BIOMÉRIEUX

REF 21346

043902- 04 - 2021-04

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VITEK® 2 NH

℞ 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 Neisseria-Haemophilus identification card (NH) is intended for use with the VITEK® 2 Systems for the automated identification of most clinically significant fastidious organisms. The VITEK® 2 NH identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

Description

The NH Card is based on established biochemical methods and newly developed substrates measuring carbon source utilization and enzymatic activities. There are 30 biochemical tests. Final identification results are available in approximately six hours.

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

Table 1: NH Well Contents

Well	Test	Mnemonic	Amount/Well
1	Arginine ARYLAMIDASE	ArgA	0.0324 mg
2	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	D-GALACTOSE	dGAL	0.3 mg
5	Leucine ARYLAMIDASE	LeuA	0.023 mg
6	ELLMAN	ELLM	0.03 mg
7	Phenylalanine ARYLAMIDASE	PheA	0.026 mg
8	L-Proline ARYLAMIDASE	ProA	0.023 mg
10	L-Pyrrolidonyl-ARYLAMIDASE	PyrA	0.018 mg
13	Tyrosine ARYLAMIDASE	TyrA	0.0279 mg
15	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.038 mg
18	D-GLUCOSE	dGLU	0.3 mg
19	GLYCOGENE	GLYG	0.18 mg
20	D-MANNOSE	dMNE	0.3 mg
22	D-MALTOSE	dMAL	0.3 mg
28	SACCHAROSE/SUCROSE	SAC	0.3 mg
33	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
36	UREASE	URE	0.15 mg
39	BETA-GALACTOPYRANOSIDASE Indoxyl	BGALi	0.006 mg
40	ORNITHINE DECARBOXYLASE	ODC	0.15 mg

Well	Test	Mnemonic	Amount/Well
41	ALPHA-ARABINOSIDASE	AARA	0.0324 mg
45	PYRUVATE	PVATE	0.15 mg
46	PHOSPHORYL CHOLINE	PHC	0.0366 mg
47	D-MALATE	dMLT	0.15 mg
51	MALTOTRIOSE	MTE	0.3 mg
52	L-GLUTAMINE	IGLM	0.15 mg
59	PHOSPHATASE	PHOS	0.05 mg
61	d-Ribose 2	dRIB2	0.3 mg
62	Phenylphosphonate	OPS	0.024 mg
64	D-XYLOSE	dXYL	0.3 mg

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

Precautions

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

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism’s Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Give special consideration to sample source.
- 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.[18,20]

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

Storage Conditions

Upon receipt, store VITEK® 2 NH 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
NH	*Campylobacter*: TSAB[2] CBA CHBA TSAHB	*Campylobacter*: 18 to 24 hours	*Campylobacter*: 35°C to 37°C or 40°C to 42°C microaerobic conditions	2.70 – 3.30 McFarland Standard	N/A [5]	≤ 30 minutes
	Haemophilus: CHOC[2] CHOC PVX[2] CHOC + B	Fastidious: 18 to 24 hours	Fastidious: 35°C to 37°C with 5% to 10% CO_2			
	Neisseria: CHOC[2] CHOC PVX[2] CHOC VCAT CHBA ML[3] NYC[4] TM[3] TSAB					
	Other Fastidious: CHOC[2] CHOC PVX[2] CBA CHBA ML[3] TM[3] TSAB TSAHB					

[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]These media were validated for *Neisseria gonorrhoeae*, *Neisseria meningitidis* and *Moraxella catarrhalis*.

[4]This medium was validated for *Neisseria gonorrhoeae*.

[5]N/A = not applicable

Culture Requirements Table — Media Abbreviations

CBA = Columbia Blood Agar with 5% Sheep Blood

CHBA = Columbia Horse Blood Agar

CHOC = Chocolate Agar

CHOC + B = Chocolate Agar with Bacitracin

CHOC PVX = Chocolate Polyvitex Agar

CHOC VCAT = Chocolate Polvitex Agar with VCAT

ML = Martin-Lewis Agar

NYC = New York City Medium

TM = Thayer-Martin Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

TSAHB = Trypticase Soy Agar with 5% Horse Blood

Test Procedure

Materials

When used with VITEK® 2 instrumentation, the NH Card is a complete system for routine identification testing of most significant fastidious organisms.

