BIOMÉRIEUX

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VITEK® 2 GP

℞ only IVD

Intended Use

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

The VITEK® 2 Gram-Positive identification card (GP) is intended for use with VITEK® 2 Systems for the automated identification of most significant Gram-positive organisms. The VITEK® 2 GP identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

Description

The GP identification card is based on established biochemical methods[2,3,7,8,9,10,11,14,20,21,22,23,27,32,37,39] and newly developed substrates. There are 43 biochemical tests measuring carbon source utilization, enzymatic activities and resistance. Final identification results are available in approximately eight hours or less.

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

Table 1: GP Well Contents

Well	Test	Mnemonic	Amount/Well
2	D-AMYGDALIN	AMY	0.1875 mg
4	PHOSPHATIDYLINOSITOL PHOSPHOLIPASE C	PIPLC	0.015 mg
5	D-XYLOSE	dXYL	0.3 mg
8	ARGININE DIHYDROLASE 1	ADH1	0.111 mg
9	BETA-GALACTOSIDASE	BGAL	0.036 mg
11	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
13	Ala-Phe-Pro ARYLAMIDASE	APPA	0.0384 mg
14	CYCLODEXTRIN	CDEX	0.3 mg
15	L-Aspartate ARYLAMIDASE	AspA	0.024 mg
16	BETA GALACTOPYRANOSIDASE	BGAR	0.00204 mg
17	ALPHA-MANNOSIDASE	AMAN	0.036 mg
19	PHOSPHATASE	PHOS	0.0504 mg
20	Leucine ARYLAMIDASE	LeuA	0.0234 mg
23	L-Proline ARYLAMIDASE	ProA	0.0234 mg
24	BETA GLUCURONIDASE	BGURr	0.0018 mg
25	ALPHA-GALACTOSIDASE	AGAL	0.036 mg
26	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
27	BETA-GLUCURONIDASE	BGUR	0.0378 mg
28	Alanine ARYLAMIDASE	AlaA	0.0216 mg
29	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg

Well	Test	Mnemonic	Amount/Well
30	D-SORBITOL	dSOR	0.1875 mg
31	UREASE	URE	0.15 mg
32	POLYMIXIN B RESISTANCE	POLYB	0.00093 mg
37	D-GALACTOSE	dGAL	0.3 mg
38	D-RIBOSE	dRIB	0.3 mg
39	L-LACTATE alkalinization	ILATk	0.15 mg
42	LACTOSE	LAC	0.96 mg
44	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
45	D-MALTOSE	dMAL	0.3 mg
46	BACITRACIN RESISTANCE	BACI	0.0006 mg
47	NOVOBIOCIN RESISTANCE	NOVO	0.000075 mg
50	GROWTH IN 6.5% NaCl	NC6.5	1.68 mg
52	D-MANNITOL	dMAN	0.1875 mg
53	D-MANNOSE	dMNE	0.3 mg
54	METHYL-B-D-GLUCOPYRANOSIDE	MBdG	0.3 mg
56	PULLULAN	PUL	0.3 mg
57	D-RAFFINOSE	dRAF	0.3 mg
58	O/129 RESISTANCE (comp.vibrio.)	O129R	0.0084 mg
59	SALICIN	SAL	0.3 mg
60	SACCHAROSE/SUCROSE	SAC	0.3 mg
62	D-TREHALOSE	dTRE	0.3 mg
63	ARGININE DIHYDROLASE 2	ADH2s	0.27 mg
64	OPTOCHIN RESISTANCE	OPTO	0.000399 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.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

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.[30,35]

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

Storage Conditions

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

Specimen Preparation

For specimen preparation information, see the Culture Requirements Table.

