



AST-YS08

IVD

Fungal Susceptibility Card

SUMMARY AND EXPLANATION

The VITEK® 2 Fungal Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of **clinically significant yeasts** to antifungal agents when used as instructed in the Product Information manual.

INSTRUCTIONS FOR USE

A package insert is provided in the kit or downloadable from www.biomerieux.com/techlib

See the Product Information manual for additional Instructions for Use.

STORAGE CONDITIONS

Store at 2° to 8° C.

CONTENTS OF THE CARD

Antimicrobial	Code	Concentration §	Calling Range		FDA Indications for Use
			≤	≥	
Amphotericin B	AB	1, 4, 16, 32	0.25	16	
Caspofungin	CAS	0.12, 0.5, 2, 8	0.125	8	N/A**
Fluconazole	FLU	2, 4, 8, 16, 32, 64	0.5	64	<i>C. dubliniensis</i> , <i>C. albicans</i> , <i>C. parapsilosis</i> , <i>C. tropicalis</i> , <i>C. guilliermondii</i> , <i>C. lusitanae</i>
Flucytosine	FCT	1, 4, 16, 32	1	64	<i>C. albicans</i> , <i>C. dubliniensis</i> , <i>C. glabrata</i> , <i>C. guilliermondii</i> , <i>C. lusitanae</i> , <i>C. parapsilosis</i> , <i>C. tropicalis</i>
Micafungin	MCF	0.06, 0.25, 1, 4	0.06	8	N/A**
Voriconazole ^{SDD}	VRC	0.5, 1, 4, 8	0.12	8	<i>C. albicans</i> , <i>C. krusei</i> , <i>C. parapsilosis</i> , <i>C. tropicalis</i> , <i>C. lusitanae</i> , <i>C. guilliermondii</i>

Numerical values are expressed in µg/ml.

§ Equivalent standard method concentration by efficacy.

**N/A = No specific FDA Indications for Use available

*CLSI@24H = CLSI Broth Microdilution expected QC range at 24 hrs

**FDA/CLSI@48H = FDA/CLSI Broth Microdilution expected QC range at 48 hrs

^{SDD} = Susceptible-Dose Dependent (SDD) reports as Intermediate (I).

QUALITY CONTROL

Antimicrobial	Code	CLSI Quality Control Organisms VITEK 2 Results	
		<i>C. parapsilosis</i> ATCC® 22019™	<i>C. krusei</i> ATCC® 6258™
Amphotericin B	AB	≤0.25 - 1	0.5 - 2
Caspofungin	CAS	0.25 - 1	≤0.12 - 1
Fluconazole	FLU	≤0.5 - 4 0.5 - 4 (CLSI@24H)* 1 - 4 (FDA/CLSI@48H)**	8 - ≥64 8 - 64 (CLSI@24H)* 16 - 128 (FDA/CLSI@48H)**
Flucytosine	FCT	≤1	4 - 32 4 - 16 (CLSI@24H)* 8 - 32 (FDA/CLSI@48H)**
Micafungin	MCF	0.25 - 2	0.12 - 0.5
Voriconazole ^{SDD}	VRC	≤0.12 - 0.25	≤0.12 - 0.5

Numerical values are expressed in µg/ml.

*CLSI@24H = CLSI Broth Microdilution expected QC range at 24 hrs

**FDA/CLSI@48H = FDA/CLSI Broth Microdilution expected QC range at 48 hrs

^{SDD} = Susceptible-Dose Dependent (SDD) reports as Intermediate (I).

LIMITATIONS

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

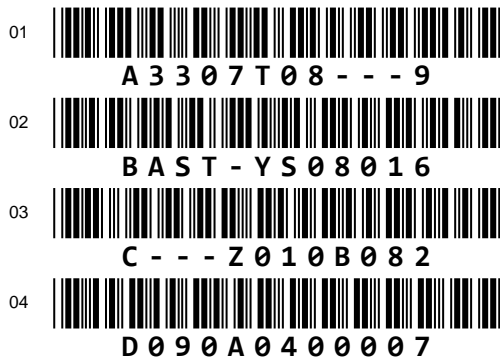
- Caspofungin: *Candida glabrata* (when applying CLSI breakpoints ≤ 0.12 S, 0.25 I, ≥ 0.5 R)
- Fluconazole: *Candida glabrata*, *C. kefyr*, *Cryptococcus neoformans*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:











- Caspofungin: *Candida albicans*, *C. glabrata*, *C. guilliermondii*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*
- Micafungin: *Candida* spp.
- Voriconazole: *Candida albicans*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, *C. lusitaniae*, *C. guilliermondii*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting. Refer to the software user manual for instructions.

↓ MUST enter the following barcodes into "Flex Panel Entry" program before first use of this Susceptibility Card.



INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Authorized representative in the European Community

PATENTS

Product covered by one or more of U.S. Patent Nos. D414,272; D437,797; 5,609,828; 5,746,980; 5,804,437; 5,869,005; 5,932,177; 5,951,952; 6,267,929; 6,309,890 and 6,340,573; and Foreign Counterparts. Other Patents Pending.

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