

## VITEK® 2 GN



### 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-Negative identification card (GN) is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant fermenting and non-fermenting Gram-negative bacilli. The VITEK® 2 GN identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

### Description

The GN card is based on established biochemical methods<sup>1,2,4,8,9,10,11,12,17,18,20,21,24,25,27</sup> and newly developed substrates measuring carbon source utilization, enzymatic activities, and resistance. There are 47 biochemical tests and one negative control well. The Decarboxylase Negative Control Well (well 52) is used as a baseline reference for the Decarboxylase test wells. Final results are available in approximately 10 hours or less.

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

**Table 1: GN Well Contents**

| Well | Test                          | Mnemonic | Amount/Well |
|------|-------------------------------|----------|-------------|
| 2    | Ala-Phe-Pro-ARYLAMIDASE       | APPA     | 0.0384 mg   |
| 3    | ADONITOL                      | ADO      | 0.1875 mg   |
| 4    | L-Pyrrolydonyl-ARYLAMIDASE    | PyrA     | 0.018 mg    |
| 5    | L-ARABITOL                    | IARL     | 0.3 mg      |
| 7    | D-CELLOBIOSE                  | dCEL     | 0.3 mg      |
| 9    | BETA-GALACTOSIDASE            | BGAL     | 0.036 mg    |
| 10   | H2S PRODUCTION                | H2S      | 0.0024 mg   |
| 11   | BETA-N-ACETYL-GLUCOSAMINIDASE | BNAG     | 0.0408 mg   |
| 12   | Glutamyl Arylamidase pNA      | AGLtp    | 0.0324 mg   |
| 13   | D-GLUCOSE                     | dGLU     | 0.3 mg      |
| 14   | GAMMA-GLUTAMYL-TRANSFERASE    | GGT      | 0.0228 mg   |
| 15   | FERMENTATION/ GLUCOSE         | OFF      | 0.45 mg     |
| 17   | BETA-GLUCOSIDASE              | BGLU     | 0.036 mg    |
| 18   | D-MALTOSE                     | dMAL     | 0.3 mg      |
| 19   | D-MANNITOL                    | dMAN     | 0.1875 mg   |
| 20   | D-MANNOSE                     | dMNE     | 0.3 mg      |
| 21   | BETA-XYLOSIDASE               | BXYL     | 0.0324 mg   |
| 22   | BETA-Alanine arylamidase pNA  | BAlap    | 0.0174 mg   |
| 23   | L-Proline ARYLAMIDASE         | ProA     | 0.0234 mg   |

| Well | Test                            | Mnemonic | Amount/Well |
|------|---------------------------------|----------|-------------|
| 26   | LIPASE                          | LIP      | 0.0192 mg   |
| 27   | PALATINOSE                      | PLE      | 0.3 mg      |
| 29   | Tyrosine ARYLAMIDASE            | TyrA     | 0.0276 mg   |
| 31   | UREASE                          | URE      | 0.15 mg     |
| 32   | D-SORBITOL                      | dSOR     | 0.1875 mg   |
| 33   | SACCHAROSE/SUCROSE              | SAC      | 0.3 mg      |
| 34   | D-TAGATOSE                      | dTAG     | 0.3 mg      |
| 35   | D-TREHALOSE                     | dTRE     | 0.3 mg      |
| 36   | CITRATE (SODIUM)                | CIT      | 0.054 mg    |
| 37   | MALONATE                        | MNT      | 0.15 mg     |
| 39   | 5-KETO-D-GLUCONATE              | 5KG      | 0.3 mg      |
| 40   | L-LACTATE alkalization          | ILATk    | 0.15 mg     |
| 41   | ALPHA-GLUCOSIDASE               | AGLU     | 0.036 mg    |
| 42   | SUCCINATE alkalization          | SUCT     | 0.15 mg     |
| 43   | Beta-N-ACETYL-GALACTOSAMINIDASE | NAGA     | 0.0306 mg   |
| 44   | ALPHA-GALACTOSIDASE             | AGAL     | 0.036 mg    |
| 45   | PHOSPHATASE                     | PHOS     | 0.0504 mg   |
| 46   | Glycine ARYLAMIDASE             | GlyA     | 0.012 mg    |
| 47   | ORNITHINE DECARBOXYLASE         | ODC      | 0.3 mg      |
| 48   | LYSINE DECARBOXYLASE            | LDC      | 0.15 mg     |
| 52   | DECARBOXYLASE BASE              | 0DEC     | N/A         |
| 53   | L-HISTIDINE assimilation        | IHISa    | 0.087 mg    |
| 56   | COUMARATE                       | CMT      | 0.126 mg    |
| 57   | BETA-GLUCURONIDASE              | BGUR     | 0.0378 mg   |
| 58   | O/129 RESISTANCE (comp.vibrio.) | O129R    | 0.0105 mg   |
| 59   | Glu-Gly-Arg-ARYLAMIDASE         | GGAA     | 0.0576 mg   |
| 61   | L-MALATE assimilation           | IMLTa    | 0.042 mg    |
| 62   | ELLMAN                          | ELLM     | 0.03 mg     |
| 64   | L-LACTATE assimilation          | ILATa    | 0.186 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 antimicrobial 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.<sup>23,26</sup> It is suggested that highly pathogenic species such as *Brucella melitensis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Escherichia coli* O157, *Francisella tularensis*, and *Yersinia pestis* be sent to your state health laboratory or other suitable reference laboratory for confirmation.**

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

## Storage Conditions

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

## Specimen Preparation

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For specimen preparation information, see the Culture Requirements Table.