Table 2: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
GP	TSAB[2,3] CBA[2,3] TSA[2,3] BP CHBA CHOC CHOC PVX CNT CPS ID MRSA ID MSA SAID TSAHB TSAL VRE	12 to 48 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non CO_2	0.50 to 0.63 McFarland Standard	N/A[4]	≤30 minutes

VITEK® 2 Card	Media	Age of Culture[1]	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
GP and AST GP pair	TSAB CBA CPS ID	18 to 24 hours	35°C to 37°C 5% to 10% CO_2 or aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	280 µL in 3.0 mL saline	< 30 minutes
GP and AST ST pair	TSAB CBA	18 to 24 hours	35°C to 37°C 5% to 10% CO_2	0.50 to 0.63 McFarland Standard	280 µL in 3.0 mL saline	< 30 minutes

[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]OMA Official Methods of Analysis validated medium.

[4]N/A = not applicable

Culture Requirements Table — Media Abbreviations

BP = Baird Parker

CBA = Columbia Blood Agar with 5% Sheep Blood

CHBA = Columbia Horse Blood Agar

CHOC = Chocolate Agar

CHOC PVX = Chocolate Polyvitex

CNT = Count-TACT® (irradiated) Trypticase Soy Agar

CPS ID = chromID™ CPS (CPS ID agar)

MRSA ID = chromID™ (MRSA ID Agar)

MSA = Mannitol Salt Agar

SAID = chromID™ S. aureus (S. aureus ID Agar)

TSA = Trypticase Soy Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

TSAL = TSA with Lecithin and P80

VRE = chromID™ VRE

Test Procedure

Materials

When used with VITEK® 2 instrumentation, the GP card is a complete system for routine identification testing of most clinically significant Gram-positive organisms.

Required materials are:

- VITEK® 2 GP Card
- DENSICHEK™ Plus Kit or VITEK® 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. To enhance and support good laboratory practices, bioMérieux recommends creating a purity plate using the transfer tube/card straw after the card has been filled in the VITEK® 2 system. Please note that underlying growth or other colony types on a purity plate may not be easily visible.

Note: Please refer to the user manual for your specific brand of dispensette to ensure the maintenance instructions are followed. The only recommended cleaning procedure for dispensettes is via autoclave. The use of chemicals or cleaning agents (like bleach or soap) can negatively impact the functionality of the dispensette as well as results. bioMérieux recommends autoclaving on a routine basis, at a minimum when a new bottle of saline is started.

Note: To enhance and support good laboratory practices, bioMérieux recommends to check for low-level saline contamination on a routine basis, by dispensing 1 mL of saline into a tubed broth media (ie. Tryptic Soy Broth, BHI, Thioglycolate, etc) and incubate at 35-37°C for 2-3 days. Check every day for growth. If the above process is not possible, discard the open bottle of saline and use a new bottle. Autoclaving the dispensette is necessary when starting a new bottle of saline and should be performed on a routine basis. Undetected contamination of the saline can lead to the reporting of inappropriate results.

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. 0.50 to 0.63 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 GP 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. 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 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 GP Slashline Taxa table belong to the GP slashline taxa.

Table 3: GP Slashline Taxa

Slashline Name	Species Belonging to the Slashline
For 7.01 Software Users	
Micrococcus luteus/lylae	*Micrococcus luteus* *Micrococcus lylae*
For 7.01 or Higher Software Users	
Dermacoccus nishinomiyaensis/ *Kytococcus sedentarius*	*Dermacoccus nishinomiyaensis* *Kytococcus sedentarius*
Listeria ivanovii	*Listeria ivanovii* ssp. *ivanovii* *Listeria ivanovii* ssp. *londoniensis*
Streptococcus mitis/ *Streptococcus oralis*	*Streptococcus mitis* *Streptococcus oralis*

Table 4: 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.

Table 5: Notes Associated with Certain Taxa

Taxa	Note
For 7.01 or Higher Software Users	
Enterococcus durans	Possibility of *Enterococcus villorum* if veterinary.
Listeria monocytogenes	Critical pathogen, check CAMP test and beta hemolysis. The species identified may have significance to patient or sample outcome and can be stopped for review.
Staphylococcus warneri	Possibility of *Staphylococcus pasteuri* if yellow pigmented.
For 8.01 or Higher Software Users	
Listeria innocua	Possibility of *Listeria monocytogenes*. Check for beta hemolysis. *Listeria innocua* strains are non-hemolytic.

