BIOMÉRIEUX

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VITEK® 2 ANC

Rx only IVD

INTENDED USE

These Instructions for Use correspond to the VITEK® 2 Systems 7.01 and 8.01 software. If you are not using VITEK® 2 Systems 7.01 or 8.01 software, please refer to the VITEK® 2 Systems Product Information that you received with your current software version.

The VITEK® 2 Anaerobic and Corynebacteria identification card (ANC) is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant anaerobic organisms and *Corynebacterium* species. The VITEK® 2 ANC identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

DESCRIPTION

The ANC card is based on established biochemical methods and newly developed substrates. There are 36 biochemical tests measuring carbon source utilization and enzymatic activities. Final results are available in approximately six hours.

For a list of well contents, see the ANC Well Contents table.

ANC Well Contents

Well	Test	Mnemonic	Amount/Well
4	D-GALACTOSE	dGAL	0.3 mg
5	Leucine ARYLAMIDASE	LeuA	0.023 mg
6	ELLMAN	ELLM	0.03 mg
7	Phenylalanine ARYLAMIDASE	PheA	0.026 mg
8	L-Proline ARYLAMIDASE	ProA	0.023 mg
10	L-Pyrrolidonyl-ARYLAMIDASE	PyrA	0.018 mg
11	D-CELLOBIOSE	dCEL	0.3 mg
13	Tyrosine ARYLAMIDASE	TyrA	0.0279 mg
15	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.038 mg
18	D-GLUCOSE	dGLU	0.3 mg
20	D-MANNOSE	dMNE	0.3 mg
22	D-MALTOSE	dMAL	0.3 mg
28	SACCHAROSE/SUCROSE	SAC	0.3 mg
30	ARBUTIN	ARB	0.1875 mg
33	*N*-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
34	5-Bromo-4-chloro-3-indoxyl-beta-glucoside	BGLUi	0.006 mg
36	UREASE	URE	0.15 mg
37	5-Bromo-4-chloro-3-indoxyl-beta-glucuronide	BGURi	0.006 mg
39	BETA-GALACTOPYRANOSIDASE Indoxyl	BGALi	0.006 mg
41	ALPHA-ARABINOSIDASE	AARA	0.0324 mg
42	5-Bromo-4-chloro-3-indoxyl-alpha-galactoside	AGALi	0.006 mg
43	BETA-MANNOSIDASE	BMAN	0.036 mg
44	ARGININE GP	ARG	0.15 mg
45	PYRUVATE	PVATE	0.15 mg
51	MALTOTRIOSE	MTE	0.3 mg

Well	Test	Mnemonic	Amount/Well
53	ESCULIN hydrolysis	ESC	0.0225 mg
54	BETA-D-FUCOSIDASE	BdFUC	0.0342 mg
55	5-Bromo-4-chloro-3-indoxyl-beta- *N*-acetyl-glucosamide	BNAGi	0.006 mg
56	5-Bromo-4-chloro-3-indoxyl-alpha-mannoside	AMANi	0.006 mg
57	ALPHA-L-FUCOSIDASE	AlFUC	0.0342 mg
59	PHOSPHATASE	PHOS	0.05 mg
60	L-ARABINOSE	lARA	0.3 mg
61	d-Ribose 2	dRIB2	0.3 mg
62	Phenylphosphonate	OPS	0.024 mg
63	ALPHA-L-ARABINOFURANOSIDE	AARAF	0.015 mg
64	D-XYLOSE	dXYL	0.3 mg

Note: Other well numbers between 1 and 64 not designated in this table are empty.

PRECAUTIONS

Note: For industry customers that need assistance on selecting the correct VITEK® 2 identification card, please refer to the VITEK® 2 Compact Instrument User Manual chapter, "Guidance to Select a VITEK® 2 Identification Card."

- 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 the 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.
- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **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 drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)

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.[17,18]

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

STORAGE CONDITIONS

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

SPECIMEN PREPARATION

For specimen preparation information, see the Culture Requirements Table.

