



AD Fosfomicin 0.25-256

Device for fosfomicin susceptibility testing with the agar dilution method.

DESCRIPTION

With an increase in the numbers of bacterial isolates resistant to first-line antibiotics, there has been a revival in the use of older drugs including fosfomicin. Although several commercial tests based on different techniques have been developed, Agar Dilution (AD) is considered the best method for performing fosfomicin susceptibility testing so far.

AD Fosfomicin 0.25-256 is a 12-well panel containing the antibiotic incorporated into an agar medium in different concentrations, i.e. 11 two-fold dilutions (0.25 - 256 µg/mL). The device is used to perform the AD method for the antimicrobial susceptibility testing of fosfomicin as recommended by CLSI and EUCAST standards but in a simpler and less time-consuming way.

KIT CONTENT (kit for 6 tests)

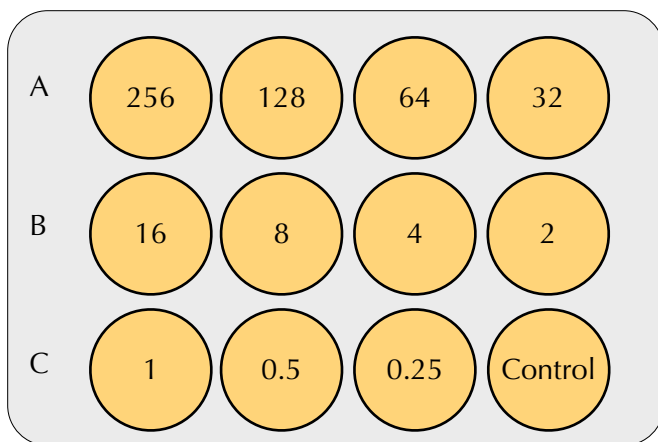
- 6 panels of AD Fosfomicin 0.25-256 (individually packed in plastic bag)
- 2 Reading Templates (transparent and black backgrounds)
- 1 Instructions Sheet also available at www.liofilchem.com/ifu-sds

ITEMS NECESSARY BUT NOT INCLUDED IN THE KIT

- McFarland 0.5 Barium Sulphate Standard (ref.80400)
- Physiological Solution (ref. 20095)

CONFIGURATION

Fosfomicin MIC range: 0.25 - 256 µg/mL



Growth-control: No antimicrobial agent in the well.

PRINCIPLE OF THE METHOD

All wells are inoculated with a standardized microbial suspension. After incubation the MIC result is read and interpreted.

COLLECTION AND STORAGE OF THE SAMPLE

AD Fosfomicin 0.25-256 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 1:10 in saline.
5. Dispense 2 µL of the inoculum solution over the agar surface (*) into each well (the final inoculum concentration should be approximately 10⁴ CFU per spot). Inoculate the growth-control well (no antimicrobial agent) first and then, starting with the lowest concentration, inoculate the other wells containing the different antimicrobial concentrations.
6. Let the inoculated panel stand at room temperature until the moisture in the inoculum spots has been absorbed into the agar (ie, until the spots are dry).
7. Cover the panel with the lid provided and incubate at 35 ± 2°C for 16-20 hours in ambient air.

* Mueller Hinton Agar (MHA) with Glucose-6-Phosphate (G-6-P):

Beef Extract 3.0 g; Acid Hydrolysate of Casein 17.5 g; Starch 1.5 g; G-6-P 0.025 g; Agar 17 g;
Distilled Water 1000 ml;
pH 7.3 ± 0.2

READING THE RESULTS

At the end of the incubation period observe the growth in the wells and establish the MIC as follow:

According to CLSI

- Record the MIC as the lowest concentration of antimicrobial agent that completely inhibit growth.
- Disregard single colonies or faint haze caused by the inoculum.

According to EUCAST

- Read the end point at the minimum concentration where there is non-confluent growth.
- Single colonies, pinpoint colonies and a thin film of growth should be ignored.

The results are read visually. Reading can be improved by placing the panel on a dark non reflecting surface.

The Reading Template provided with the kit allows to easily determine the correct MIC result.

Note: Ensure that the panel is properly positioned before reading the results, the ABC on the template must match the ABC on the panel.

Refer to the Reading Guide for specific examples.

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 (copy as many forms as necessary).

INTERPRETATION OF THE RESULTS

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

USER QUALITY CONTROL

Quality control of AD Fosfomicin 0.25-256 is performed using the following reference strains:

Strain		MIC range (µg/mL)
<i>Escherichia coli</i>	ATCC® 25922	0.5-2
<i>Staphylococcus aureus</i>	ATCC® 29213	0.5-4
<i>Pseudomonas aeruginosa</i>	ATCC® 27853	2-8
<i>Enterococcus faecalis</i>	ATCC® 29212	32-128

FACTORS THAT MAY INVALIDATE THE RESULTS

Contaminated culture; poor standardization of the inoculum; clinical material unsuitable; use of expired panels or expired supplementary reagents; non compliance with temperatures and times of incubation.

PRECAUTIONS

The product AD Fosfomicin 0.25-256 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. AD Fosfomicin 0.25-256 is a disposable device 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.