Required materials are:

- VITEK® 2 NH 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. 2.70 to 3.30 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and NH 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.

Table 3: 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 4: Notes Associated with Certain Taxa

Taxa	Note
For 7.01 or Higher Software Users	

<table>
<tr><th>Taxa</th><th colspan="4">Note</th></tr>
<tr><td>Haemophilus influenzae</td><td colspan="4">Haemophilus aegyptius is a recognized species, but there is controversy as to whether it should be retained as a legitimate species. Haemophilus aegyptius is indistinguishable from H. influenzae by either DNA/DNA hybridization or by any single phenotypic test. Isolates of H. aegyptius exhibit distinct pathogenicity and are associated with cases of acute purulent conjunctivitis. Haemophilus influenzae biogroup Aegyptius is also indistinguishable from H. aegyptius and H. influenzae, but is considered the etiologic agent of Brazilian purpuric fever, which is a systemic pediatric infection that is typically preceded by purulent conjunctivitis that resolves before the onset of the systemic infection. Consequently, isolates of H. aegyptius, H. influenzae biogroup Aegyptius, and other biogroups of H. influenzae will all identify as H. influenzae when tested with the NH card.</td></tr>
<tr><td>Neisseria gonorrhoeae
Neisseria meningitidis</td><td colspan="4">Critical pathogen
The species identified may have significance to patient or sample outcome and can be stopped for review.</td></tr>
<tr><td rowspan="5">Neisseria sicca</td><td colspan="4">Possibility of N. flavescens or N. mucosa.
Isolates of these species may be misidentified as N. sicca. In order to rule them out, perform the following tests:</td></tr>
<tr><td></td><td>YELLOW</td><td>GLU</td><td>NO3</td></tr>
<tr><td>N. flavescens</td><td>+</td><td>-</td><td>-</td></tr>
<tr><td>N. mucosa</td><td>+</td><td>+</td><td>+</td></tr>
<tr><td>N. sicca</td><td>-</td><td>+</td><td>-</td></tr>
<tr><td colspan="5">For 9.02 Software Users and Higher</td></tr>
<tr><td>Neisseria cinerea</td><td colspan="4">Possibility of Neisseria gonorrhoeae</td></tr>
</table>

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.”

Campylobacter jejuni ssp. *jejuni* could potentially trigger “Non or low reactive biopattern” if a test was atypical or fell within the uncertainty zone.

Quality Control

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

Note: *Staphylococcus epidermidis* ATTC® 12228™ needs to be tested at a McFarland Standard No. 0.5 to 0.63. All other QC strains are tested at a McFarland Standard No. 2.70 to 3.30.

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 Chocolate or Chocolate Polyvitex agar and incubate at 35°C to 37°C in 5% to 10% CO_2. Incubate for 18 to 24 hours or until sufficient growth is obtained.
3. Check for purity. Perform second subculture for testing.
4. Use Chocolate or Chocolate Polyvitex agar and incubate at 35°C to 37°C in 5% to 10% CO_2. Incubate for 18 to 24 hours.

Short-Term Storage Conditions

Short-term storage is not recommended. Cultures maintained by other methods, specifically those maintained on agar plates or slants for long periods of time at room temperature or at 2°C to 8°C are subject to loss or change of important biochemical characteristics.

Long-Term Storage Conditions

1. Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.
2. Freeze at -70°C.
3. Subculture twice to Chocolate or Chocolate Polyvitex agar 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.

Streamlined quality control may be used to confirm acceptable performance of the NH card after shipping/storage. This methodology may be performed with the NH card by following the instructions for quality control testing as described in the NH Instructions for Use and meeting the criteria stated in the CLSI® M50-A Quality Control for Commercial Microbial Identification Systems.

Testing may be conducted using *Eikenella corrodens* ATCC® BAA-1152™ and evaluating the performance of the PHOS well. Testing at bioMérieux, Inc. has shown that the PHOS well is the most labile well on the NH card and *E. corrodens* ATCC® BAA-1152™ is the most sensitive strain for detecting degradation of this well with a false positive reaction. (See NH Quality Control table for more details).