**Table 2: Culture Requirements Table**

| VITEK® 2 Card         | Media   | Age of Culture <sup>1</sup> | Incubation Conditions                        | McFarland Standards                   | Dilution for AST           | Age of Suspension Before Loading Instrument |
|-----------------------|---|-----------------------------|--|---------------------------------------|----------------------------|---|
| GN                    | TSA <sup>2,3</sup><br>CBA <sup>2,3</sup><br>MAC <sup>2,3</sup><br>BCP<br>CET<br>CLED<br>CHOC<br>CHOC PVX<br>CHBA<br>CNT<br>CPS ID<br>DENA<br>DRIG<br>HEK<br>SM ID<br>TSAHB<br>TSAB<br>TSAL<br>VRBG<br>XLD | 18 to 24 hours              | 35°C to 37°C<br>Aerobic, non-CO <sub>2</sub> | 0.50 to 0.63<br>McFarland<br>Standard | N/A <sup>4</sup>           | ≤ 30 minutes                                |
| GN and AST<br>GN pair | CBA<br>MAC<br>TSAB<br>CPS ID  | 18 to 24 hours              | 35°C to 37°C<br>Aerobic, non-CO <sub>2</sub> | 0.50 to 0.63<br>McFarland<br>Standard | 145 µL in 3.0<br>mL saline | < 30 minutes                                |

<sup>1</sup>Cultures with scant or poor growth may give unidentified or incorrect results even when the Age of Culture requirements are met.

<sup>2</sup>These media were used in the identification product database development and will give optimal performance.

<sup>3</sup>OMA Official Methods of Analysis validated medium.

<sup>4</sup>N/A = not applicable

#### **Culture Requirements Table — Media Abbreviations**

BCP = Bromcresol Purple Agar

CBA = Columbia Blood Agar with 5% Sheep Blood

CET = Cetrimide Agar

CHBA = Columbia Horse Blood Agar

CHOC = Chocolate Agar

CHOC PVX = Chocolate Polyvitex  
CLED = Cystine Lactose Electrolyte Deficient Agar  
CNT = Count-TACT® (irradiated) Trypticase Soy Agar  
CPS ID = chromID™ CPS (CPS ID agar)  
DENA = DE Neutralizing Agar  
DRIG = Drigalski Agar  
HEK = Hektoen Agar  
MAC = MacConkey Agar  
SM ID = chromID™ Salmonella (SM ID2 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  
VRBG = Violet Red Bile Glucose Agar  
XLD = Xylose Lysine Desoxycholate

## Test Procedure

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### Materials

When used with VITEK® 2 instrumentation, the GN card is a complete system for routine identification testing of most significant fermenting and non-fermenting Gram-negative bacilli.

Required materials are:

- VITEK® 2 GN 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 GN 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 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 GN Slashline Taxa table belong to the GN slashline taxa.

**Table 3: GN Slashline Taxa**

| Slashline Name                            | Species Belonging to the Slashline  |
|---|---|
| <b>For 7.01 or Higher Software Users</b>  |   |
| <i>Acinetobacter baumannii</i> complex    | <i>Acinetobacter baumannii</i><br><i>Acinetobacter calcoaceticus</i><br><i>Acinetobacter pittii</i> ( <i>Acinetobacter</i> genomospecies 3)<br><i>Acinetobacter nosocomialis</i> ( <i>Acinetobacter</i> genomospecies TU13) |
| <i>Brevundimonas diminuta/vesicularis</i> | <i>Brevundimonas diminuta</i><br><i>Brevundimonas vesicularis</i>   |

| Slashline Name                                 | Species Belonging to the Slashline  |
|--|---|
| <i>Burkholderia cepacia</i> group              | <i>Burkholderia cepacia</i><br><i>Burkholderia multivorans</i><br><i>Burkholderia stabilis</i><br><i>Burkholderia vietnamiensis</i>   |
| <i>Enterobacter cloacae</i> complex            | <i>Enterobacter cloacae</i> ssp. <i>cloacae</i><br><i>Enterobacter hormaechei</i><br><i>Enterobacter kobei</i><br><i>Enterobacter ludwigii</i><br><i>Enterobacter cloacae</i> ssp. <i>dissolvens</i>                              |
| <i>Moraxella</i> group                         | <i>Moraxella lacunata</i><br><i>Moraxella nonliquefaciens</i><br><i>Moraxella osloensis</i>   |
| <i>Neisseria animaloris/zoodegmatidis</i>      | <i>Neisseria animaloris</i><br><i>Neisseria zoodegmatidis</i>   |
| <i>Salmonella</i> group                        | <i>Salmonella enterica</i> ssp. <i>enterica</i><br><i>Salmonella</i> ser. Enteritidis<br><i>Salmonella</i> ser. Paratyphi B<br><i>Salmonella</i> ser. Paratyphi C<br><i>Salmonella</i> spp.<br><i>Salmonella</i> ser. Typhimurium |
| <i>Serratia liquefaciens</i> group             | <i>Serratia grimesii</i><br><i>Serratia liquefaciens</i><br><i>Serratia proteamaculans</i>  |
| <i>Shigella</i> group                          | <i>Shigella boydii</i><br><i>Shigella dysenteriae</i><br><i>Shigella flexneri</i>   |
| <i>Yersinia enterocolitica/frederiksenii</i>   | <i>Yersinia enterocolitica</i><br><i>Yersinia frederiksenii</i>   |
| <b>For 7.01, 8.01, and 9.01 Software Users</b> |   |
| <i>Aeromonas hydrophila/caviae</i>             | <i>Aeromonas caviae</i><br><i>Aeromonas hydrophila</i>  |

| Slashline Name                                | Species Belonging to the Slashline  |
|---|---|
| <i>Cronobacter sakazakii</i> group            | <i>Cronobacter genomospecies 1</i><br><i>Cronobacter dublinensis</i> ssp. <i>dublinensis</i><br><i>Cronobacter dublinensis</i> ssp. <i>lausannensis</i><br><i>Cronobacter dublinensis</i> ssp. <i>lactaridi</i><br><i>Cronobacter malonaticus</i><br><i>Cronobacter sakazakii</i><br><i>Cronobacter turicensis</i><br><i>Cronobacter muytjensii</i> |
| <b>For 9.02 and Higher Software Users</b>     |   |
| <i>Aeromonas hydrophila/punctata (caviae)</i> | <i>Aeromonas punctata (caviae)</i><br><i>Aeromonas hydrophila</i>   |
| <i>Cronobacter sakazakii</i> group            | <i>Cronobacter universalis</i><br><i>Cronobacter dublinensis</i> ssp. <i>dublinensis</i><br><i>Cronobacter dublinensis</i> ssp. <i>lausannensis</i><br><i>Cronobacter dublinensis</i> ssp. <i>lactaridi</i><br><i>Cronobacter malonaticus</i><br><i>Cronobacter sakazakii</i><br><i>Cronobacter turicensis</i><br><i>Cronobacter muytjensii</i>     |