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:

- *Alloiococcus otitis*
- *Dermacoccus nishinomiyaensis*
- *Gemella bergeri*
- *Kocuria rosea*
- *Kocuria varians*
- *Kytococcus sedentarius*
- *Leuconostoc mesenteroides* ssp. *cremoris*
- *Micrococcus lylae*
- *Staphylococcus auricularis*
- *Streptococcus pluranimalium*

Quality Control

Quality control organisms and their expected results are listed in the VITEK® 2 GP 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. Use Trypticase Soy with 5% sheep blood agar (TSAB) and incubate at 35°C to 37°C in 5% to 10% CO_2 for approximately 18 to 24 hours.
3. Check for purity. Perform second subculture for testing.
4. Use Trypticase Soy with 5% sheep blood agar (TSAB) and incubate at 35°C to 37°C in 5% to 10% CO_2 for approximately 18 to 24 hours.

Short-Term Storage Conditions

1. Subculture to a TSAB plate or slant.
2. Incubate for 24 hours at 35°C to 37°C in 5% to 10% CO_2.
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 TSAB 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 GP. (See GP 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.[6]

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:[5]

- 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.

GP Quality Control Tables:

***Enterococcus casseliflavus* ATCC® 700327™** (for streamlined or comprehensive quality control)

***Streptococcus salivarius* ssp. *thermophilus* ATCC® 19258™** (for comprehensive quality control)

For 7.01, 8.01, 9.01, 9.02, and 9.03 Software Users

***Kocuria kristinae* ATCC® BAA-752™** (for comprehensive quality control)

For 9.04 Software Users

Rothia kristinae (formerly known as ***Kocuria kristinae***) **ATCC® BAA-752™**

***Listeria monocytogenes* ATCC® BAA-751™** (for comprehensive quality control)

***Streptococcus pneumoniae* ATCC® 49619™** (for comprehensive quality control)

***Staphylococcus saprophyticus* ATCC® BAA-750™** (for streamlined or comprehensive quality control)

***Staphylococcus sciuri* ATCC® 29061™** (for comprehensive quality control)

***Streptococcus equi* ssp. *zooepidemicus* ATCC® 43079™** (for comprehensive quality control)

***Enterococcus saccharolyticus* ATCC® 43076™** (for comprehensive quality control)

***Staphylococcus aureus* ATCC® 29213™** (for comprehensive quality control)*

**Staphylococcus aureus* ATCC® 29213™ is available in the QC software with the 9.04 and higher software.

The GP 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.

Table 6: QC Organism: *Enterococcus casseliflavus* ATCC® 700327™ (for streamlined or comprehensive quality control)

AMY	+	CDEX	-	BGURr	-	URE	-	dMAL	+	PUL	-
PIPLC	-	AspA	v[1]	AGAL	+	POLYB	+	BACI	+	dRAF	+
dXYL	+	BGAR	+	PyrA	+	dGAL	+	NOVO	+	O129R	+
ADH1	v[2]	AMAN	v	BGUR	-	dRIB	+	NC6.5	+	SAL	+
BGAL	+	PHOS	-	AlaA	v	ILATk	-	dMAN	+	SAC	+
AGLU	v	LeuA	v	TyrA	+	LAC	+	dMNE	+	dTRE	+
APPA	v	ProA	-	dSOR	v	NAG	+	MBdG	+	ADH2s	v
										OPTO	+

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

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

[2]Reaction updated to variable but will not appear in QC software until 9.02.

