BIOMÉRIEUX

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VITEK® 2 AST-YS08

Rx only IVD

INTENDED USE

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.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions.[2] The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 24 to 48 hours for yeast. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

STORAGE CONDITIONS

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

PRINCIPLE OF THE TEST

The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach.[15,16] The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.[1]

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period of time (up to 36 hours for yeast). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Table 1: Contents of the Card

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Amphotericin B	ab01n	1, 4, 16, 32	0.25	16	**N/A

Antimicrobic	Code	Concentration §	Calling Range ≤	Calling Range ≥	FDA Indications for Use
Caspofungin	cas02n	0.12, 0.5, 2, 8	0.125	8	*C. albicans*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, *C. guilliermondii*, *C. glabrata*
Fluconazole	flu02n	2, 4, 8, 16, 32, 64	0.5	64	*C. dubliniensis*, *C. albicans*, *C. parapsilosis*, *C. tropicalis*, *C. guilliermondii*, *C. lusitaniae*
Flucytosine	fct02n	1, 4, 16, 32	1	64	*C. albicans*, *C. dubliniensis*, *C. glabrata*, *C. guilliermondii*, *C. lusitaniae*, *C. parapsilosis*, *C. tropicalis*
Micafungin	mcf02n	0.06, 0.25, 1, 4	0.06	8	*C. albicans*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, *C. guilliermondii*, *C. glabrata*
Voriconazole[SDD]	vrc01n	0.5, 1, 4, 8	0.12	8	*C. albicans*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, *C. lusitaniae*, *C. guilliermondii*

Numerical values are expressed in µg/mL.

§ Equivalent standard method concentration by efficacy.

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

[SDD] = Susceptible-Dose Dependent (SDD) reports as Intermediate (I).

PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in the Instructions for Use.
- It is highly recommended that Good Laboratory Practices (e.g., FDA, CLSI, ISO, etc.) also be followed, according to local guidelines or requirements.

- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or local therapy guidelines.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in AST. Additional testing may be required.[17]

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions [18,20]

INSTRUMENT

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial and yeast pathogens to available antimicrobial agents. For detailed information on the use and operation of these devices, refer to the appropriate Instrument User Manual.

SPECIMEN PREPARATION

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	McFarland Standards	Dilution for AST	Age of Suspension Before Loading Instrument
AST YEAST	SDA SDA-E CBA CHBA TSA TSAB CID CPS ID	18 to 96 hours	35°C to 37°C aerobic, non-CO_2	1.80 to 2.20	280 µL in 3.0 mL 0.45% saline	VITEK® 2 Compact: ≤ 30 minutes VITEK® 2: ≤ 1 hour
YST and AST YEAST Pair	SDA[1] SDA-E[1] TSAB[1] CBA TSA CHBA CID CPS ID	18 to 72 hours	35°C to 37°C aerobic, non-CO_2	1.80 to 2.20	280 µL in 3.0 mL 0.45% saline	≤ 30 minutes

[1] These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CBA = Columbia Sheep Blood Agar

CHBA = Columbia Horse Blood Agar

CID = chromID™ Candida (Candida ID2 Agar)

CPS ID = chromID™ CPS (CPS ID Agar)

SDA = Sabouraud Dextrose Agar

SDA-E = Sabouraud Dextrose Agar (Emmons)

TSA = Trypticase Soy Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TEST PROCEDURE

Warning: Failure to properly follow instructions and recommendations provided in this section for performing laboratory tasks may cause erroneous or delayed results.

Materials

Materials provided are:

- VITEK® 2 DensiCHEK™ Kit, VITEK® 2 DensiCHEK™ Plus Kit, or VITEK® 2 DensiCHEK® Kit
- VITEK® 2 DensiCHEK™ Standards Kit, VITEK® 2 DensiCHEK™ Plus Standards Kit, or VITEK® 2 DensiCHEK® Plus Standards Kit
- VITEK® 2 Cassette
- Adjustable volume saline dispenser
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- VITEK® 2 60 or VITEK® 2 XL only: VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Loops, sterile sticks or swabs
- Appropriate agar medium (See the Culture Requirements Table.)
- QC isolates
- VITEK® 2 AST Cards
- Micropipettors to deliver 280 µL
- Disposable pipette tips

Optional Accessories:

- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. (See the Culture Requirements Table for product-specific information.)

Note: Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

1. Do one of the following:
   - Select isolated colonies from a primary plate if culture requirements are met.
   - Subculture the organism to be tested to appropriate agar medium and incubate accordingly.
2. Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).

