautionary measures by qualified specialist staff. It is important to work aseptically during the whole test procedure. For further information, refer to “BioSafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 99-8395, 4th Edition (April 1999)“, and to the corresponding federal, state, and local regulations and requirements. Apply established precautions against microbiological hazards throughout all procedures.

This medium is not suitable for direct use with specimens or other materials that contain mixed microbial cultures. It may be used as a supplementary enrichment broth in addition to primary cultivation media. Refer to respective reference literature and guidelines for further information.

2.4 Disposing of product, samples, and packaging

After use, vials, specimen containers and other contaminated materials must be sterilized by suitable procedures, for example, autoclaving, before discarding in accordance with federal, state, and local regulations.

3 Product description

In accordance with ISO 20776-1, *in vitro* antimicrobial susceptibility tests are performed on micro-organisms that are suspected of causing disease, particularly if the organism is thought to belong to a species that may exhibit resistance to frequently used antimicrobial agents. The tests are also important in resistance surveillance, epidemiological studies of susceptibility and in comparisons of new and existing agents. Standardized Mueller Hinton II is required for cultivation of microorganisms using the broth microdilution reference method and other susceptibility tests that require at least a short cultivation of microorganisms in liquid media.

3.1 Test principle

Mueller Hinton II for broth microdilution in accordance with ISO 20776-1 contains:

- Beef Extract
- Acid Hydrolysate of Casein
- Starch
- Ca^{2+}, MG^{2+}

and is used to measure quantitatively and qualitatively the *in vitro* activity of an antimicrobial agent against a given bacterial isolate.

Acid hydrolysate of casein and beef extract supply amino acids and other nitrogenous substances, minerals, some vitamins and other nutrients support the growth of microorganisms. Starch acts as a protective colloid against toxic substances that may be present in the medium. Hydrolysis of the starch during autoclaving provides a small amount of dextrose, which is a source of energy.

Mueller Hinton II must be used with UMIC products for antimicrobial susceptibility testing of non-fastidious aerobic, Gram negative and Gram positive bacteria based on broth microdilution as mentioned in the respective EUCAST and/or CLSI standards. Refer to the respective IFUs for further information that can be downloaded from www.bruker.com/IFU

3.2 Product content

• 20 glass vials, containing 5.0 ml Mueller Hinton II, each

• Ready for use

3.3 Materials required but not included

For antimicrobial susceptibility testing, for example, in accordance with ISO 20776-1, additional culture media, reagents, consumables, quality control organisms and laboratory equipment are required. Refer to the respective procedures.

For performance of the antimicrobial susceptibility testing with UMIC products, refer to the respective IFU that can be downloaded from www.bruker.com/IFU

3.4 Storage and stability

On receipt, Mueller Hinton II must be stored at 2-25 °C away from light. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light.

Mueller Hinton II broth vials are for single use only.

For shelf life of the media stored as labeled please follow the expiration date printed on the product.

4 Quality control

Mueller Hinton II is subject to quality controls that are carried out systematically at different stages of the production.

The bacteriological quality control can be carried out with the following strains:

Strain	**ATCC No**[1]	**DSMZ No**[2]	**Growth**
Staphylococcus aureus	ATCC 29213	DSM 2569	good
Escherichia coli	ATCC 25922	DSM 1103	good
Pseudomonas aeruginosa	ATCC 27853	DSM 1117	good
Enterococcus faecalis	ATCC 29212	DSM 2570	good

Inoculum for productivity: 10^4 CFU/vial

Incubation Conditions: 18 h ± 2 h at 35 ± 1 °C

[1] *ATCC = American Type Culture Collection*

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

5 Test procedure

Microorganisms to be subcultured or incubated using Mueller Hinton II must first be isolated in pure culture on blood or tryptic soy agar plates without additives.

Generally, transfer isolates and materials using standard bacteriologic techniques and pre-heat tubes at 35 ºC or under conditions that are appropriate for the respective organism that is being cultured.

For susceptibility testing that uses UMIC broth microdilution assays, typically a certain number of microorganisms is required. Refer to the respective Instruction for Use of UMIC products for preparation of standardized suspensions, further sample processing, and evaluation and interpretation of results.

6 Limitations of the method

You may use the Mueller Hinton II only in combination with the UMIC products.

7 Performance characteristics

The general requirements apply to DIN EN ISO 20776-1. For monitoring the accuracy for minimal inhibitory concentrations (MICs), refer to the acceptable limits for quality control strains according to the relevant version of “Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST” (http://www.eucast.org) or the relevant version of “Performance Standards for Antimicrobial Susceptibility Testing; CLSI Document M100” http://www.clsi.org).

The performance of Mueller Hinton II can only be assessed in combination with the respective UMIC products that are used. For performance data, refer to the corresponding Instructions for Use of UMIC products.

8 References

- The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST in the currently valid version. http://www.eucast.org.
- Performance Standards for Antimicrobial Susceptibility Testing; CLSI Document M100 in the currently valid version. http://www.clsi.org
- ISO 20776-1: Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases in the currently valid version
- BioSafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC) 99-8395, 4th Edition (April 1999)

9 Symbols

The following symbols are used in the labeling:

	Do not re-use
	Contains sufficient for <*n*> tests
	Temperature limit
	Keep away from sunlight
	Consult instructions for use
	Use-by date
	CE mark
	*In vitro* diagnostic medical device
	Batch code
	Catalog number
	Global Trade Item Number
	Manufacturer

10 Manufacturer

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Descriptions and specifications supersede all previous information.