Table 7: QC Organism: *Streptococcus salivarius* ssp. *thermophilus* ATCC® 19258™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	-	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	v	AlaA	v	ILATk	v	dMAN	v	SAC	v
AGLU	-	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	v	NAG	-	MBdG	v	ADH2s	v
										OPTO	v

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

Table 8: QC Organism: *Kocuria kristinae ATCC® BAA-752™ (for comprehensive quality control)**

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	–	AGAL	–	POLYB	v	BACI	–	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	–	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	–	PHOS	v	AlaA	v	ILATk	v	dMAN	v	SAC	v
AGLU	+	LeuA	+	TyrA	v	LAC	–	dMNE	v	dTRE	v
APPA	–	ProA	+	dSOR	v	NAG	v	MBdG	v	ADH2s	v
										OPTO	v

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

*For 7.01, 8.01, 9.01, 9.02, and 9.03 software users, *Kocuria kristinae*.

*For 9.04 software users, *Rothia kristinae*, formerly known as *Kocuria kristinae*.

Table 9: QC Organism: *Listeria monocytogenes* ATCC® BAA-751™ (for comprehensive quality control)

AMY	+	CDEX	+	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	+	AspA	v	AGAL	v	POLYB	+	BACI	v	dRAF	–
dXYL	v	BGAR	–	PyrA	v	dGAL	–	NOVO	v	O129R	v
ADH1	–	AMAN	+	BGUR	v	dRIB	v	NC6.5	+	SAL	v
BGAL	–	PHOS	v	AlaA	v	lLATk	v	dMAN	–	SAC	–
AGLU	+	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	v	NAG	+	MBdG	v	ADH2s	v
										OPTO	v

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

Table 10: QC Organism: *Streptococcus pneumoniae* ATCC® 49619™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	–	dRAF	v[1]
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	–
ADH1	v	AMAN	–	BGUR	v	dRIB	–	NC6.5	–	SAL	v[1]
BGAL	v	PHOS	v	AlaA	+	ILATk	v	dMAN	v	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v[1]	ProA	v	dSOR	v	NAG	v	MBdG	v	ADH2s	v
										OPTO	–

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

[1]Reaction updated to variable but will not appear in QC software until 9.02

Table 11: QC Organism: *Staphylococcus saprophyticus* ATCC® BAA-750™ (for streamlined or comprehensive quality control)

AMY	-	CDEX	-	BGURr	-	URE	+	dMAL	+	PUL	-
PIPLC	-	AspA	-	AGAL	-	POLYB	-	BACI	v	dRAF	-
dXYL	-	BGAR	-	PyrA	v	dGAL	v	NOVO	+	O129R	v
ADH1	v	AMAN	-	BGUR	-	dRIB	v	NC6.5	+	SAL	-
BGAL	+	PHOS	v	AlaA	-	ILATk	v	dMAN	+	SAC	+
AGLU	v	LeuA	-	TyrA	-	LAC	+	dMNE	v[1]	dTRE	+
APPA	v	ProA	-	dSOR	-	NAG	v	MBdG	-	ADH2s	-
										OPTO	+

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

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

Table 12: QC Organism: *Staphylococcus sciuri* ATCC® 29061™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	+	URE	–	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	–	BACI	v	dRAF	–
dXYL	–	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	v
ADH1	+	AMAN	v	BGUR	+	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	+	AlaA	–	lLATk	v	dMAN	v	SAC	v
AGLU	v	LeuA	–	TyrA	–	LAC	–	dMNE	v	dTRE	+
APPA	–	ProA	v	dSOR	v	NAG	v	MBdG	+	ADH2s	–
										OPTO	v

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

Table 13: QC Organism: *Streptococcus equi* ssp. *zooepidemicus* ATCC® 43079™ (for comprehensive quality control)

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v[1]
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	+	NOVO	v	O129R	v
ADH1	+[2]	AMAN	v	BGUR	v	dRIB	v[3]	NC6.5	v	SAL	v
BGAL	v	PHOS	+	AlaA	v	lLATk	v	dMAN	v	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	–
APPA	+[2]	ProA	v	dSOR	v	NAG	v	MBdG	v	ADH2s	+
										OPTO	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.

[2]Reaction updated to positive but will not appear in QC software until 9.02.

[3]Reaction updated to variable but will not appear in QC software until 9.02.