**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.<br>Separate by supplemental testing. Must resolve to mate with susceptibility card.                            |
| Inconclusive<br>or<br>Unidentified Organism | >3<br>or<br>0 | N/A  | Either > 3 taxa exhibit same biopattern<br>or<br>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   |
|--|--|
| <b>For 7.01 or Higher Software Users</b> |  |
| <i>Brucella melitensis</i>               | <b>Important!</b> Presumptive Identification<br>Highly pathogenic organism.<br>The following are included in an identification of <i>Brucella melitensis</i> :<br><i>Brucella abortus</i><br><i>Brucella canis</i><br><i>Brucella melitensis</i><br><i>Brucella neotamae</i><br><i>Brucella ovis</i><br><i>Brucella suis</i> |
| <i>Burkholderia mallei</i>               | <b>Important!</b> Presumptive Identification<br>Highly pathogenic organism.  |
| <i>Burkholderia pseudomallei</i>         | Highly pathogenic organism. Isolates of <i>Burkholderia thailandensis</i> are biochemically similar to <i>Burkholderia pseudomallei</i> . Since the possibility of <i>Burkholderia thailandensis</i> exists, the user should send the isolate to their state lab or other suitable reference laboratory for confirmation.    |
| <i>Escherichia coli</i> O157             | Confirm by serological tests.<br>Highly pathogenic organism.   |
| <i>Francisella tularensis</i>            | Confirm by serological tests.<br>Highly pathogenic organism.   |

| Taxa   | Note   |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
|--|--|---------|----------|---------------|---------------|---------------------|---|---|---|-------------------------|---|---|---|--------------------------|---|---|---|
| <i>Salmonella enterica</i> ssp. <i>arizonae</i><br><i>Salmonella enterica</i> ssp. <i>diarizonae</i><br><i>Salmonella</i> group<br><i>Salmonella</i> ser. Gallinarum<br><i>Salmonella</i> ser. Paratyphi A<br><i>Salmonella</i> ser. Typhi | Confirm by serological tests.  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>Shigella</i> group<br><i>Shigella sonnei</i>  | Confirm by serological tests.  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>Vibrio cholerae</i>   | Critical pathogen.<br>The species identified may have significance to patient or sample outcome and can be stopped for review.   |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>Yersinia pestis</i>   | <b>Important!</b> Presumptive Identification<br>Highly pathogenic organism.  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <b>For 9.02 and Higher Software Users</b>  |  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>Ochrobactrum anthropi</i>   | Possibility of <i>Brucella</i> spp.  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <b>For 9.04 Software Users</b>   |  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>Bordetella bronchiseptica</i>   | Possibility of <i>Bordetella pertussis</i> or <i>Bordetella parapertussis</i> .<br>Isolates of these species maybe misidentified as <i>B. bronchiseptica</i> , in order to rule them out, perform the following tests:   |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
|  | <table border="1"> <thead> <tr> <th></th> <th>Oxidase</th> <th>Motility</th> <th>Brown Pigment</th> </tr> </thead> <tbody> <tr> <td><i>B. pertussis</i></td> <td>+</td> <td>-</td> <td>-</td> </tr> <tr> <td><i>B. parapertussis</i></td> <td>-</td> <td>-</td> <td>+</td> </tr> <tr> <td><i>B. bronchiseptica</i></td> <td>+</td> <td>+</td> <td>-</td> </tr> </tbody> </table> |         | Oxidase  | Motility      | Brown Pigment | <i>B. pertussis</i> | + | - | - | <i>B. parapertussis</i> | - | - | + | <i>B. bronchiseptica</i> | + | + | - |
|  |  | Oxidase | Motility | Brown Pigment |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
|  | <i>B. pertussis</i>  | +       | -        | -             |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>B. parapertussis</i>  | -  | -       | +        |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
| <i>B. bronchiseptica</i>   | +  | +       | -        |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
|  |  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |
|  |  |         |          |               |               |                     |   |   |   |                         |   |   |   |                          |   |   |   |

**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 species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

- *Acinetobacter haemolyticus*
- *Acinetobacter lwoffii*
- *Actinobacillus ureae*
- *Aeromonas salmonicida*
- *Brucella melitensis*
- *Francisella tularensis*
- *Methylobacterium* spp.
- *Moraxella lacunata*
- *Moraxella nonliquefaciens*

- *Moraxella osloensis*
- *Pasteurella multocida*
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas stutzeri*

## Quality Control

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

### Short-Term Storage Conditions

1. Streak to a TSAB plate or slant.
2. Incubate for 24 hours at 35°C to 37°C.
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

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**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 GN. See the GN Quality Control tables.

## 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.<sup>6</sup>

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:<sup>5</sup>

- 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.

### GN Quality Control Tables:

***Enterobacter hormaechei* ATCC® 700323™** (for streamlined or comprehensive quality control)

***Stenotrophomonas maltophilia* ATCC® 17666™** (for streamlined or comprehensive quality control)

***Acinetobacter baumannii* ATCC® BAA-747™** (for comprehensive quality control)

***Elizabethkingia meningoseptica* ATCC® 13253™** (for comprehensive quality control)

***Klebsiella oxytoca* ATCC® 700324™** (for comprehensive quality control)

***Ochrobactrum anthropi* ATCC® BAA-749™** (for comprehensive quality control)

***Proteus vulgaris* ATCC® 6380™** (for comprehensive quality control)

***Pseudomonas aeruginosa* ATCC® 9721™** (for comprehensive quality control)

***Pseudomonas aeruginosa* ATCC® BAA-1744™** (for comprehensive quality control)

**Note:** *Pseudomonas aeruginosa* ATCC® BAA-1744™ may contain two morphologically distinct colony types; however, either will provide proper expected reactions when tested for quality control.