3. Using sterile technique, prepare a homogenous organism suspension with a density equivalent to the appropriate McFarland standard or McFarland Reference using a compatible benchtop densitometer (see the Culture Requirements Table).
   Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 60 or VITEK® 2 XL, and less than 30 minutes when using VITEK® 2 Compact.
4. Choose one of the following:
   - **For an automatic dilution (VITEK® 2 60 or VITEK® 2 XL only):** Place the suspension tube prepared in step 3 into the cassette with or without an identification card. In the next cassette slot, place an empty tube and an AST card. The instrument will automatically dilute the bacterial suspension to prepare an inoculum suitable for the susceptibility card.
   - **For a manual dilution (VITEK® 2 Compact, VITEK® 2 60 or VITEK® 2 XL):** In a second tube containing 3.0 mL of saline, transfer 280 µL of the suspension prepared in step 3. Then place this tube in the cassette with a susceptibility card. The tube with the initial bacterial suspension can also be used for inoculation of an identification card.

   Note: Check the saline level in the tubes after filling. When it is evident by the saline level in the tube that a card has been improperly filled, do not load the card if using VITEK® 2 Compact; **or**, eject the card if using VITEK® 2 60 or VITEK® 2 XL.

   Note: Refer to the appropriate Instrument User Manual for detailed information regarding data entry, processing, etc.
5. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

QUALITY CONTROL

Quality Control organisms should be processed according to the Test Card Setup Procedure.

Table 3: Quality Control

CLSI® Quality Control Organisms VITEK® 2 Results			
Antimicrobic	Code	*C. parapsilosis* ATCC® 22019™	*C. krusei* ATCC® 6258™
Amphotericin B	ab01n	≤ 0.25 - 1	≤ 0.25 - 2
Caspofungin	cas02n	0.25 - 1 (FDA/CLSI@24H = FDA/ CLSI Broth Microdilution expected QC range at 24 hours.)	≤ 0.12 - 1 (FDA@24H = FDA Broth Microdilution expected QC range at 24 hours.)
Fluconazole	flu02n	≤ 0.5 - 4*	8 - ≥ 64**
Flucytosine	fct02n	≤ 1	4 - 32†
Micafungin	mcf02n	0.25 - 1	0.12 - 0.5
Voriconazole	vrc01n	≤ 0.12 - 0.25	≤ 0.12 - 0.5

Numerical values are expressed in µg/mL.

*0.5 - 4 (CLSI@24H)
1 - 4 (FDA/CLSI@48H)

**8 - 64 (CLSI@24H)
16 - 128 (FDA/CLSI@48H)

†4 - 16 (CLSI@24H)
8 - 32 (FDA/CLSI@48H)

Certification Statement

This is to certify that bioMérieux complies with ISO 13485 and FDA Quality System Regulation (QSR) requirements for design, development, and manufacture of antimicrobial susceptibility systems.

Frequency of QC Testing

Refer to *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* CLSI® and/or your local guidelines.[2]

Preparation of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. Subculture to Sabouraud Dextrose Agar (SDA) or Sabouraud Dextrose Agar (Emmons) SDA-E.
3. Incubate at 35°C for 24 hours.
4. Check for purity.
5. Subculture to SDA plate.
6. Incubate at 35°C for 24 hours (*Candida* species).

Short-Term Storage Conditions

1. Streak to an SDA plate or slant.
2. Incubate for 24 hours.
3. Refrigerate at 2°C to 8°C for up to two weeks.
4. Subculture once as described above and use for QC.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture to SDA twice before running QC.
   Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

RESULTS

Susceptibility Analytical Techniques

The system evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., *Staphylococcus aureus*/oxacillin).

In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, Comité de l'Antibiogramme de la Société Française de Microbiologie (CASFM), European Committee for Antimicrobial Susceptibility Testing (EUCAST), or to an adaptation of the global settings according to other local guidelines.

Note: When FDA and CLSI® breakpoints differ, VITEK® 2 Systems AST tests are cleared for use with FDA breakpoints applied.

Antimicrobial Deduction

Antimicrobials that have been deduced will only report an interpretive result and will be noted with a **+**.