Comprehensive Quality Control

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

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

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

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

NH Quality Control Tables:

***Eikenella corrodens* ATCC® BAA-1152™** (for streamlined or comprehensive quality control)

***Aggregatibacter aphrophilus* ATCC® 33389™** (for comprehensive quality control)

***Haemophilus influenzae* ATCC® 9007™** (for comprehensive quality control)

***Neisseria gonorrhoeae* ATCC® 19424™** (for comprehensive quality control)

***Neisseria lactamica* ATCC® 23970™** (for comprehensive quality control)

***Oligella urethralis* ATCC® 17960™** (for comprehensive quality control)

***Paenibacillus polymyxa* ATCC® 7070™** (for comprehensive quality control)

***Staphylococcus epidermidis* ATCC® 12228™** (for comprehensive quality control)

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

***Enterobacter aerogenes* ATCC® 13048™** (for comprehensive quality control)

For 9.04 Software Users

Klebsiella aerogenes (formerly known as *Enterobacter aerogenes*) **ATCC® 13048™** (for comprehensive quality control)

The NH 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 a misidentified result may occur when all expected quality control reactions are correct.

Note: The NH card uses unclaimed taxa for quality control testing. These strains will give an unidentified or a misidentified result.

Table 5: QC Organism: *Eikenella corrodens* ATCC® BAA-1152™ (for streamlined or comprehensive quality control)

ArgA	-	PheA	-	GLYG	-	BGALi	-	MTE	-
GGT	-	ProA	+	dMNE	-	ODC	+	IGLM	v
LysA	-	PyrA	-	dMAL	-	AARA	-	*PHOS**	-
dGAL	-	TyrA	-	SAC	-	PVATE	-	dRIB2	-
LeuA	+	APPA	+	NAG	-	PHC	-	OPS	-
ELLM	+	dGLU	-	URE	-	dMLT	v	dXYL	-

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

*Key well for streamlined quality control.

Table 6: QC Organism *Aggregatibacter aphrophilus* ATCC® 33389™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	+	MTE	+
GGT	+	ProA	–	dMNE	+	ODC	–	IGLM	–
LysA	v	PyrA	v	dMAL	+	AARA	v	PHOS	+
dGAL	v	TyrA	v	SAC	+	PVATE	–	dRIB2	v
LeuA	v	APPA	–	NAG	v	PHC	v	OPS	v
ELLM	v	dGLU	+	URE	–	dMLT	v	dXYL	v

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

Table 7: QC Organism: *Haemophilus influenzae* ATCC® 9007™ (for comprehensive quality control)

ArgA	v	PheA	+	GLYG	v	BGALi	–	MTE	v
GGT	–	ProA	–	dMNE	v	ODC	v	IGLM	v
LysA	v	PyrA	–	dMAL	–	AARA	v	PHOS	+
dGAL	+	TyrA	v	SAC	v	PVATE	v	dRIB2	+
LeuA	+	APPA	–	NAG	v	PHC	+	OPS	+
ELLM	v	dGLU	+	URE	+	dMLT	+	dXYL	+

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

Table 8: QC Organism: *Neisseria gonorrhoeae* ATCC® 19424™ (for comprehensive quality control)

ArgA	+	PheA	v	GLYG	v	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	–	IGLM	–
LysA	v	PyrA	v	dMAL	v	AARA	–	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	+	NAG	v	PHC	–	OPS	v
ELLM	–	dGLU	v	URE	v	dMLT	–	dXYL	v

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

Table 9: QC Organism: *Neisseria lactamica* ATCC® 23970™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	+	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	-	PyrA	v	dMAL	v	AARA	+	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	v	NAG	v	PHC	v	OPS	-
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

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

Table 10: QC Organism: *Oligella urethralis* ATCC® 17960™ (for comprehensive quality control)

ArgA	–	PheA	+	GLYG	–	BGALi	v	MTE	–
GGT	+	ProA	+	dMNE	–	ODC	v	IGLM	+
LysA	v	PyrA	v	dMAL	v	AARA	v	PHOS	–
dGAL	–	TyrA	+	SAC	–	PVATE	+	dRIB2	–
LeuA	v	APPA	v	NAG	–	PHC	v	OPS	v
ELLM	+	dGLU	–	URE	v	dMLT	+	dXYL	–

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

Table 11: QC Organism: *Enterobacter aerogenes ATCC® 13048™ (for comprehensive quality control)**

ArgA	v	PheA	v	GLYG	v	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	+	PyrA	+	dMAL	v	AARA	v	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	v	NAG	+	PHC	v	OPS	v
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	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, *Enterobacter aerogenes*.