### For 7.01 Software Users

***Shigella sonnei* ATCC® 25931™** (for comprehensive quality control)

### For 8.01 or Higher Software Users

***Escherichia coli* ATCC® 25922™** (for comprehensive quality control)

The GN 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: *Enterobacter hormaechei* ATCC® 700323™ (for streamlined or comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | - | AGLTp | - | BXYL  | + | SAC   | + | SUCT  | v | CMT   | - |
| ADO  | + | dGLU  | + | BAlap | - | dTAG  | - | NAGA  | + | BGUR  | v |
| PyrA | - | GGT   | + | ProA  | v | dTRE  | + | AGAL  | + | O129R | + |
| IARL | - | OFF   | + | LIP   | v | CIT   | + | PHOS  | v | GGAA  | - |
| dCEL | + | BGLU  | - | PLE   | + | MNT   | + | GlyA  | v | IMLTa | - |
| BGAL | + | dMAL  | + | TyrA  | v | 5KG   | - | ODC   | + | ELLM  | - |
| H2S  | - | dMAN  | + | URE   | - | ILATk | v | LDC   | - | ILATa | - |
| BNAG | + | dMNE  | + | dSOR  | + | AGLU  | - | IHISa | - |       |   |

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

**Table 7: QC Organism: *Stenotrophomonas maltophilia* ATCC® 17666™ (for streamlined or comprehensive quality control)**

|      |   |       |   |      |   |     |   |      |   |     |   |
|------|---|-------|---|------|---|-----|---|------|---|-----|---|
| APPA | + | AGLTp | - | BXYL | - | SAC | - | SUCT | v | CMT | - |
|------|---|-------|---|------|---|-----|---|------|---|-----|---|

|      |   |      |   |       |   |       |   |       |   |       |   |
|------|---|------|---|-------|---|-------|---|-------|---|-------|---|
| ADO  | - | dGLU | - | BAlap | - | dTAG  | - | NAGA  | - | BGUR  | - |
| PyrA | - | GGT  | v | ProA  | + | dTRE  | - | AGAL  | - | O129R | - |
| IARL | - | OFF  | - | LIP   | + | CIT   | v | PHOS  | + | GGAA  | + |
| dCEL | - | BGLU | v | PLE   | - | MNT   | v | GlyA  | - | IMLTa | - |
| BGAL | - | dMAL | - | TyrA  | v | 5KG   | - | ODC   | - | ELLM  | - |
| H2S  | - | dMAN | - | URE   | - | ILATk | v | LDC   | v | ILATa | - |
| BNAG | v | dMNE | - | dSOR  | - | AGLU  | v | IHISa | - |       |   |

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

**Table 8: QC Organism: *Acinetobacter baumannii* ATCC® BAA-747™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | v | AGLTp | v | BXYL  | v | SAC   | v | SUCT  | + | CMT   | v |
| ADO  | v | dGLU  | v | BAlap | v | dTAG  | v | NAGA  | v | BGUR  | v |
| PyrA | v | GGT   | v | ProA  | v | dTRE  | v | AGAL  | v | O129R | v |
| IARL | v | OFF   | v | LIP   | v | CIT   | + | PHOS  | - | GGAA  | v |
| dCEL | v | BGLU  | v | PLE   | v | MNT   | + | GlyA  | v | IMLTa | v |
| BGAL | v | dMAL  | v | TyrA  | + | 5KG   | v | ODC   | v | ELLM  | v |
| H2S  | v | dMAN  | v | URE   | v | ILATk | + | LDC   | v | ILATa | v |
| BNAG | v | dMNE  | v | dSOR  | v | AGLU  | v | IHISa | + |       |   |

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

**Table 9: QC Organism: *Elizabethkingia meningoseptica* ATCC® 13253™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | + | AGLTp | + | BXYL  | v | SAC   | v | SUCT  | - | CMT   | v |
| ADO  | v | dGLU  | - | BAlap | v | dTAG  | v | NAGA  | + | BGUR  | v |
| PyrA | + | GGT   | v | ProA  | v | dTRE  | v | AGAL  | v | O129R | v |
| IARL | v | OFF   | - | LIP   | v | CIT   | v | PHOS  | v | GGAA  | + |
| dCEL | v | BGLU  | v | PLE   | v | MNT   | v | GlyA  | + | IMLTa | v |
| BGAL | v | dMAL  | v | TyrA  | v | 5KG   | v | ODC   | v | ELLM  | v |
| H2S  | v | dMAN  | v | URE   | v | ILATk | - | LDC   | v | ILATa | v |
| BNAG | + | dMNE  | v | dSOR  | v | AGLU  | + | IHISa | v |       |   |

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

**Table 10: QC Organism: *Klebsiella oxytoca* ATCC® 700324™ (for comprehensive quality control)**

|      |   |       |   |       |                |       |                |       |   |       |   |
|------|---|-------|---|-------|----------------|-------|----------------|-------|---|-------|---|
| APPA | - | AGLTp | v | BXYL  | v              | SAC   | v              | SUCT  | v | CMT   | v |
| ADO  | v | dGLU  | + | BAlap | v              | dTAG  | +              | NAGA  | v | BGUR  | - |
| PyrA | v | GGT   | - | ProA  | -              | dTRE  | +              | AGAL  | + | O129R | v |
| IARL | + | OFF   | + | LIP   | -              | CIT   | v              | PHOS  | v | GGAA  | - |
| dCEL | + | BGLU  | + | PLE   | +              | MNT   | v              | GlyA  | - | IMLTa | v |
| BGAL | + | dMAL  | v | TyrA  | v <sup>2</sup> | 5KG   | v <sup>1</sup> | ODC   | - | ELLM  | v |
| H2S  | v | dMAN  | + | URE   | +              | ILATk | v              | LDC   | + | ILATa | v |
| BNAG | - | dMNE  | + | dSOR  | v              | AGLU  | -              | IHISa | v |       |   |

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

<sup>1</sup>Reaction is mostly positive although occasional negative reaction may occur.

<sup>2</sup>Reaction is mostly negative although occasional positive reaction may occur.

