



ComASP® Dalbavancin 0.002-32

System for Dalbavancin susceptibility testing
with broth microdilution method, according to ISO 20776-1.

ENGLISH

INTENDED PURPOSE

ComASP® Dalbavancin 0.002-32 is a panel for quantitative determination of the minimum inhibitory concentration (MIC) of Dalbavancin against a broad range of Gram-positive bacteria.

DESCRIPTION

ComASP® Dalbavancin 0.002-32 is a 2-test panel containing the dried-up antibiotic in 15 two-fold dilutions:

Dalbavancin concentration ranges 0.002 to 32 µg/ml.

The ComASP® system is a compact version of the broth microdilution (BMD) reference method allowing to perform the antimicrobial susceptibility testing of Dalbavancin as recommended by international standards (i.e. CLSI, EUCAST, ISO) but in a simpler and less time-consuming way.

The procedure identified in this type of devices is for manual testing only.

KIT CONTENT

- 4 Systems (panels) of ComASP® Dalbavancin 0.002-32 (panels individually packed in foil with silica gel desiccant)
- 8 Tubes of Mueller Hinton II Broth w P80 0.002% (3.6 ml)
- Sealing Film
- Instructions Sheet and Test Results Form

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as:

- loops
- pipettes
- physiological solutions
- swabs
- culture media
- incubator
- test tubes
- 0.5 McFarland turbidity standard
- quality control organisms

CONFIGURATION

Test	Dalbavancin concentration (µg/ml)							
	A	Growth	0.002	0.004	0.008	0.016	0.032	0.064
	0.25	0.5	1	2	4	8	16	32
B	Growth	0.002	0.004	0.008	0.016	0.032	0.064	0.125
	0.25	0.5	1	2	4	8	16	32

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

PRINCIPLE OF THE METHOD

Two bacterial isolates may be tested on a single panel.

All wells related to either test A or B are rehydrated with a standardized microbial suspension.

After incubation for 16-20 hours the result is read and interpreted.

SPECIMEN COLLECTION AND PREPARATION

ComASP® Dalbavancin 0.002-32 is not for use directly with clinical or other specimens. The microorganism to be tested must first be isolated on a nonselective culture medium, such as blood agar or tryptic soy agar (TSA). In case of mixed culture, selected colonies should be purified by subculturing. Differential media harboring chromogenic or fluorogenic substrates should not be used for the subculture. It is recommended that cultures be no more than 24 hours old unless additional incubation is required to achieve sufficient growth.

TEST PROCEDURE

1. Take a panel from its envelope and leave it at room temperature for 10 min, DO NOT DISCARD THE ENVELOPE until both tests have been carried out.
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 0.4 ml of Solution A to a tube of MH II Broth w P80* provided in the kit to obtain the **Solution B**.
6. Dispense 100 µl of Solution B into each well (test A or B).
7. Cover the panel with the lid provided and incubate at 35 ± 1°C for 16-20 hours in ambient air.

* Mueller Hinton II Broth w P80: Beef Extract 3.0 g; Acid Hydrolysate of Casein 17.5 g; Starch 1.5 g; Polysorbate 80 0.002%; 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. 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 new rows in the same panel or 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).

NOTE: Each individual panel is used for performing two tests. If only one test (either A or B) has been performed, use the film provided in the kit to seal the inoculated rows so to prevent any leakage of contaminated fluids. Then, return the panel into its own desiccant envelope and into the refrigerator (see STORAGE).

USER QUALITY CONTROL

QC of ComASP® Dalbavancin 0.002-32 is performed using the following reference strains:

Control strain	MIC QC range (µg/ml)
<i>Staphylococcus aureus</i> ATCC® 29213; NCTC 12973	0.03-0.12
<i>Enterococcus faecalis</i> ATCC® 29212; NCTC 12697	0.03-0.12

LIMITATIONS

Invalid results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.

WARNINGS AND PRECAUTIONS

- 1) **For research use only (RUO).**
- 2) **For laboratory professional use only.**
- 3) Operators must be trained and have certain experience. Please read the instructions carefully before using the kit. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.
- 4) Do not use if a panel, tube or packaging appears to be damaged.
- 5) Avoid cross-contamination of samples by using disposable tips and changing them after each sample.
- 6) Do not mix reagents of different batches. Please use the kit within the validity period.
- 7) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- 8) Ensure laboratory equipment is calibrated and maintained in accordance with the laboratory's procedure.

STORAGE

Store ComASP® Dalbavancin 0.002-32 at 2-8°C in the original packaging. Once an envelope is opened the panel shall be used within 7 days and stored at 2-8°C. 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® Dalbavancin 0.002-32 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. 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.
2. CLSI. Performance Standards for Antimicrobial Susceptibility Testing. 35th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2025.
3. CLSI. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically. 12th ed. CLSI standard M07. Clinical and Laboratory Standards Institute; 2024.
4. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 15.0, 2025. <https://www.eucast.org>.
5. The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control for MIC determination and disk diffusion as recommended by EUCAST. Version 15.0, 2025. <http://www.eucast.org>

Product	Packaging	Ref.
ComASP® Dalbavancin 0.002-32	4x2 tests	75012

Table of Symbols

	For Research Use Only
	Catalogue number
	Batch code
	Do not reuse
	Fragile, handle with care
	Manufacturer
	Use by
	Contains sufficient for <n> tests
	Consult instructions for use
	Keep away from heat
	Temperature limits

Revision History

Revision	Release Date	Change Summary
0	09 Sep 2025	Initial release

Note: Minor typographical, grammar, and formatting changes are not included in revision history.

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EUCAST stands for European Committee on Antimicrobial Susceptibility Testing. These data have been made available at no cost by EUCAST and can be accessed freely on the EUCAST website: www.eucast.org. EUCAST recommendations are frequently updated and the latest versions are available at www.eucast.org.

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