ENGLISH

ComASP™ Antifungal

System for antifungal susceptibility testing with the broth microdilution method.

DESCRIPTION

ComASP™ Antifungal is used to establish the minimum inhibitory concentrations (MICs) of 6 antifungals.

The test panel contains the dried up antimycotic agents in the following concentration ranges (two-fold dilutions):

1. Fluconazole, 1 to 8 µg/ml
2. Voriconazole, 0.06 to 0.5 µg/ml
3. Caspofungin, 0.12 to 4 µg/ml
4. Anidulafungin, 0.12 to 4 µg/ml
5. Itraconazole, 0.06 to 0.5 µg/ml
6. Micafungin, 0.06 to 4 µg/ml

The system allows to perform the broth microdilution (BMD) method for antifungal susceptibility testing (AFST) of yeasts, including species of *Candida* and *Cryptococcus*, as recommended by CLSI but in a simpler and less time-consuming way.

KIT CONTENT

- 4 Systems (panels) of ComASP Antifungal
  (panels individually packed in foil with silica gel desiccant)
- 4 Tubes of RPMI Broth (9.9 ml)
- 1 Instructions Sheet (includes 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

Antifungals concentration (µg/ml)							
FLU 1	**FLU** 2	**FLU** 4	**FLU** 8	**VO** 0.06	**VO** 0.12	**VO** 0.25	**VO** 0.5
CAS 0.12	**CAS** 0.25	**CAS** 0.5	**CAS** 1	**CAS** 2	**CAS** 4	**AND** 0.12	**AND** 0.25
AND 0.5	**AND** 1	**AND** 2	**AND** 4	**ITC** 0.06	**ITC** 0.12	**ITC** 0.25	**ITC** 0.5
MIC 0.06	**MIC** 0.12	**MIC** 0.25	**MIC** 0.5	**MIC** 1	**MIC** 2	**MIC** 4	**Growth**

FLU, Fluconazole; VO, Voriconazole; CAS, Caspofungin; AND, Anidulafungin; ITC, Itraconazole; MIC, Micafungin;
Growth indicates growth control: No antimicrobial agent in the well.

PRINCIPLE OF THE METHOD

A panel allows the susceptibility testing of 1 isolate.
All 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 Antifungal is not for use directly with clinical or other specimens. The microorganism to be tested must first be isolated on a suitable culture medium, either selective or non-selective. In case of mixed culture, selected colonies should be purified by subculturing.

TEST PROCEDURE

1. Take a panel from its envelop and leave it at room temperature for 10 min.
2. Prepare a suspension of the test organism using the colony suspension method.
   NOTES: Choose 5 colonies that are at least 1 mm in diameter. Select colonies from 24-hours-old cultures of *Candida* spp. or 48-hour-old cultures of *C. neoformans*.
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 0.1 ml of Solution A to a tube of RPMI Broth* provided in the kit to obtain the **Solution B**.
6. Dispense 200 µl of Solution B into each well.
7. Cover the panel with the lid provided and incubate at 35 ± 2°C in ambient air for 24 hours (or up to 48 h for isolates that are not growing well at 24 h) for *Candida* species. When testing *C. neoformans*, panels should be incubated for a total of 70 to 74 hours before determining the results.

* RPMI Broth: RPMI 1640 10.4 g; MOPS 34.53 g; Distilled Water 1000 ml; pH 7.0 ± 0.1

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 an antifungal that causes a prominent decrease (50%) in visible growth/turbidity compared with the growth-control (antifungal agent-free) 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.

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.

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 CLSI interpretive criteria.

QUALITY CONTROL

Quality control of ComASP Antifungal is performed using the following reference strains:

Strain	
Candida krusei	ATCC® 6258
Candida albicans	ATCC® 90028
Candida parapsilosis	ATCC® 22019
Candida tropicalis	ATCC® 750

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 ComASP Antifungal 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 Antifungal is a disposable device intended for professional use only. 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 Antifungal 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 Antifungal 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 of Yeasts; 1st ed. CLSI Supplement M60. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.
2. CLSI. Reference Method for Broth Dilution Antifungal Susceptibility Testing for Yeasts. 4th ed. CLSI standard M27. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

PRESENTATION

Product	µg/ml	Packaging	Ref.
ComASP™ Antifungal	1 - 8 (fluconazole) 0.06 - 0.5 (voriconazole) 0.12 - 4 (caspofungin) 0.12 - 4 (anidulafungin) 0.06 - 0.5 (itraconazole) 0.06 - 4 (micafungin)	4 test	75101

TABLE OF SYMBOLS

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

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TEST RESULTS FORM

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Appendix

ComASP™ Antifungal

System for antifungal susceptibility testing with the broth microdilution method.

Patient data
Name
Surname
Age
Gender
Specimen
Notes

Indicate with the sign **+** the microbial growth.

Indicate with the sign **−** the absence of microbial growth.

Read the MIC and interpret the result according to current CLSI interpretive criteria.

ANTIFUNGAL CONCENTRATION (µg/ml)							
FLU				VO			
1	2	4	8	0.06	0.12	0.25	0.5
CAS						AND	
0.12	0.25	0.5	1	2	4	0.12	0.25
AND				ITC			
0.5	1	2	4	0.06	0.12	0.25	0.5
MIC							Growth
1	2	4	8	16	32	64	

MIC VALUE AND INTERPRETATION	
FLU	Fluconazole
VO	Voriconazole
CAS	Caspofungin
AND	Anidulafungin
ITC	Itraconazole
MIC	Micafungin

Date of Test	**Operator**