**Table 11: QC Organism: *Ochrobactrum anthropi* ATCC® BAA-749™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | v | AGLTp | v | BXYL  | v | SAC   | v | SUCT  | v | CMT   | v |
| ADO  | v | dGLU  | v | BAlap | v | dTAG  | v | NAGA  | v | BGUR  | v |
| PyrA | + | GGT   | v | ProA  | + | dTRE  | v | AGAL  | v | O129R | – |
| IARL | v | OFF   | v | LIP   | v | CIT   | v | PHOS  | – | GGAA  | v |
| dCEL | v | BGLU  | v | PLE   | v | MNT   | v | GlyA  | + | IMLTa | v |
| BGAL | v | dMAL  | v | TyrA  | v | 5KG   | v | ODC   | v | ELLM  | + |
| H2S  | v | dMAN  | v | URE   | v | ILATk | v | LDC   | v | ILATa | v |
| BNAG | v | dMNE  | v | dSOR  | v | AGLU  | v | IHISa | v |       |   |

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

**Table 12: QC Organism: *Proteus vulgaris* ATCC® 6380™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | v | AGLTp | v | BXYL  | v | SAC   | + | SUCT  | v | CMT   | v |
| ADO  | – | dGLU  | v | BAlap | v | dTAG  | v | NAGA  | v | BGUR  | v |
| PyrA | v | GGT   | v | ProA  | – | dTRE  | – | AGAL  | – | O129R | v |
| IARL | v | OFF   | v | LIP   | – | CIT   | v | PHOS  | + | GGAA  | v |
| dCEL | – | BGLU  | + | PLE   | v | MNT   | – | GlyA  | v | IMLTa | v |
| BGAL | – | dMAL  | v | TyrA  | v | 5KG   | v | ODC   | v | ELLM  | + |
| H2S  | + | dMAN  | – | URE   | + | ILATk | v | LDC   | – | ILATa | v |
| BNAG | v | dMNE  | – | dSOR  | – | AGLU  | v | IHISa | v |       |   |

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

**Table 13: QC Organism: *Pseudomonas aeruginosa* ATCC® 9721™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | v | AGLTp | v | BXYL  | v | SAC   | v | SUCT  | v | CMT   | v |
| ADO  | v | dGLU  | v | BAlap | + | dTAG  | v | NAGA  | v | BGUR  | v |
| PyrA | v | GGT   | v | ProA  | v | dTRE  | v | AGAL  | v | O129R | v |
| IARL | v | OFF   | v | LIP   | v | CIT   | v | PHOS  | v | GGAA  | v |
| dCEL | v | BGLU  | v | PLE   | v | MNT   | v | GlyA  | v | IMLTa | v |
| BGAL | v | dMAL  | – | TyrA  | v | 5KG   | v | ODC   | v | ELLM  | v |
| H2S  | v | dMAN  | v | URE   | v | ILATk | + | LDC   | v | ILATa | v |
| BNAG | v | dMNE  | v | dSOR  | v | AGLU  | v | IHISa | v |       |   |

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

**Table 14: QC Organism: *Pseudomonas aeruginosa* ATCC® BAA-1744™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |      |   |       |                |
|------|---|-------|---|-------|---|-------|---|------|---|-------|----------------|
| APPA | v | AGLTp | v | BXYL  | v | SAC   | v | SUCT | v | CMT   | +              |
| ADO  | v | dGLU  | v | BAlap | v | dTAG  | v | NAGA | v | BGUR  | v              |
| PyrA | v | GGT   | v | ProA  | v | dTRE  | v | AGAL | v | O129R | v              |
| IARL | v | OFF   | v | LIP   | v | CIT   | v | PHOS | v | GGAA  | v              |
| dCEL | v | BGLU  | v | PLE   | v | MNT   | v | GlyA | v | IMLTa | +              |
| BGAL | v | dMAL  | v | TyrA  | v | 5KG   | v | ODC  | v | ELLM  | v              |
| H2S  | v | dMAN  | v | URE   | v | ILATk | v | LDC  | v | ILATa | v <sup>1</sup> |

|      |   |      |   |      |   |      |   |       |   |  |  |
|------|---|------|---|------|---|------|---|-------|---|--|--|
| BNAG | v | dMNE | v | dSOR | v | AGLU | v | IHISa | v |  |  |
|------|---|------|---|------|---|------|---|-------|---|--|--|

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

<sup>1</sup>Reaction is mostly positive although occasional negative reaction may occur.

**Note:** Culture may contain two morphologically distinct colony types; however, either will provide proper expected reactions when tested for quality control.

#### For 7.01 Software Users

**Table 15: QC Organism: *Shigella sonnei* ATCC® 25931™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | v | AGLTp | v | BXYL  | – | SAC   | – | SUCT  | v | CMT   | + |
| ADO  | v | dGLU  | v | BAlap | v | dTAG  | v | NAGA  | – | BGUR  | + |
| PyrA | v | GGT   | – | ProA  | v | dTRE  | v | AGAL  | v | O129R | v |
| IARL | v | OFF   | v | LIP   | v | CIT   | – | PHOS  | v | GGAA  | v |
| dCEL | v | BGLU  | – | PLE   | – | MNT   | – | GlyA  | v | IMLTa | v |
| BGAL | v | dMAL  | + | TyrA  | + | 5KG   | v | ODC   | + | ELLM  | v |
| H2S  | v | dMAN  | v | URE   | v | ILATk | v | LDC   | v | ILATa | v |
| BNAG | – | dMNE  | v | dSOR  | v | AGLU  | v | IHISa | v |       |   |

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

#### For 8.01 or Higher Software Users

**Table 16: QC Organism: *Escherichia coli* ATCC® 25922™ (for comprehensive quality control)**

|      |   |       |   |       |   |       |   |       |   |       |   |
|------|---|-------|---|-------|---|-------|---|-------|---|-------|---|
| APPA | v | AGLTp | v | BXYL  | – | SAC   | – | SUCT  | v | CMT   | + |
| ADO  | v | dGLU  | v | BAlap | v | dTAG  | v | NAGA  | – | BGUR  | + |
| PyrA | v | GGT   | – | ProA  | v | dTRE  | v | AGAL  | v | O129R | v |
| IARL | v | OFF   | v | LIP   | v | CIT   | – | PHOS  | v | GGAA  | v |
| dCEL | v | BGLU  | – | PLE   | – | MNT   | – | GlyA  | v | IMLTa | v |
| BGAL | v | dMAL  | + | TyrA  | + | 5KG   | v | ODC   | + | ELLM  | v |
| H2S  | v | dMAN  | v | URE   | v | ILATk | v | LDC   | v | ILATa | v |
| BNAG | – | dMNE  | v | dSOR  | v | AGLU  | v | IHISa | v |       |   |

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

## Limitations

The VITEK® 2 GN card cannot be used with direct clinical samples 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 GN 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

#### For 7.01 Software Users

In a multi-site clinical study\*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN

correctly identified 96.2% of the isolates, including 6.8% low discrimination with the correct species listed. Misidentifications occurred at 3.4% and no identifications occurred at 0.4%.