Table 14: QC Organism: *Enterococcus saccharolyticus* ATCC® 43076™ (for comprehensive quality control)

AMY	v	CDEX	+	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	+	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	–	dGAL	v	NOVO	v	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	v	AlaA	v	lLATk	v	dMAN	+	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	+	NAG	v	MBdG	v	ADH2s	v
										OPTO	v

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

Table 15: QC Organism: *Staphylococcus aureus ATCC® 29213™ (for comprehensive quality control)**

AMY	v	CDEX	v	BGURr	v	URE	v	dMAL	v	PUL	v
PIPLC	v	AspA	v	AGAL	v	POLYB	v	BACI	v	dRAF	v
dXYL	v	BGAR	v	PyrA	v	dGAL	v	NOVO	v	O129R	v
ADH1	v	AMAN	v	BGUR	v	dRIB	v	NC6.5	v	SAL	v
BGAL	v	PHOS	v	AlaA	v	lLATk	+	dMAN	v	SAC	v
AGLU	v	LeuA	v	TyrA	v	LAC	v	dMNE	v	dTRE	v
APPA	v	ProA	v	dSOR	v	NAG	v	MBdG	v	ADH2s	v
										OPTO	v

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

**Staphylococcus aureus* ATCC® 29213™ is available in the QC software with the 9.04 and higher software.

Limitations

The VITEK® 2 GP 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.

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

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

For 7.01 Software Users and Higher

Granulicatella elegans is not capable of growth using GP culture requirements and is no longer a claimed species. This species will be removed from the GP knowledge base in a future software update. Use an alternate method to identify this species.

Performance Characteristics

For 7.01, 8.01, and 9.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 GP identification card was evaluated using 457 clinical and stock isolates of both commonly and rarely observed species of gram-positive cocci. The reference identification was determined with API® STAPH and API® 20 STREP identification kits. Overall, the VITEK® 2 GP correctly identified 96.1% of the isolates, including 3.9% low discrimination with the correct species listed. Misidentifications occurred at 3.5% and no identifications occurred at 0.4%.

For 9.02 Software Users or Higher

In a multi-site clinical study*, the performance of the VITEK® 2 GP identification card was evaluated using 457 clinical and stock isolates of both commonly and rarely observed species of gram-positive cocci. The reference identification was determined with API® STAPH and API® 20 STREP identification kits. Overall, the VITEK® 2 GP correctly identified 95.8% of the isolates, including 3.5% low discrimination with the correct species listed. Misidentifications occurred at 3.5% and no identifications occurred at 0.7%.

*Data on file at bioMérieux, Inc.

Organisms Identified

Claims are for all software users unless otherwise stated.

- *Abiotrophia defectiva*
- *Aerococcus urinae*
- *Aerococcus viridans*
- *Alloiococcus otitis*
- *Dermacoccus nishinomiyaensis/Kytococcus sedentarius*
- *Enterococcus avium*
- *Enterococcus casseliflavus*
- *Enterococcus cecorum*
- *Enterococcus columbae*
- *Enterococcus durans*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Enterococcus gallinarum*
- *Enterococcus hirae*
- *Enterococcus raffinosus*
- *Enterococcus saccharolyticus*
- *Erysipelothrix rhusiopahiae*
- *Facklamia hominis*
- *Gardnerella vaginalis*
- *Gemella bergeri*
- *Gemella haemolysans*
- *Gemella morbillorum*
- *Gemella sanguinis*
- *Globicatella sanguinis*
- *Globicatella sulfidifaciens*