Culture Requirements

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
ANC	Corynebacteria: CBA[2] CNA TSAB TSAHB	Corynebacteria: 18 to 24 hours	Corynebacteria: 35°C to 37°C CO_2 or non-CO_2	2.70 to 3.30 McFarland Standard	N/A[3]	≤ 30 minutes
	Anaerobes: CBA[2] CDC[2] BRU CHBA TSAB TSAHB	Anaerobes: 18 to 72 hours	Anaerobes: 35°C to 37ºC anaerobic environment			
	Gram-Positive Anaerobes ONLY: CNA CDC PEA PEA					

[1]Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

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

[3]N/A = not applicable

Culture Requirements Table — Media Abbreviations

BRU = Brucella Agar with 5% Sheep Blood, Hemin, and Vitamin K

CBA = Columbia Blood Agar with 5% Sheep Blood

CDC = CDC Anaerobe Agar with 5% Sheep Blood

CDC PEA = CDC Blood Agar with PEA

CHBA = Columbia Horse Blood Agar

CNA = Columbia CNA Agar with 5% Sheep Blood

PEA = Phenylethyl Alcohol Agar with 5% Sheep Blood

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

TEST PROCEDURE

Materials

When used with VITEK® 2 instrumentation, the ANC card is a complete system for routine identification testing of most clinically significant anaerobic organisms and *Corynebacterium* species.

Required materials are:

- VITEK® 2 ANC Card
- VITEK® 2 DensiCHEK™ Plus Kit or VITEK® 2 DensiCHEK™ Kit
- DensiCHEK™ Plus Standards Kit or DensiCHEK™ Standards Kit
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (see Culture Requirements table).

Optional accessories:

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

Procedure

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

For product-specific information, see the Culture Requirements table.

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. Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous organism suspension with a density equivalent to a McFarland No. 2.70 to 3.30 using a calibrated VITEK® 2 DensiCHEK™ Plus or VITEK® 2 DensiCHEK™.
   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and ANC card in the cassette.
5. Refer to the appropriate Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.
6. In addition to the internal tests included on the card, three offline tests are required in the ANC ID algorithm. The offline tests selected for use in the ANC ID product are Gram stain, morphology, and aerotolerance. The ANC Offline Test results can be entered at the Smart Carrier Station (VITEK® 2 60 or VITEK® 2 XL only) or the workstation.

ANC Offline Tests

Test Name	Test	Result	Definition
AERO	Aerotolerance	–	Anaerobe
		+	Aerobe
		?	Facultative
GRAM	Gram stain results	–	Gram Negative
		+	Gram Positive
		?	Gram Variable

Test Name	Test	Result	Definition
MORPH	Morphology	–	Bacilli
		+	Cocci
		?	Coccobacilli

7. Follow your local inspecting agency's guidelines for disposal of hazardous waste.

RESULTS

Identification Analytical Techniques

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The species in the ANC Slashline Taxa table belong to the ANC slashline taxa.

ANC Slashline Taxa

Slashline Name	Species Belonging to the Slashline
Clostridium group	*Clostridium innocuum* *Clostridium limosum* *Clostridium novyi*

Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	N/A
Very Good	1	93 to 95	N/A
Good	1	89 to 92	N/A
Acceptable	1	85 to 88	N/A
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	Two to three taxa exhibit same biopattern. Separate by supplemental testing.
Inconclusive or Unidentified Organism	> 3 or 0	N/A	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

PERCENT PROBABILITY

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that

of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

ADDITIONAL INFORMATION ON LAB REPORT

Supplemental test — External (offline) test that allows the user to resolve a slashline or Low Discrimination identification. Numbers in parentheses indicate percent positive reaction for the species/test listed.

Contraindicating test — Test result that is unusual for a reported taxon.

Notes Associated with Certain Taxa

Taxa	Note
Actinomyces israelii	*Actinomyces israelii* represents a complex of two closely related species, *A. israelii* and *A. gerencseriae* (formerly known as *A. israelii serotype II*).
Corynebacterium diphtheriae	Critical pathogen. The species identified may have significance to patient or sample outcome and can be stopped for review.

Notes Associated with an Improperly Filled Card or with a Negative Profile (Biopattern)

- For the case where the time between two readings is greater than 40 minutes: “CARD ERROR — Missing data.”
- For the case where there is a negative profile: “Organism with low reactivity biopattern — please check viability.”
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be “Non or low reactive biopattern.”

The following non-reactive species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

- *Clostridium clostridioforme*
- *Fusobacterium nucleatum*
- *Fusobacterium mortiferum*

QUALITY CONTROL

Quality control organisms and their expected results are listed in the VITEK® 2 ANC Quality Control Tables. Process these according to the procedure for test isolates outlined in this document.

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 microbial identification systems.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency’s guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Instructions for Use results.

If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method and contact bioMérieux.