#### For 8.01 and 9.01 Software Users

In a multi-site clinical study\*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 95.4% of the isolates, including 6.6% low discrimination with the correct species listed. Misidentifications occurred at 4.1% and no identifications occurred at 0.5%.

#### For 9.02 Software Users

In a multi-site clinical study\*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 95.2% of the isolates, including 6.4% low discrimination with the correct species listed. Misidentifications occurred at 4.3% and no identifications occurred at 0.5%.

#### For 9.04 Software Users

In a multi-site clinical study\*, the performance of the VITEK® 2 GN identification card was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with API® 20 E and API® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 94.8% of the isolates, including 6.6% low discrimination with the correct species listed. Misidentifications occurred at 4.8% and no identifications occurred at 0.3%.

\*Data on file at bioMérieux, Inc.

## Organisms Identified

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Claims are for all software users unless otherwise stated.

### **Enterobacteriaceae**

- *Budvicia aquatica*
- *Buttiauxella agrestis*
- *Cedecea davisae*\*
- *Cedecea lapagei*\*
- *Citrobacter amalonaticus*\*
- *Citrobacter braakii*\*
- *Citrobacter farmeri*\*
- *Citrobacter freundii*\*
- *Citrobacter koseri*\*
- *Citrobacter sedlakii*
- *Citrobacter youngae*\*
- *Cronobacter sakazakii* group+
- *Edwardsiella hoshinae*\*
- *Edwardsiella tarda*\*
- *Enterobacter aerogenes*\*
- *Enterobacter amnigenus* 1\*
- *Enterobacter amnigenus* 2\*
- *Enterobacter asburiae*\*
- *Enterobacter cancerogenus*\*
- *Enterobacter cloacae* complex+
- *Escherichia coli*\*
- *Escherichia coli* O157\*
- *Escherichia fergusonii*\*
- *Enterobacter gergoviae*\*



- *Escherichia hermannii*\*
- *Escherichia vulneris*\*
- *Ewingella americana*\*
- *Hafnia alvei*\*
- *Klebsiella oxytoca* \*
- *Klebsiella pneumoniae* ssp. *ozaenae*
- *Klebsiella pneumoniae* ssp. *pneumoniae*\*
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis*
- *Kluyvera ascorbata*\*
- *Kluyvera cryocrescens*
- *Kluyvera intermedia*\* (formerly known as *Enterobacter intermedius*)
- *Leclercia adecarboxylata*\*
- *Moellerella wisconsensis*\*
- *Morganella morganii* ssp. *morganii*\*
- *Morganella morganii* ssp. *sibonii*
- *Pantoea agglomerans*\*
- *Pantoea* spp.
- *Plesiomonas shigelloides*
- *Proteus hauseri*
- *Proteus mirabilis*\*
- *Proteus penneri*\*
- *Proteus vulgaris*
- *Providencia alcalifaciens*\*
- *Providencia rettgeri*
- *Providencia rustigianii*
- *Providencia stuartii*\*
- *Rahnella aquatilis*\*
- *Raoultella ornithinolytica*
- *Raoultella planticola*
- *Salmonella enterica* ssp. *arizonae*\*
- *Salmonella enterica* ssp. *diarizonae*
- *Salmonella* group\*
- *Salmonella* ser. *Gallinarum*\*
- *Salmonella* ser. *Paratyphi A*\*
- *Salmonella* ser. *Typhi*\*
- *Serratia ficaria*\*
- *Serratia fonticola*\*
- *Serratia liquefaciens* group\*
- *Serratia marcescens*\*
- *Serratia odorifera*\*
- *Serratia plymuthica*\*
- *Serratia rubidaea*\*
- *Shigella* group\*
- *Shigella sonnei*\*
- *Yersinia aldovae*
- *Yersinia enterocolitica/frederiksenii*\*
- *Yersinia intermedia*\*
- *Yersinia kristensenii*\*
- *Yersinia pestis*
- *Yersinia pseudotuberculosis*\*
- *Yersinia ruckeri*\*

- *Yokenella regensburgei*

**Additional Claims and Taxonomy Changes For 8.01 or Higher Software Users**

- *Hafnia paralvei*
- *Lelliottia amnigena* 1\* (formerly known as *Enterobacter amnigenus* 1)
- *Lelliottia amnigena* 2\* (formerly known as *Enterobacter amnigenus* 2)
- *Pandoraea* spp.
- *Pluralibacter gergoviae*\* (formerly known as *Enterobacter gergoviae*)
- *Tatumella ptyseos*

**Additional Claims For 9.02 Software Users or Higher Software Users**

- *Citrobacter werkmanii*

**Additional Taxonomy Changes For 9.04 Software Users**

- *Klebsiella aerogenes* (formerly known as *Enterobacter aerogenes*)
- *Pseudoescherichia vulneris* (formerly known as *Escherichia vulneris*)

**Non-Enterobacteriaceae**

- *Achromobacter denitrificans*
- *Achromobacter xylosoxidans*
- *Acinetobacter baumannii* complex
- *Acinetobacter haemolyticus*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Acinetobacter radioresistens*
- *Acinetobacter ursingii*
- *Actinobacillus ureae*
- *Aeromonas hydrophila*/*Aeromonas caviae*
- *Aeromonas salmonicida*
- *Aeromonas sobria*
- *Aeromonas veronii*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella bronchiseptica*
- *Bordetella hinzii*
- *Bordetella trematum*
- *Brevundimonas diminuta/vesicularis*
- *Brucella melitensis*
- *Burkholderia cepacia* group+
- *Burkholderia gladioli*\*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- *Chromobacterium violaceum*
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Comamonas testosteroni*
- *Cupriavidus pauculus*
- *Delftia acidovorans*
- *Elizabethkingia meningoseptica*
- *Francisella tularensis*
- *Grimontia hollisae*
- *Mannheimia haemolytica*
- *Methylobacterium* spp.