- *Granulicatella adiacens*
- *Granulicatella elegans* - See Limitations
- *Helcococcus kunzii*
- *Kocuria kristinae*
- *Kocuria rhizophila*
- *Kocuria rosea*
- *Kocuria varians*
- *Lactococcus garvieae*
- *Lactococcus lactis* ssp. *cremoris*
- *Lactococcus lactis* ssp. *lactis*
- *Lactococcus raffinolactis*
- *Leuconostoc citreum*
- *Leuconostoc lactis*
- *Leuconostoc mesenteroides* ssp. *cremoris*
- *Leuconostoc mesenteroides* ssp. *dextranicum*
- *Leuconostoc mesenteroides* ssp. *mesenteroides*
- *Leuconostoc pseudomesenteroides*
- *Listeria grayi*+
- *Listeria innocua*+
- *Listeria ivanovii*+
- *Listeria monocytogenes*+
- *Listeria seeligeri*+
- *Listeria welshimeri*+
- *Micrococcus luteus*
- *Micrococcus lylae*
- *Pediococcus acidilactici*
- *Pediococcus pentosaceus*
- *Rothia dentocariosa*
- *Rothia mucilaginosa*
- *Staphylococcus arlettae*
- *Staphylococcus aureus* *+
- *Staphylococcus auricularis*
- *Staphylococcus capitis*
- *Staphylococcus caprae*
- *Staphylococcus carnosus* ssp. *carnosus*
- *Staphylococcus chromogenes*
- *Staphylococcus cohnii* ssp. *cohnii*
- *Staphylococcus cohnii* ssp. *urealyticus*
- *Staphylococcus epidermidis*+
- *Staphylococcus equorum*
- *Staphylococcus gallinarum*
- *Staphylococcus haemolyticus*
- *Staphylococcus hominis* ssp. *hominis*
- *Staphylococcus hominis* ssp. *novobiosepticus*
- *Staphylococcus hyicus*+
- *Staphylococcus intermedius*+
- *Staphylococcus kloosii*
- *Staphylococcus lentus*
- *Staphylococcus lugdunensis*
- *Staphylococcus pseudintermedius*
- *Staphylococcus saprophyticus*

- *Staphylococcus schleiferi*
- *Staphylococcus sciuri*
- *Staphylococcus simulans*
- *Staphylococcus vitulinus*
- *Staphylococcus warneri*
- *Staphylococcus xylosus*
- *Streptococcus agalactiae*
- *Streptococcus alactolyticus*
- *Streptococcus anginosus*
- *Streptococcus canis*
- *Streptococcus constellatus* ssp. *constellatus*
- *Streptococcus constellatus* ssp. *pharyngis*
- *Streptococcus cristatus*
- *Streptococcus downei*
- *Streptococcus dysgalactiae* ssp. *dysgalactiae*
- *Streptococcus dysgalactiae* ssp. *equisimilis*
- *Streptococcus equi* ssp. *equi*
- *Streptococcus equi* ssp. *zooepidemicus*
- *Streptococcus equinus*
- *Streptococcus gallolyticus* ssp. *gallolyticus*
- *Streptococcus gallolyticus* ssp. *pasteurianus*
- *Streptococcus gordonii*
- *Streptococcus hyointestinalis*
- *Streptococcus infantarius* ssp. *coli* (formerly known as *Streptococcus lutetiensis*)
- *Streptococcus infantarius* ssp. *infantarius*
- *Streptococcus intermedius*
- *Streptococcus mitis/Streptococcus oralis*
- *Streptococcus mutans*
- *Streptococcus ovis*
- *Streptococcus parasanguinis*
- *Streptococcus pluranimalium*
- *Streptococcus pneumoniae*
- *Streptococcus porcinus*
- *Streptococcus pseudoporcinus*
- *Streptococcus pyogenes*
- *Streptococcus salivarius* ssp. *salivarius*
- *Streptococcus salivarius* ssp. *thermophilus*
- *Streptococcus sanguinis*
- *Streptococcus sobrinus*
- *Streptococcus suis* I
- *Streptococcus suis* II
- *Streptococcus thoraltensis*
- *Streptococcus uberis*
- *Streptococcus vestibularis*
- *Vagococcus fluvialis*

Additional Claims For 8.01 or Higher Software Users

- *Listeria fleischmannii*
- *Listeria rocourtiae*
- *Streptococcus iniae*

Taxonomy Changes For 9.02 Software Users or Higher

- *Streptococcus suis* (formerly *Streptococcus suis* I and II)

Additional Claims and Taxonomy Changes For 9.04 Software Users

- *Aerococcus sanguinicola*
- *Staphylococcus felis*
- *Rothia kristinae* (formerly known as *Kocuria kristinae*)

**Staphylococcus aureus* claim contains only the subspecies *aureus.*

+ OMA Official Methods of Analysis validated claim.