Note: *Enterobacter aerogenes* is an unclaimed taxa for the NH card.

*For 9.04 software users, *Klebsiella aerogenes* (formerly known as *Enterobacter aerogenes*).

Note: *Klebsiella aerogenes* is an unclaimed taxa for the NH card.

Table 12: QC Organism: *Paenibacillus polymyxa* ATCC® 7070™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	+	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	v	PyrA	v	dMAL	v	AARA	v	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	v	APPA	v	NAG	v	PHC	v	OPS	v
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

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

Note: *Paenibacillus polymyxa* is an unclaimed taxa for the NH card.

Table 13: QC Organism: *Staphylococcus epidermidis* ATCC® 12228™ (for comprehensive quality control)

ArgA	v	PheA	v	GLYG	v	BGALi	v	MTE	v
GGT	v	ProA	v	dMNE	v	ODC	v	IGLM	v
LysA	v	PyrA	v	dMAL	v	AARA	v	PHOS	v
dGAL	v	TyrA	v	SAC	v	PVATE	v	dRIB2	v
LeuA	–	APPA	v	NAG	v	PHC	v	OPS	v
ELLM	v	dGLU	v	URE	v	dMLT	v	dXYL	v

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

Note: *Staphylococcus epidermidis* is an unclaimed taxa for the NH card.

Limitations

The VITEK® 2 NH 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 NH 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 NH identification card was evaluated using 371 clinical and stock isolates of both commonly and rarely observed species of fastidious organisms. The reference identification was determined by 16S rRNA gene sequencing. Overall, the VITEK® 2 NH correctly identified 96.5% of these isolates, including 10.2% low discrimination with the correct species listed. Misidentifications occurred at 2.7% and no identifications occurred at 0.8%.

For 8.01 Software Users and Higher

In a multi-site clinical study*, the performance of the VITEK® 2 NH identification card was evaluated using 371 clinical and stock isolates of both commonly and rarely observed species of fastidious organisms. The reference identification was determined by 16S rRNA gene sequencing. Overall, the VITEK® 2 NH correctly identified 95.7% of these isolates, including 10.5% low discrimination with the correct species listed. Misidentifications occurred at 3.2% and no identifications occurred at 1.1%.

*Data on file at bioMérieux, Inc.

Organisms Identified

Claims are for all software users unless otherwise stated.

- *Actinobacillus ureae*
- *Aggregatibacter actinomycetemcomitans*
- *Aggregatibacter aphrophilus*
- *Aggregatibacter segnis*
- *Campylobacter coli*
- *Campylobacter fetus* ssp. *fetus*
- *Campylobacter jejuni* ssp. *jejuni*
- *Capnocytophaga* spp.
- *Cardiobacterium hominis*
- *Eikenella corrodens*
- *Gardnerella vaginalis*
- *Haemophilus haemolyticus*
- *Haemophilus influenzae*
- *Haemophilus parahaemolyticus*
- *Haemophilus parainfluenzae*
- *Kingella denitrificans*
- *Kingella kingae*
- *Moraxella (Branhamella) catarrhalis*
- *Neisseria cinerea*
- *Neisseria elongata*
- *Neisseria gonorrhoeae*
- *Neisseria lactamica*
- *Neisseria meningitidis*
- *Neisseria sicca*
- *Oligella urethralis*
- *Suttonella indologenes*

Additional Claims For 8.01 or Higher Software Users

- *Actinobacillus pleuropneumoniae*
- *Actinobacillus suis*
- *Histophilus somni*
- *Moraxella (Neisseria) ovis*
- *Neisseria weaveri*
- *Riemerella anatipestifer*

Additional Claims and Taxonomy Changes For 9.04 Software Users

- *Campylobacter lari*
- *Glaesserella parasuis*
- *Moraxella (Branhamella) catarrhalis* is now *Moraxella catarrhalis*
- *Ornithobacterium rhinotracheale*

Supplemental Tests

Table 14: NH Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
For 7.01 or Higher Software Users				