- *Moraxella* group
- *Myroides* spp.
- *Neisseria animaloris/zoodegmatis*
- *Ochrobactrum anthropi*
- *Oligella ureolytica*
- *Paracoccus yeei*
- *Pasteurella aerogenes*
- *Pasteurella canis*
- *Pasteurella dagmatis*
- *Pasteurella multocida*
- *Pasteurella pneumotropica*
- *Pasteurella testudinis*
- *Photobacterium damsela*
- *Pseudomonas aeruginosa*\*
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*\*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oleovorans*
- *Pseudomonas oryzae*
- *Pseudomonas putida*
- *Pseudomonas stutzeri*
- *Ralstonia mannitolilytica*
- *Ralstonia pickettii*
- *Rhizobium radiobacter*
- *Roseomonas gilardii*
- *Shewanella algae*
- *Shewanella putrefaciens*
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingobacterium thalpophilum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia*
- *Vibrio alginolyticus*\*
- *Vibrio cholerae*\*
- *Vibrio fluvialis*\*
- *Vibrio metschnikovii*\*
- *Vibrio mimicus*\*
- *Vibrio parahaemolyticus*\*
- *Vibrio vulnificus*\*

**Additional Claims For 8.01 or Higher Software Users**

- *Pandoraea* species
- *Ralstonia insidiosa*

**Additional Claims For 9.02 Software Users or Higher Software Users**

- *Aeromonas hydrophila/Aeromonas punctata* (formerly known as *Aeromonas caviae*)
- *Bergeyella zoohelcum*

**Additional Taxonomy Changes For 9.04 Software Users**

- *Rodentibacter pneumotropicus* (formerly known as *Pasteurella pneumotropica*)

### Highly Pathogenic Organisms

- *Brucella melitensis*\*
- *Burkholderia mallei*\*
- *Burkholderia pseudomallei*\*
- *Escherichia coli* O157\*
- *Francisella tularensis*\*
- *Yersinia pestis*\*

\* OMA Official Methods of Analysis validated claim.

+ Species within this group or complex that are OMA Official Methods of Analysis validated claims are *Burkholderia cepacia*, *Cronobacter sakazakii*, and *Enterobacter cloacae*.

### Supplemental Tests

**Table 17: GN Supplemental Tests**

| Abbreviation   | Test Name   | Description  | Comments  | Reference  |
|--|---|--|---|--|
| <b>For 7.01 or Higher Software Users</b>   |   |  |   |  |
| 41C  | GROWTH AT 41°C  | Ability of certain species to grow at 41°C.  | N/A   | 18, 20   |
| 42C  | GROWTH AT 42°C  | Ability of certain species to grow at 42°C.  | N/A   | 20, 22   |
| 44C  | GROWTH AT 44°C  | Ability of certain species to grow at 44°C.  | N/A   | 21   |
| ADONITOL<br>dCELLOB<br>dMALTOSE<br>dMANNITOL<br>dMELIBIOSE<br>dSORBITOL<br>dTREHALOSE<br>dTURANOSE<br>DUL<br>INOSITOL<br>LACTOSE<br>IRHAMNOSE<br>SACCHAROSE<br>SALICIN | ADONITOL acidification<br>D-CELLOBIOSE acidification<br>D-MALTOSE acidification<br>D-MANNITOL acidification<br>D-MELIBIOSE acidification<br>SORBITOL acidification<br>D-TREHALOSE acidification<br>TURANOSE acidification<br>DULCITOL acidification<br>INOSITOL acidification<br>LACTOSE acidification<br>L-RHAMNOSE acidification<br>SACCHAROSE/SUCROSE acidification<br>SALICIN acidification | Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple, etc.).   | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 2, 8, 10, 12, 13, 14, 16, 17, 19, 21, 22, 27, 28 |
| Arg.hydr.  | ARGININE dihydrolase  | Hydrolysis of arginine releases an amine resulting in alkalization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red). | N/A   | 7, 10, 12, 17, 18, 19, 20, 22, 25, 27            |
| B-HEM  | BETA HEMOLYSIS  | Certain species possess hemolysins that give a transparent zone around colonies on blood-based agar.   | N/A   | 3, 9, 20, 27                                     |
| DNase  | DNase test  | Ability of certain species to produce DNase resulting in the degradation of DNA.   | N/A   | 17, 20, 27                                       |

| Abbreviation         | Test Name  | Description  | Comments  | Reference                         |
|----------------------|--|--|---|-----------------------------------|
| ESCULIN              | ESCULIN hydrolysis   | Hydrolysis of esculin forms esculentin that produces a black pigment in the presence of iron salts.  | N/A   | 12, 17, 19, 20, 27                |
| GELATIN              | GELATIN hydrolysis   | Mediated by a gelatinase enzyme, a positive reaction is observed by liquefaction of the gelatin substrate.   | N/A   | 3, 9, 18, 19, 20, 22, 24          |
| dGLUf                | Glucose fermentation   | Fermentation of glucose observed with pH indicators (e.g. phenol red, bromcresol purple, etc.).  | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 29                                |
| IND                  | INDOLE   | Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlich's, DMAC reagents, etc.).        | N/A   | 10, 12, 16, 17, 19, 20, 27        |
| JordanTART           | Jordan_Tartrate  | Fermentation of tartrate results in acidification of the medium observed with a pH indicator (e.g., yellow color formation in the presence of phenol red).                       | N/A   | 19                                |
| Lysine dec.          | Lysine decarboxylase   | Hydrolysis of lysine releases an amine resulting in alkalization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple). | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 21, 22                            |
| MNTka                | MALONATE alkalization  | Utilization of malonate as sole carbon source.   | N/A   | 15, 16, 30                        |
| MOB                  | MOTILITY   | Test for motility using hanging drop procedure or wet mount.   | Bacterial motility can be observed by placing a drop of bacterial suspension on a slide and viewing it under a microscope.  | 4, 12, 17, 19, 20, 25, 27, 28, 30 |
| NAT                  | SODIUM-ACETATE alkalization  | Ability of certain species to utilize acetate as a sole source of carbon.  | N/A   | 29                                |
| NO2<br>NO3<br>NO3→N2 | NITRITE REDUCTION<br>NITRATE REDUCTION<br>NITROGEN PRODUCTION FROM NO3 | Test for the ability to reduce<br>NO2: nitrate to nitrogen gas<br>NO3: nitrate to nitrile and/or nitrogen gas<br>NO3→N2: nitrate to nitrogen gas                                 | N/A   | 10, 20, 22, 29, 30                |
| NaCl 0%<br>NaCl 6%   | GROWTH IN 0% NaCl<br>GROWTH IN 6% NaCl                                 | Ability of certain species to grow in the presence or absence of 6.0% NaCl.  | N/A   | 7, 8, 20, 21, 22                  |
| O/129 R              | O/129 RESISTANCE   | Ability of certain species to grow in the presence of the vibriostatic compound O/129.   | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 8, 11                             |