Testing and Storage of QC Organisms

1. Rehydrate the organism according to the manufacturer's instructions.
2. *Corynebacterium*: Use Columbia Blood agar with 5% sheep blood (CBA) and incubate at 35°C to 37°C in non-CO_2 aerobic conditions. Incubate for 18 to 24 hours or until sufficient growth is obtained.

3. Anaerobes: Use Columbia Blood agar with 5% sheep blood and incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours or until sufficient growth is obtained.
4. Check for purity. Perform second subculture for testing.
5. *Corynebacterium*: Use Columbia Blood agar with 5% sheep blood and incubate at 35°C to 37°C in non-CO_2 aerobic conditions. Incubate for 18 to 24 hours.
6. Anaerobes: Use Columbia Blood agar with 5% sheep blood and incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours.

Short-Term Storage Conditions - *Corynebacterium*

1. Streak to a CBA plate or slant.
2. Incubate at 35°C to 37°C in non-CO_2 aerobic conditions. Incubate for 18 to 24 hours.
3. Refrigerate at 2°C to 8°C for up to five days.
4. Subculture to CBA. Incubate at 35°C to 37°C in non-CO_2 aerobic conditions for 18 to 24 hours. Use for QC.

Short-Term Storage Conditions - Anaerobes

1. Streak to a CBA plate or slant.
2. Incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours or until sufficient growth is obtained.
3. Store at room temperature in anaerobic conditions for up to five days.
4. Subculture to CBA. Incubate at 35°C to 37°C in anaerobic conditions for 18 to 24 hours. 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 CBA 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.

STREAMLINED QUALITY CONTROL

Note: Industrial Use Only laboratories should perform quality control following the Streamlined Quality Control section. No additional testing is required for these users.

As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: one that is mostly positive and the other, which is mostly negative for reactions on ANC. (See ANC Quality Control tables for more details).

COMPREHENSIVE QUALITY CONTROL

Customers who do not qualify for streamlined quality control testing are required to perform comprehensive quality control testing, which entails demonstration of a positive and negative reaction for each substrate of an identification product.[4]

In order to qualify initially for streamlined quality control testing, the CLSI® M50-A standard requires that the user perform and document either of the following:[3]

- Verification testing to show that performance is equivalent to the manufacturer's claims.
- Comprehensive quality control testing of at least three lots over at least three different seasons.

Refer to the complete CLSI® M50-A standard for information regarding continued qualification and further details of requirements and responsibilities for both the user and the manufacturer related to streamlined quality control testing.

ANC Quality Control Tables:

***Clostridium septicum* ATCC® 12464™** (for streamlined or comprehensive quality control)

***Bacteroides ovatus* ATCC® BAA-1296™** (for streamlined or comprehensive quality control)

***Bacteroides vulgatus* ATCC® 8482™** (for comprehensive quality control)

***Clostridium perfringens* ATCC® 13124™** (for comprehensive quality control)

***Clostridium sordellii* ATCC® 9714™** (for comprehensive quality control)

***Corynebacterium striatum* ATCC® BAA-1293™** (for comprehensive quality control)

***Parabacteroides distasonis* ATCC® BAA-1295™** (for comprehensive quality control)

The ANC card typically identifies the quality control organisms as one-choice or within a low discrimination or slashline identification. However, strains are chosen for reaction performance over identification performance. Therefore, an unidentified or misidentified result may occur when all expected quality control reactions are correct.

QC Organism: *Clostridium septicum* ATCC® 12464™ (for streamlined or comprehensive quality control)

dGAL	-	dCEL	-	SAC	-	BGALi	+	MTE	-	PHOS	-	GRAM	+
LeuA	-	TyrA	-	ARB	-	AARA	v	ESC	-	IARA	-	MORPH	-
ELLM	-	APPA	-	NAG	-	AGALi	-	BdFUC	+	dRIB2	-	AERO	-
PheA	-	dGLU	-	BGLUi	-	BMAN	-	BNAGi	-	OPS	+		
ProA	-	dMNE	-	URE	-	ARG	-	AMANi	v	AARAF	-		
PyrA	v	dMAL	-	BGURi	-	PVATE	-	AIFUC	-	dXYL	-		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

QC Organism: *Bacteroides ovatus* ATCC® BAA-1296™ (for streamlined or comprehensive quality control)

dGAL	+	dCEL	+	SAC	v	BGALi	+	MTE	+	PHOS	v	GRAM	-
LeuA	-	TyrA	-	ARB	v	AARA	+	ESC	+	IARA	+	MORPH	-
ELLM	+	APPA	+	NAG	+	AGALi	+	BdFUC	v	dRIB2	+	AERO	-
PheA	-	dGLU	+	BGLUi	v	BMAN	v	BNAGi	-	OPS	v		
ProA	-	dMNE	+	URE	-	ARG	-	AMANi	v[1]	AARAF	+		
PyrA	-	dMAL	+	BGURi	v	PVATE	v	AIFUC	v	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

[1]Reaction is mostly positive although occasional negative reaction may occur.