Abbreviation	Test Name	Description	Comments	Reference
25C	GROWTH AT 25degC	Ability of certain species to grow at 25°C.	N/A	14, 17
42C	GROWTH AT 42degC	Ability of certain species to grow at 42°C.	N/A	17
AGAR 35	GROWTH AT 35C (NUTRIENT AGAR)	Ability of certain species to grow at 35°C on nutrient agar.	N/A	16, 17
CAT	CATALASE	Colony placed on a drop of hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	N/A	11, 12, 14, 17, 25
COCCI	COCCUS SHAPE	Coccus (round) shape of the bacterial cell examined with gram stain.	N/A	11, 14, 17
DNAse	DNAse	Ability of certain species to produce DNAse resulting in the degradation of DNA.	N/A	12, 16, 17
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin that produces a black pigment in the presence of iron salts.	N/A	11, 17, 21
HEMO-horse	Horse blood hemolysis	Certain species possess hemolysins that give a transparent zone around the colonies on blood-based agars.	Hemolysis on horse blood is used as a differential test in the identification of *Haemophilus* spp.	17
HIP	HIPPURATE hydrolysis	Hydrolysis of sodium hippurate releases glycine that produces a blue colored product after addition of ninhydrin.	Of the *Campylobacter* species, only *Campylobacter jejuni* gives a positive hippurate reaction.	17
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlichs, DMAC reagents).	N/A	11, 17, 22
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.	17, 22
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.	N/A	11, 12, 17, 22, 24
ONPG	BETA-GALACTOSIDASE	Presence of beta-galactosidase cleaves o-nitrophenol-beta-D-galactopyranoside to produce a yellow colored product.	N/A	10, 11, 16, 17
OX	OXIDASE	Detection of the presence of cytochrome C.	N/A	11, 17, 19

Abbreviation	Test Name	Description	Comments	Reference
THAYER M.	Thayer Martin Agar	Growth on selective medium used in the differentiation of *Neisseria* spp.	Thayer Martin Agar, New York City Agar, or Chocolate Polyvitex Agar with VCAT can be used for this test.	11, 17
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	11, 17
V FACTOR	V FACTOR (NAD) REQUIREMENT	NAD required for growth.	N/A	16, 17, 19
X FACTOR	X FACTOR (HEMIN) REQUIREMENT	Hemin required for growth.	N/A	11, 17, 19
dFRUCTOSE dGALACTOSE dGLUCOSE LACTOSE dMALTOSE dMANNITOL dMANNOSE dRAFFINOSE SACCHAROSE dTREHALOSE	D-FRUCTOSE acidification D-GALACTOSE acidification D-GLUCOSE acidification LACTOSE acidification D-MALTOSE acidification D-MANNITOL acidification D-MANNOSE acidification D-RAFFINOSE acidification SACCHAROSE/SUCROSE acidification D-TREHALOSE acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	8, 9, 11, 12, 14, 17, 19, 21, 22, 23, 25, 26
For 8.01 or Higher Software Users				
22C	GROWTH AT 22degC	Ability of certain species to grow at 22 °C.	N/A	12
A-HEM	ALPHA HEMOLYSIS	Certain species produce incomplete hemolysis resulting in a green zone around colonies on blood based media.	N/A	3
MICROAER.	MICROAEROBIC GROWTH	Growth requiring a lower concentration of oxygen than is present in the atmosphere.	N/A	14
NO2	NITRITE REDUCTION	Test for the ability to reduce nitrite to nitrogen gas (NO2), nitrate to nitrite, and /or nitrogen gas from nitrate (NO3 to N2)	N/A	12
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on non-differential media.	N/A	3
dXYLOSE	D-XYLOSE acidifcation	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromcresol purple).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	8, 9, 11, 12, 14, 17, 19, 21, 22
For 9.04 Software Users				

Abbreviation	Test Name	Description	Comments	Reference
INDA	INDOXYL ACETATE HYDROLYSIS	Hydrolysis of indoxyl acetate forms indoxyl that produces a blue color in the presence of air.	N/A	24

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Use this Instructions for Use with VITEK® 2 Product No. 21346.

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	043902-04	Technical change	Updated for 9.04 software release Updated sections: • Specimen Preparation • Test Procedure • Additional Information on Lab Report • Quality Control • Comprehensive Quality Control • Performance Characteristics • Organisms Identified • References
2019-03	043902-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Testing of QC Organisms • Organisms Identified

Release Date	Part Number	Change Type	Change Summary
2016-10	043902-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual
2016-05	043902-01	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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