| Abbreviation                             | Test Name                | Description   | Comments  | Reference                                  |
|--|--------------------------|---|---|--|
| ONPG                                     | BETA_GALACTOSIDASE       | Presence of beta-galactosidase cleaves o-nitrophenol-beta-D-galactopyranoside to produce a yellow colored product.  | N/A   | 8, 12, 17, 19, 20                          |
| Ornith.dec                               | Ornithine decarboxylase  | Hydrolysis of ornithine releases an amine resulting in alkalization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple). | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 8, 10, 17, 19, 20, 27                      |
| OX                                       | OXIDASE                  | Detection of the presence of cytochrome C.  | Characteristic useful in identifying many species of non-fermenters. All members of <i>Enterobacteriaceae</i> are oxidase negative.                                       | 10, 12, 17, 18, 19, 20, 21, 22, 25, 27, 28 |
| PURPLE                                   | PURPLE PIGMENT           | Ability of certain species to produce purple colonies on non-differential media.  | Characteristic of <i>Chromobacterium violaceum</i> .  | 19, 20                                     |
| PYOCYANIN                                | PYOCYANIN pigment        | Ability of species to produce blue pigment (pyocyanin) or fluorescent pigment (pyoverdin).  | Presence of both pyocyanin and pyoverdin is characteristic of <i>Pseudomonas aeruginosa</i> producing greenish fluorescent colonies.                                      | 1, 20                                      |
| PYOVERDIN                                | PYOVERDIN pigment        |   |   |  |
| RM                                       | Methyl Red               | Test for acid production, requiring positive organisms to produce acid from glucose.  | N/A   | 21   |
| UREASE                                   | Urease                   | Hydrolysis of urea releases ammonia resulting in alkalization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).                 | N/A   | 10, 12, 17, 19, 20, 25, 27                 |
| VP                                       | VOGES PROSKAUER          | Ability of some species to produce acetoin from glucose fermentation.   | N/A   | 12, 17, 19, 20, 25, 30                     |
| YELLOW                                   | YELLOW PIGMENT           | Ability of certain species to produce yellow pigmented colonies on nondifferential media.   | N/A   | 12, 17, 19, 20, 29                         |
| <b>For 7.01 Software Users Only</b>      |                          |   |   |  |
| dFRUCTOSEa                               | D-FRUCTOSE assimilation  | Capability of organisms to grow using a specific sole carbon source.  | N/A   | 2, 4, 17, 18                               |
| dGLUCOSEa                                | D-GLUCOSE assimilation   |   |   |  |
| dMANNITOLa                               | D-MANNITOL assimilation  |   |   |  |
| dMELa                                    | D-MELIBIOSE assimilation |   |   |  |
| ISORBOSEa                                | L-SORBOSE assimilation   |   |   |  |
| dMLZ                                     | MELEZITOSE acidification | Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple, etc.).  | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 8, 10, 12, 13, 14, 16, 17, 19, 21, 22, 27  |
| <b>For 8.01 or Higher Software Users</b> |                          |   |   |  |

| Abbreviation                                 | Test Name  | Description  | Comments  | Reference  |
|--|--|--|---|--|
| dGLUCOSE<br>dMELEZIT.<br>dXYLOSE<br>ISORBOSE | D-GLUCOSE acidification<br>MELEZITOSE acidification<br>D-XYLOSE acidification<br>L-SORBOSE acidification | Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple, etc.). | Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods. | 2, 8, 10, 12, 13, 14, 16, 17, 19, 21, 22, 27, 28 |
| COL R  | COLISTIN RESISTANCE  | Ability of certain species to grow in the presence of the colistin.                                    | N/A   | 28   |







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Use this Instructions for Use with VITEK® 2 Product No. 21341.

## Index of Symbols

| Symbol  | Meaning                            |
|---|------------------------------------|
|  | Catalog number                     |
|  | In Vitro Diagnostic Medical Device |
|  | Legal Manufacturer                 |
|  | Temperature limitation             |
|  | Use by date                        |
|  | Batch code                         |



| Symbol  | Meaning  |
|---|--|
|  | 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

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## 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  |
|--------------|-------------|------------------|---|
| 2021-05      | 044066-05   | Technical change | Updated sections: <ul style="list-style-type: none"> <li>• Specimen Preparation</li> <li>• Results</li> <li>• Additional Information on Lab Report</li> <li>• Comprehensive Quality Control</li> <li>• Performance Characteristics</li> <li>• Organisms Identified</li> <li>• Supplemental Tests</li> </ul>   |
| 2020-03      | 044066-04   | Technical change | Updated sections: <ul style="list-style-type: none"> <li>• Testing of QC Organisms</li> <li>• Organisms Identified</li> </ul>   |
| 2019-03      | 044066-03   | Technical change | Updated for 9.02 software release.<br>Updated sections: <ul style="list-style-type: none"> <li>• Intended Use</li> <li>• Precautions</li> <li>• Culture Requirements</li> <li>• Additional Information on Lab Report</li> <li>• Testing of QC Organisms</li> <li>• Performance Characteristics</li> <li>• Organisms Identified</li> <li>• References</li> </ul> |
| 2016-10      | 044066-02   | Technical change | <ul style="list-style-type: none"> <li>• Updated content to reflect the 8.01 Product Information Manual</li> </ul>  |
|              |             | Correction       | <ul style="list-style-type: none"> <li>• Performance Characteristics</li> </ul>   |
| 2016-05      | 044066-01   | Administrative   | <ul style="list-style-type: none"> <li>• Formatting changes do not affect the fit, form, or function of the product</li> </ul>  |
|              |             | Technical change | <ul style="list-style-type: none"> <li>• New IFU derived from product chapter in the Product Information Manual</li> <li>• Updated Limited Warranty section</li> <li>• Updated with RX only information</li> </ul>  |

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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