QC Organism: *Bacteroides vulgatus* ATCC® 8482™ (for comprehensive quality control)

dGAL	v	dCEL	v	SAC	v	BGALi	v	MTE	v	PHOS	+	GRAM	–
LeuA	v	TyrA	v	ARB	v	AARA	+	ESC	v	IARA	v	MORPH	–
ELLM	+	APPA	+	NAG	v	AGALi	v	BdFUC	+	dRIB2	v	AERO	–
PheA	v	dGLU	v	BGLUi	v	BMAN	v[1]	BNAGi	v[1]	OPS	v		
ProA	v	dMNE	v	URE	v	ARG	v	AMANi	-	AARAF	+		
PyrA	v	dMAL	v	BGURi	v[1]	PVATE	v	AIFUC	+	dXYL	+		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

QC Organism: *Clostridium perfringens* ATCC® 13124™ (for comprehensive quality control)

dGAL	v	dCEL	v	SAC	+	BGALi	v	MTE	+	PHOS	+	GRAM	+
LeuA	v	TyrA	v	ARB	v	AARA	v	ESC	v	IARA	v	MORPH	–
ELLM	–	APPA	–	NAG	v	AGALi	+	BdFUC	v	dRIB2	+	AERO	–
PheA	v	dGLU	v	BGLUi	v	BMAN	v	BNAGi	v	OPS	+		
ProA	v	dMNE	v	URE	v	ARG	+	AMANi	v	AARAF	–		
PyrA	+	dMAL	+	BGURi	v	PVATE	–	AIFUC	v	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

QC Organism: *Clostridium sordellii* ATCC® 9714™ (for comprehensive quality control)

dGAL	–	dCEL	v	SAC	–	BGALi	–	MTE	v	PHOS	v	GRAM	+
LeuA	v	TyrA	v	ARB	v	AARA	–	ESC	–	IARA	v	MORPH	–
ELLM	v	APPA	v	NAG	v	AGALi	–	BdFUC	–	dRIB2	v	AERO	–
PheA	v	dGLU	v	BGLUi	–	BMAN	–	BNAGi	v	OPS	–		
ProA	+	dMNE	-	URE	+	ARG	v	AMANi	–	AARAF	v		
PyrA	v	dMAL	v	BGURi	v	PVATE	v	AIFUC	v	dXYL	–		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

QC Organism: *Corynebacterium striatum* ATCC® BAA-1293™ (for comprehensive quality control)

dGAL	+	dCEL	–	SAC	+	BGALi	–	MTE	–	PHOS	–	GRAM	+
LeuA	+	TyrA	+	ARB	–	AARA	v	ESC	v	IARA	–	MORPH	–
ELLM	v	APPA	v	NAG	–	AGALi	v	BdFUC	–	dRIB2	–	AERO	+
PheA	v	dGLU	+	BGLUi	v	BMAN	v	BNAGi	v	OPS	v		
ProA	+	dMNE	+	URE	v	ARG	v	AMANi	v	AARAF	v		
PyrA	–	dMAL	–	BGURi	v	PVATE	+	AIFUC	v	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

QC Organism: *Parabacteroides distasonis* ATCC® BAA-1295™ (for comprehensive quality control)

dGAL	v	dCEL	v	SAC	v	BGALi	v	MTE	v	PHOS	v	GRAM	–
LeuA	v	TyrA	v	ARB	+	AARA	v	ESC	+	IARA	v	MORPH	–
ELLM	v	APPA	v	NAG	+	AGALi	v	BdFUC	v	dRIB2	v	AERO	–
PheA	v[1]	dGLU	v	BGLUi	+	BMAN	v	BNAGi	v	OPS	v		
ProA	v	dMNE	v	URE	v	ARG	v	AMANi	v	AARAF	v		
PyrA	+	dMAL	v	BGURi	–	PVATE	v	AIFUC	–	dXYL	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1]Reaction is mostly positive although occasional negative reaction may occur.