Supplemental Tests

Table 16: GP Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
For 7.01 or Higher Software Users				
A-HEM	ALPHA HEMOLYSIS	Certain species produce incomplete hemolysis resulting in a green zone around colonies on blood based media.	N/A	21, 22, 23, 26, 27
	Acidification of:	Acidification of carbon source observed with pH indicators (e.g., phenol red, bromcresol purple).	Some tests also appear on the GP card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods.	2, 3, 4, 8, 10, 14, 16, 17, 21, 22, 23, 26 , 27, 28, 31, 32, 33, 34, 36, 40, 42, 43, 44
AMD/STARCH	AMIDON/STARCH			
GLYCOGENac	GLYCOGEN			
lARABINOSE	L-ARABINOSE acid.			
INULIN	INULIN			
MdG	METHYL-A-DGLUCOPYRANOSIDE			
MdM	METHYL-A-DMANNOPYRANOSIDE			
PULLULAN	PULLULAN			
SACCHAROSE	SACCHAROSE (SUCROSE)			
dGALACTOSE	D-GALACTOSE			
dMALTOSE	D-MALTOSE			
dMANNITOL	D-MANNITOL			
dMANNOSE	D-MANNOSE			
dMELEZIT	D-MELEZITOSE			
dMELIBIOSE	D-MELIBIOSE			
dRAFFINOSE	D-RAFFINOSE			
dRIBOSE	D-RIBOSE			
dSORBITOL	D-SORBITOL			
dTREHALOSE	D-TREHALOSE			
dXYLOSE	D-XYLOSE			
lRHAMNOSE	L-RHAMNOSE			
ANANE	ALPHA-D-N-ACETYLNEURAMINIDASE	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.	7, 11, 21, 22, 23, 27, 28, 29, 31, 34, 39
AIFUC	ALPHA-L-FUCOSIDASE			
BGLU	BETA-GLUCOSIDASE			
BGURase	BETA-GLUCURONIDASE			
BNAG	BETA-N-ACETYLGLUCOSAMINIDASE			
BNAGA	BETA-N-ACETYLGALACTOSAMINIDASE			
BdFUC	BETA-D-FUCOSIDASE			
PAL	ALKALINE PHOSPHATASE			
Pyrro. Ary.	Pyrrolidonyl ARYLAMIDASE			

Abbreviation	Test Name	Description	Comments	Reference
Adherence	Adherence to agar	Sticking of colonies to the agar surface	Characteristic of *Rothia mucilaginosa*	27
AER.GROWTH	AEROBIC GROWTH	Growth in air	N/A	22
Arg.hydr.	ARGININE dihydrolase	Hydrolysis of arginine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple).	N/A	2, 21, 22, 27, 36
B-HEM	BETA HEMOLYSIS	Certain species possess hemolysins that give a transparent zone around colonies on blood-based agars.	N/A	21, 22, 27, 37
BILE SOL	BILE SOLUBILITY	Pneumococcal colonies completely lyse and disappear when exposed to a 10% solution of deoxycholate.	Rapid test for *Streptococcus pneumoniae*	27
CAMP (S.au)	CAMP TEST (*Staph. aureus*)	Synergistic hemolysis of *Listeria monocytogenes* colonies by beta-toxin producing colonies of *Staphylococcus aureus*.	N/A	27
CAT	CATALASE	Colony placed on a drop of 3% hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	Differentiation of *Micrococcaceae* (+) from *Streptococcaceae* (–)	21, 22, 27, 38, 43, 44
CLINDA.S	Clindamycin susceptible	Zone of inhibition around the clindamycin disk > 20mm	Used to differentiate *Lactococcus lactis* and *Lactococcus garvieae.*	15
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin which produces a black pigment in the presence of iron salts.	N/A	3, 18, 21, 22, 24, 27
Gas prod.	Gas production	Production of CO_2 from degradation carbohydrate (e.g., glucose) metabolism.	N/A	27
HIP	HIPPURATE hydrolysis	Hydrolysis of sodium hippurate releases glycine that produces a blue colored product after addition of ninhydrin.	N/A	12, 21, 22, 26, 27
LAP	LEUCINE AMINOPEPTIDASE	The substrate leucine-beta-naphthylamide is hydrolyzed by the enzyme leucine aminopeptidase and released beta-naphthylamide combines with the cinnamaldehyde reagent to form a bright pink to cherry red pigment.	N/A	19, 45