Clinical Efficacy and Indications for Use

AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections caused by all organisms that may be tested. For interpreting and reporting of antimicrobial results that have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

LIMITATIONS

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

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

- Caspofungin (cas02n): *Candida glabrata* (when applying CLSI breakpoints 0.12 S, 0.25 I, 0.5 R)
- Fluconazole (flu02n): *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 (cas02n): *Candida albicans, C. glabrata, C. guilliermondii, C. krusei, C. parapsilosis, C. tropicalis*
- Micafungin (mcf02n): *Candida* spp.
- Voriconazole (vrc01n): *Candida albicans, C. krusei, C. parapsilosis, C. tropicalis, C. lusitaniae, C. guilliermondii*

Additional limitations for Caspofungin (cas02n) are as follows:

- Caspofungin (cas02n): One non-susceptible isolate of *C. glabrata* gave a susceptible Caspofungin MIC result during comparative testing, a potential very major error.
- Caspofungin (cas02n): The ability of VITEK® 2 AST-YS to detect resistance to Caspofungin is unknown because nonsusceptible strains were not available for comparative testing. Isolates yielding Caspofungin MIC results suggestive of a "non-susceptible" category (≥ 2 µg/mL) should be submitted to a reference laboratory for further testing.

Additional limitations for Micafungin (mcf02n) are as follows:

The ability of the AST card to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory for further testing.

- Micafungin (mcf02n): *Candida glabrata*

EXPECTED VALUES

Expected results for susceptibility tests will vary based on location and institution. VITEK® 2 Systems were tested at several geographically diverse locations to ensure that trends that occurred by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established using the manual and autodilution modes (on a VITEK® 2 System) at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a CLSI® reference method. Essential agreement (EA) represents VITEK® 2 results which agree exactly or are within a ± twofold dilution (± two doubling dilutions for antifungal) of the reference result.

Category agreement (CA) occurs when the VITEK® 2 and the reference interpretative results agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors. For a description of interpretive errors, refer to the footnotes below the table that follows (Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage demonstrates that the antimicrobial retains an acceptable overall performance.

There are instances when the performance is based solely on category agreement (CA) because at the time performance was established, less than five discrete twofold dilutions were evaluated. A minimum of five dilutions is necessary to calculate essential agreement (EA) based on ± one twofold dilution. These instances are designated by a "c" footnote in the Contents of the Card table. The following performance tables have values for CA only when EA was not established at the time of FDA clearance.

The reproducibility of the VITEK® 2 system was established by testing a set of on-scale organisms.*

*Data on file at bioMérieux, Inc

Table 4: Performance Characteristics for Yeast Antimicrobial Susceptibility Testing

Antimicrobial	Anti-microbial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement				Category Agreement				% Repro-ducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Amphotericin B	AB	ab01n	Global	E, Csp, Ref. = 24 hr	99.1	33.3	0.0	0.5	86.4	100	0.0	12.9	100
				E, Csp, Ref. = 48 hr	96.7	62.5	0.0	2.1	39.4	100	0.0	58.7	
				E, Cne, Ref. = 48 hr	98.6	0.0	1.6	0.0	89.9	0.0	1.6	8.7	
				E, Cne, Ref. = 72 hr	98.6	0.0	1.9	0.0	78.3	0.0	1.9	20.3	
Caspofungin	CAS	cas02n	CLSI	E, Csp, Ref = 24 hr	99.6	0.0	0.0	0.2	87.2	45.5	0.3	12.0	100
				#, E	99.7	33.3	0.0	0.0	97.0	66.7*	0.0	0.0	
Fluconazole	FLU	flu02n	CLSI	E,Csp, Ref. = 24 hr	96.3	4.0	2.1	1.0	93.7	8.0	2.8	3.2	100
			CLSI (FDA)	#, E, Csp, Ref. = 24 hr	96.1	0.0	0.4	2.2	94.3	0.0	0.4	5.3	
Flucytosine	FCT	fct02n	CLSI (FDA)	#, E, CSP, Ref. = 24 hr	98.8	3.2	0.0	1.0	98.5	3.2	0.0	1.3	100
Micafungin	MCF	mcf02n	CLSI	E, Csp, Ref. = 24 hr	98.9	0.0	0.3	0.4	96.6	16.7	0.3	3.0	100
				#, E[3]	98.9	N/A	N/A	N/A	96.6	16.7	0.3	3.0	
Voriconazole	VRC	vrc01n	CLSI	#, E, Csp, Ref. = 24 hr	99.2	0.0	0.2	0.0	99.2	0.0	0.3	0.5	98.2
				#, E, Csp, Ref. = 48 hr	96.9	16.7	0.3	0.0	98.7	16.7	0.3	0.8	

* = One error was resolved upon repeat testing.

[1] Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

[2] Comment — Specific organism groups are designated as Csp for Candida species, Cne for *Cryptococcus neoformans*.