LIMITATIONS

The VITEK® 2 ANC card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora.

Newly described or rare species may not be included in the ANC database. Selected species will be added as strains become available.

Warning: Testing of unclaimed species may result in an unidentified result or a misidentification.

PERFORMANCE CHARACTERISTICS

In a multi-site clinical study*, the performance of the VITEK® 2 ANC identification card was evaluated using 365 clinical and stock isolates of both commonly and rarely observed species. The reference identification was determined using 16S rRNA gene sequencing. Overall, the VITEK® 2 ANC correctly identified 94.0% of these isolates, including 9.0% low discrimination with the correct species listed. Misidentifications occurred at 5.8% and no identifications occurred at 0.3%.

*Data on file at bioMérieux, Inc.

ORGANISMS IDENTIFIED

- *Actinobaculum schaalii*
- *Actinomyces bovis*
- *Actinomyces israelii*
- *Actinomyces meyeri*
- *Actinomyces naeslundii*
- *Actinomyces neuii*

- *Actinomyces odontolyticus*
- *Actinomyces turicensis*
- *Anaerococcus prevotii*
- *Arcanobacterium haemolyticum*
- *Atopobium vaginae*
- *Bacteroides caccae*
- *Bacteroides eggerthii*
- *Bacteroides fragilis*
- *Bacteroides ovatus*
- *Bacteroides stercoris*
- *Bacteroides thetaiotaomicron*
- *Bacteroides uniformis*
- *Bacteroides vulgatus*
- *Bifidobacterium* spp.
- *Campylobacter ureolyticus* (formerly known as *Bacteroides ureolyticus*)
- *Clostridium baratii*
- *Clostridium bifermentans*
- *Clostridium butyricum*
- *Clostridium cadaveris*
- *Clostridium chauvoei*
- *Clostridium clostridioforme*
- *Clostridium difficile*
- *Clostridium glycolicum*
- *Clostridium* group
- *Clostridium histolyticum*
- *Clostridium paraputrificum*
- *Clostridium perfringens*
- *Clostridium ramosum*
- *Clostridium septicum*
- *Clostridium sordellii*
- *Clostridium sporogenes*
- *Clostridium subterminale*
- *Clostridium tertium*
- *Collinsella aerofaciens*
- *Corynebacterium amycolatum*
- *Corynebacterium diphtheriae*
- *Corynebacterium jeikeium*
- *Corynebacterium minutissimum*
- *Corynebacterium pseudodiphtheriticum*
- *Corynebacterium striatum*
- *Corynebacterium ulcerans*
- *Corynebacterium urealyticum*
- *Eggerthella lenta*
- *Eggerthia catenaformis* (formerly known as *Lactobacillus catenaformis*)
- *Eubacterium limosum*
- *Finegoldia magna*
- *Fusobacterium mortiferum*
- *Fusobacterium necrophorum*
- *Fusobacterium nucleatum*
- *Fusobacterium varium*
- *Lactobacillus acidophilus*
- *Lactobacillus buchneri*

- *Lactobacillus casei*
- *Lactobacillus fermentum*
- *Lactobacillus gasseri*
- *Lactobacillus hilgardii*
- *Lactobacillus parabuchneri*
- *Lactobacillus paracasei*
- *Lactobacillus plantarum*
- *Microbacterium flavescens*
- *Microbacterium* spp.
- *Parabacteroides distasonis*
- *Parabacteroides merdae*
- *Parvimonas micra*
- *Peptoniphilus asaccharolyticus*
- *Peptoniphilus indolicus*
- *Peptostreptococcus anaerobius*
- *Porphyromonas gingivalis*
- *Prevotella bivia*
- *Prevotella buccae*
- *Prevotella disiens*
- *Prevotella denticola*
- *Prevotella intermedia*
- *Prevotella melaninogenica*
- *Prevotella oralis*
- *Prevotella oris*
- *Propionibacterium acnes*
- *Propionibacterium granulosum*
- *Propionibacterium propionicum* (formerly known as *Propionibacterium propionicus*)
- *Staphylococcus saccharolyticus*
- *Trueperella pyogenes* (formerly known as *Arcanobacterium pyogenes*)
- *Turicella otitidis*
- *Veillonella* spp.