* In USA, AD Fosfomicin 0.25-256 is available for Research Use Only (RUO) and should not be used for diagnostic purposes.

STORAGE

Store AD Fosfomicin 0.25-256 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, AD Fosfomicin 0.25-256 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; 30th ed. CLSI Supplement M100S. Wayne, PA: Clinical and Laboratory Standards Institute; 2020.
2. CLSI. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; 11th ed. CLSI standard M07. 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 10.0, 2020. <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 10.0, 2020. <http://www.eucast.org>.

PRESENTATION

Product	µg/mL	Packaging	Ref.
AD Fosfomicin	0.25-256	6 test	77061
AD Fosfomicin	0.25-256	1 test	77001

TABLE OF SYMBOLS

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


Liofilchem srl
 Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (TE) Italy
 Tel +39 0858930745 Fax +39 0858930330
 Headquarter, Manufacturing Site, International distribution
www.liofilchem.com

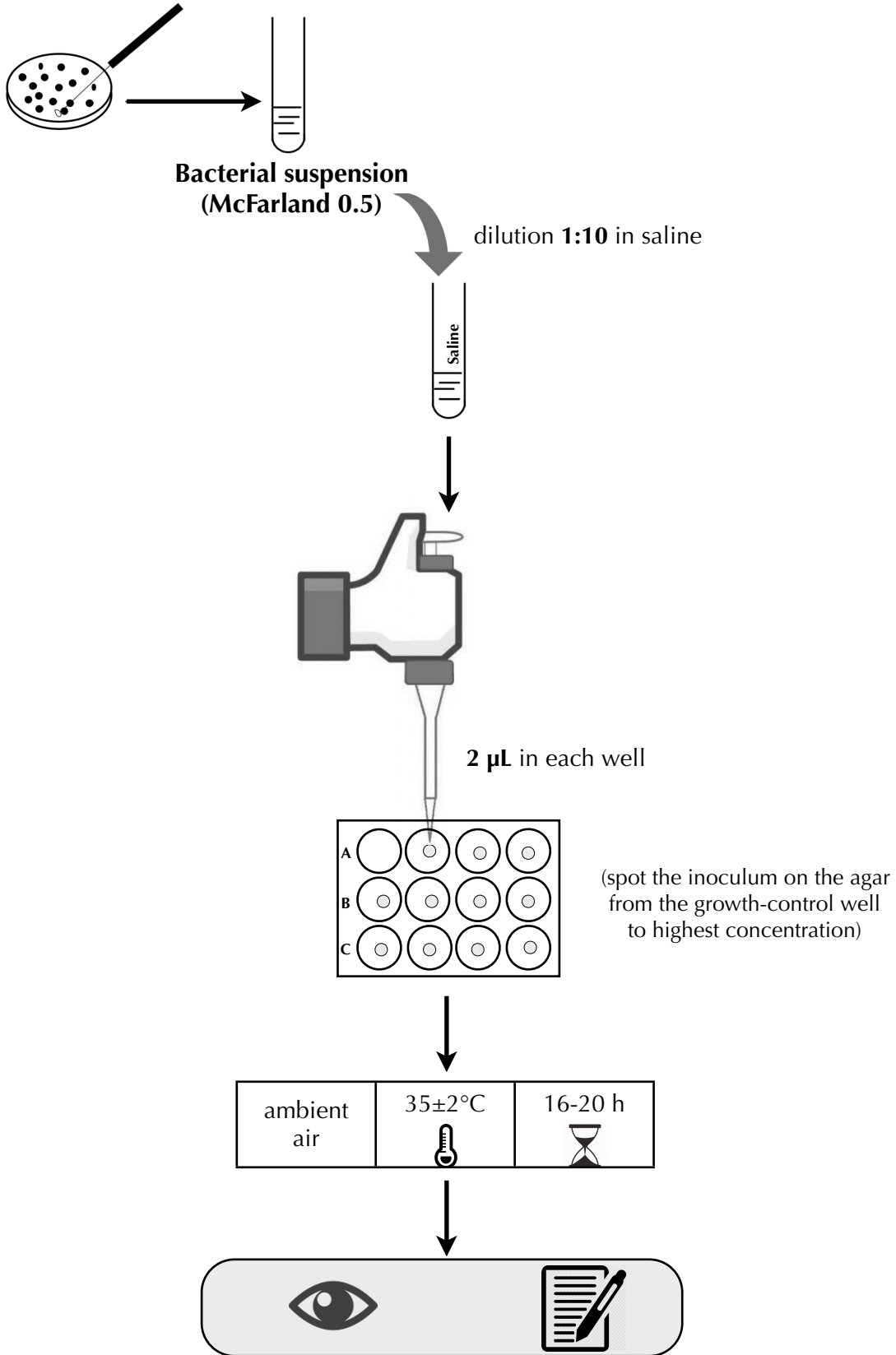


Liofilchem, Inc. In US available as RUO device

465 Waverley Oaks Rd. Suite 317, Waltham, MA 02452, USA
 Tel 781-902-0312
 US Distribution Center



AD Fosfomicin Workflow



Liofilchem srl

Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (TE) Italy
Tel +39 0858930745 Fax +39 0858930330 www.liofilchem.com
Headquarter, Manufacturing Site, International distribution



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