Abbreviation	Test Name	Description	Comments	Reference
LitmusMILK	Litmus Milk Medium	Acid production in Litmus Milk	N/A	16
NaCl 6.5%	GROWTH IN 6.5% NaCl	Growth in 6.5% NaCl broth	N/A	16, 19
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.	N/A	21, 22, 38
NOVO_R OPTO_R VANCO_R	NOVOBIOCIN_RESISTANCE OPTOCHIN_RESISTANCE VANCOMYCIN_RESISTANCE	Ability of certain species to grow in the presence of specific antibacterial compounds	N/A	20, 21, 22, 27, 40, 41
NaCl 7.5%	GROWTH IN 7.5% NACL	Ability of certain species to grow in the presence of a high concentration of NaCl	N/A	22
PI/OR/RED	PINK/ORANGE/RED PIGMENT	Ability of certain species to produce pink, orange, or red colonies on nondifferential media	Characteristic of *Kocuria rosea*	22, 27, 28
PVATE	PYRUVATE	Ability to use pyruvate as a sole carbon source	N/A	28
SATELLITE	SATELLITE behavior	Appearance of satellite colonies of nutritionally deficient *Streptococcaceae* around colonies of *Staphylococcus epidermidis*.	Nutritionally deficient *Streptococcaceae* require nutritional factors supplied by metabolism of colonies of *Staphylococcus epidermidis*.	9, 27
Str.sero.A Str.sero.B Str.sero.C Str.sero.D Str.sero.G	Strepto Serology A Strepto Serology B Strepto Serology C Strepto Serology D Strepto Serology G	Agglutination tests for *Streptococcus* groups A,B,C,D, and G	N/A	1, 13, 18, 21, 22, 24, 27, 28, 36
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).	N/A	21, 22, 25, 27
VP	VOGES PROSKAUER	Ability of some species to produce acetoin from glucose fermentation.	N/A	20, 21, 27, 34
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on nondifferential media.	For example, used to differentiate *E. casseliflavus* (+) from *E. gallinarum* (–).	21, 22, 27, 28
For 7.01 Software Users Only				
BILE ESC	BILE ESCULIN	Bile-esculin positive organisms are able to grow in the presence of 40% bile and to hydrolyze esculin.	N/A	18, 24
CAROTENOID	CAROTENOID PIGMENT	Presence of red, pink, or orange pigment	N/A	28

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Use this Instructions for Use with VITEK® 2 Product No. 21342.

Index of Symbols

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

Instructions for use provided in the kit or downloadable from http://www.biomerieux.com.

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
2021-04	043900-04	Technical change	Updated for 9.04 software release Updated sections: • Test Procedure • Comprehensive Quality Control • Performance Characteristics • Organisms Identified • Supplemental Tests • References
2019-03	043900-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Additional Information on Lab Report • Testing of QC Organisms • Performance Characteristics • Organisms Identified • References
2016-10	043900-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual

Release Date	Part Number	Change Type	Change Summary
2016-05	043900-01	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

For users in the European Union (Regulation (EU) 2017/746) and in countries with similar requirements: Should a serious incident occur during the use of this device or as a result of its use, please report it to the manufacturer and/or their authorized representative as well as to your national authority.

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