[3]VITEK® 2 Micafungin (mcf02n) MIC values for *C. albicans* and *C. glabrata* tended to be one or more doubling dilution higher compared to reference broth microdilution. VITEK® 2 Micafungin (mcf02n) MIC values for *C. krusei* and *C. parapsilosis* tended to be one doubling dilution lower compared to reference broth microdilution.

Key:

= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
E = External performance data
I = Internal performance data
– = Not available
N/A = Not applicable
Ref. = Reference method for clinical performance study.

LIST OF CLAIMS

Note: If the organism is not in the VITEK® 2 susceptibility database, results will not be reported.

Yeast Organisms Claimed for AST-YS (keyID)

- *Candida albicans*
- *Candida ciferrii* (formerly known as *Stephanoascus ciferrii*)
- *Candida dubliniensis*

- *Candida duobushaemulonii*
- *Candida glabrata*
- *Candida guilliermondii*
- *Candida haemulonii*
- *Candida inconspicua*
- *Candida intermedia*
- *Candida kefyr*
- *Candida krusei*
- *Candida krusei* ATCC® 6258™
- *Candida lipolytica*
- *Candida lusitaniae*
- *Candida norvegensis*
- *Candida parapsilosis*
- *Candida parapsilosis* ATCC® 22019™
- *Candida pelliculosa*
- *Candida rugosa*
- *Candida tropicalis*
- *Candida utilis*
- *Cryptococcus neoformans*

REFERENCES

1. Barry, AL The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA. 1976.
2. Clinical Laboratory Standards Institute (CLSI®), Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, M7- A7, Wayne, Pennsylvania, January 2006.
3. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement, M100-S18, Vol. 27, No. 1, January 2008.
4. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-third Informational Supplement, M100-S22, January 2012.
5. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fourth Informational Supplement; M100-S24, January 2014.
6. Clinical and Laboratory Standards Institute (CLSI®), Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement, M100-S25, January 2015.
7. Comité de l'Antibiogramme de la Société Française de Microbiologie. Communiqué 1996. Path Biol, 1996, 44, n° 8, I-VIII.
8. Comité de l'Antibiogramme de la Société Française de Microbiologie, Communiqué 2007.
9. Comite de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), Recommendations 2012.
10. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2014.
11. Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM). Communiqué 2015.
12. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 2.0, January 2012.
13. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 4.0, January 2014.
14. European Committee on Antimicrobial Susceptibility Testing (EUCAST), version 5.0, January 2015.
15. Gerlach, EH Microdilution 1: A Comparative Study, p. 63-76, In: Balows, A. (ed.), Current Techniques for Antibiotic Susceptibility Testing, Charles C. Thomas, Springfield, IL. 1974.
16. MacLowry, JD, and HH Marsh. 1968. Semi-automatic microtechnique for serial dilution antibiotic sensitivity testing in the clinical laboratory. J. Lab. Clin. Med. 1968;72:685-687.
17. Murray, PR, Baron EJ, Pfaller MA, Tenover FC, and Yolken RH, editors. Manual of Clinical Microbiology, 8th ed. American Society for Microbiology, Washington, D.C. 2003.
18. National Committee for Clinical Laboratory Standards, M29-A, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Approved Guideline (1997).
19. National Committee for Clinical Laboratory Standards, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard — Third Edition, M27-A3, Vol. 22, No. 15, 2008.
20. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Office of Health and Safety, Biosafety in Microbiological and Biomedical Laboratories, 1988.

Permission to incorporate portions of M100 (Performance Standards for Antimicrobial Susceptibility Testing: Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI®. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

BARCODES

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

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	In Vitro Diagnostic Medical Device
	Legal Manufacturer
	Temperature limitation
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture
Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European Community
Rx only	For US Only : Caution : US Federal Law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use provided in the kit or downloadable from www.biomerieux.com/techlib

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the “System”) other than as set forth in the IFU.

WASTE DISPOSAL

All hazardous waste must be disposed of by following your local inspecting agency's guidelines.

REVISION HISTORY TABLE

Change type categories	
N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release Date	Part Number	Change Type	Change Summary
2016-12	046699-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• Combined product package insert content with VITEK® 2 Product Information Manual AST content • Updated Limited Warranty section • Updated with RX only information • Updated with EUCAST limitations

Release Date	Part Number	Change Type	Change Summary
2020-01	046699-02	Technical change	The following sections have updated warnings and 8.01 content: • Precautions • Test Procedure • Quality Control > Certification Statement • Results > Clinical Efficacy and Indications for Use • Limitations > EUCAST Limitations • Performance Characteristics • References • Revision History Table

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