For 8.01 Software Users

- *Terrisporobacter glycolicus* (formerly known as *Clostridium glycolicum*)

SUPPLEMENTAL TESTS

ANC Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
AFUC	Alpha-Fucosidase	Presence of enzyme cleaves substrate generating detectable leaving group (e.g., p-nitrophenol, methyl umbelliferone, beta-naphthylamide, p-nitroaniline, 7-amino-methyl-coumarin).	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a non-colored product that forms color upon addition of a specific reagent.	16
BNAG	BETA-N-ACETYL-GLUCOSAMINIDASE	Presence of respective enzyme cleaves substrate generating detectable leaving group (e.g., p-nitrophenol, methyl umbelliferone, beta-naphthylamide, beta-naphthol, p-nitroaniline, 7-amidomethyl-coumarin).	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a noncolored product that forms color upon addition of a specific reagent.	16

Abbreviation	Test Name	Description	Comments	Reference
Branch.flt	BRANCHING FILAMENTS	Appearance of branching filaments on microscopic examination.	N/A	8, 9, 15
CAT	CATALASE	Colony placed on a drop of hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	N/A	7, 9, 15, 16
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin, which produces a black pigment in the presence of iron salts.	Some tests also appear on the ANC card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	5, 8, 9, 15, 16
GELATIN	Gelatin hydrolysis	Mediated by a gelatinase enzyme. A positive reaction is evidenced by liquefaction of the gelatin substrate.	N/A	7, 9, 15, 16
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlichs, DMAC reagents).	N/A	7, 15, 16
LECITHIN.	LECITHINASE	A precipitate surrounding the colony on egg yolk agar indicates lecithinase activity of alphatoxin produced by the organism.	N/A	7, 9, 16
LIP	LIPASE	An iridescent pearly sheen on the surface of the colony on egg yolk agar indicates lipase activity.	N/A	7, 9, 16
LIPOPHILY	LIPOPHILY	Lipophilic	Enhanced growth in the presence of lipids in the culture medium.	16
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.	N/A	7, 9, 15, 16
PAL	ALKALINE PHOSPHATASE	Presence of enzyme cleaves substrate generating detectable leaving group.	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a non-colored product that forms color upon addition of a specific reagent.	16
PIGMENT	Pigment	Ability of certain species to produce pigmented colonies on nondifferential media.	N/A	16
Point.ends	POINTED ENDS	Appearance of thin gram-negative rods with pointed ends is a microscopic characteristic for *Fuscobacterium nucleatum*.	N/A	9
PYRAZINAM.	PYRAZINAMIDASE	Test for the activity of the enzyme pyrazinamidase, which hydrolyses pyrazinamide to pyrazinoic acid.	N/A	16

Abbreviation	Test Name	Description	Comments	Reference
SPOR	SPORE	Microscopic examination for spores. Phase-contrast microscopy is recommended.	N/A	16
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	Some tests also appear on the ANC card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	7, 8, 9, 15, 16
lARABINOSE	L-ARABINOSE acidification	Anaerobe: PRAS* method *Corynebacterium*: acid from carbohydrate. Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple).	Some tests also appear on the ANC card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	7, 8, 9, 15, 16, 19
dCELLOB	DCELLOBIOSE acidification			
dFRUCTOSE	D-FRUCTOSE acidification			
dGALACTOSE	DGALACTOSE acidification			
dGLUCOSE	D-GLUCOSE acidification			
LACTOSE	Lactose acidification			
dMALTOSE	D-MALTOSE acidification			
dMANNITOL	D-MANNITOL acidification			
dMANNOSE	D-MANNOSE acidification			
dRAFFINOSE	dRAFFINOSE acidification			
lRHAMNOSE	L-RHAMNOSE acidification			
dRIBOSE	dRIBOSE acidification			
SACCHAROSE	SACCHAROSE/SUCROSE acidification			
SALICIN	SALICIN			
STARCHac	STARCH acidification			
dTREHALOSE	dTREHALOSE acidification			
XYL	XYLOSE			
XYLAN	XYLAN acidification			

*PRAS: Pre-reduced anaerobically sterilized media

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Use this Instructions for Use with VITEK® 2 Product No. 21347.

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
	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

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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
2016-10	043907-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual
2016-05	043907-01	Administrative	• Formatting changes do not affect the fit, form, or function of the product
		Technical change	• New IFU derived from product chapter in the Product Information Manual • Updated Limited Warranty section • Updated with RX only information

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