BIOMÉRIEUX

REF 21343

043908- 04 - 2021-04

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VITEK® 2 YST

℞ 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 Yeast identification card (YST) is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant yeasts and yeast-like organisms. The VITEK® 2 YST identification card is a single-use disposable. For a list of claimed species, see the Organisms Identified section.

Description

The YST card is based on established biochemical methods[1,6,8,10,11] and newly developed substrates. There are 46 biochemical tests measuring carbon source utilization, nitrogen source utilization, and enzymatic activities. Final results are available in approximately 18 hours.

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

Table 1: YST Well Contents

Well	Test	Mnemonic	Amount/Well
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	L-MALATE assimilation	lMLTa	0.15 mg
5	Leucine-ARYLAMIDASE	LeuA	0.0234 mg
7	ARGININE	ARG	0.15 mg
10	ERYTHRITOL assimilation	ERYa	0.3 mg
12	GLYCEROL assimilation	GLYLa	0.16 µL
13	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
14	BETA-N-ACETYL-GLUCOSAMINIDASE	BNAG	0.0408 mg
15	ARBUTIN assimilation	ARBa	0.3 mg
18	AMYGDALIN assimilation	AMYa	0.3 mg
19	D-GALACTOSE assimilation	dGALa	0.3 mg
20	GENTOBIOSE assimilation	GENa	0.3 mg
21	D-GLUCOSE assimilation	dGLUa	0.3 mg
23	LACTOSE assimilation	LACa	0.96 mg
24	METHYL-A-D-GLUCOPYRANOSIDE assimilation	MAdGa	0.3 mg
26	D-CELLOBIOSE assimilation	dCELa	0.3 mg
27	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
28	D-MALTOSE assimilation	dMALa	0.3 mg
29	D-RAFFINOSE assimilation	dRAFa	0.3 mg
30	PNP-N-acetyl-BD-galactosaminidase 1	NAGA1	0.0306 mg

Well	Test	Mnemonic	Amount/Well
32	D-MANNOSE assimilation	dMNEa	0.3 mg
33	D-MELIBIOSE assimilation	dMELa	0.3 mg
34	D-MELEZITOSE assimilation	dMLZa	0.3 mg
38	L-SORBOSE assimilation	lSBEa	0.3 mg
39	L-RHAMNOSE assimilation	lRHAa	0.3 mg
40	XYLITOL assimilation	XLTa	0.3 mg
42	D-SORBITOL assimilation	dSORa	0.1875 mg
44	SACCHAROSE/SUCROSE assimilation	SACa	0.3 mg
45	UREASE	URE	0.15 mg
46	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
47	D-TURANOSE assimilation	dTURa	0.3 mg
48	D-TREHALOSE assimilation	dTREa	0.3 mg
49	NITRATE assimilation	NO3a	0.03 mg
51	L-ARABINOSE assimilation	lARAa	0.3 mg
52	D-GALACTURONATE assimilation	dGATa	0.15 mg
53	ESCULIN hydrolysis	ESC	0.225 mg
54	L-GLUTAMATE assimilation	lGLTa	0.15 mg
55	D-XYLOSE assimilation	dXYLa	0.3 mg
56	DL-LACTATE assimilation	LATa	0.15 mg
58	ACETATE assimilation	ACEa	0.15 mg
59	CITRATE (SODIUM) assimilation	CITa	0.15 mg
60	GLUCURONATE ASSIMILATION	GRTas	0.15 mg
61	L-PROLINE assimilation	lPROa	0.15 mg
62	2-KETO-D-GLUCONATE assimilation	2KGa	0.15 mg
63	N-ACETYL-GLUCOSAMINE assimilation	NAGa	0.15 mg
64	D-GLUCONATE assimilation	dGNTa	0.15 mg

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

Precautions

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

- For *In Vitro* Diagnostic Use Only.
- For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For professional use only.
- Suspensions not within the appropriate zone on the VITEK® 2 DENSICHEK™ Plus or the VITEK® 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.

- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting the identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems, following the instructions contained in these Instructions for Use.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the cassette has been processed to ensure proper filling of card.
  - VITEK® 2 60 or VITEK® 2 XL: Eject improperly filled cards.
  - VITEK® 2 Compact: Do not load improperly filled cards.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. (See the Supplemental Tests section.)
- Do not clean saline dispenser with chemical agents. The use of chemical agents may impact card performance.

Warning: All patient specimens, microbial cultures, and inoculated VITEK® 2 cards, along with associated materials, are potentially infectious and should be treated with universal precautions.[13,17]

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

Storage Conditions

Upon receipt, store VITEK® 2 YST 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
YST	SDA[2] SDA-E[2] TSAB[2] CBA IMA TSA CHBA CID CPS ID	18 to 72 hours	30°C to 37°C aerobic, non-CO_2 (or 25°C to 30°C for species that do not tolerate 30°C to 37°C)	1.80 to 2.20 McFarland Standard	N/A[3]	≤ 30 minutes

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

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

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

[3]N/A = not applicable

Culture Requirements Table — Media Abbreviations

CBA = Columbia Blood Agar with 5% Sheep Blood

CHBA = Columbia Horse Blood Agar

CID = chromID™Candida (Candida ID2 agar)

CPS ID = chromID™ CPS (CPS ID agar)

IMA = Inhibitory Mould Agar

SDA = Sabouraud Dextrose Agar

SDA-E = Sabouraud Dextrose Agar (Emmons)

TSA = Trypticase Soy Agar

TSAB = Trypticase Soy Agar with 5% Sheep Blood

Test Procedure

Materials

When used with VITEK® 2 instrumentation, the YST card is a complete system for routine identification testing of most clinically significant yeasts and yeast-like organisms.

Required materials are:

- VITEK® 2 YST 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 the homogenous organism suspension with a density equivalent to a McFarland No. 1.80 to 2.20 using a calibrated VITEK® 2 DENSICHEK™ Plus or VITEK® 2 DENSICHEK™.
   Note: Filamentous species may pick up small amounts of glucose from the isolation media. This has the potential for causing false positive reactions. Avoid scraping or rubbing the agar when preparing the organism suspension. For strains that do not readily form a smooth suspension in saline, it is recommended that a wet swab be used to make the suspension. Do not rub the agar surface when preparing a suspension using a wet swab.

   Note: Age of suspension must not exceed 30 minutes before inoculating card.
4. Place the suspension tube and YST 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 Slashline (Mixed) Taxa Identification table belong to the YST slashline taxa.

Table 3: Slashline (Mixed) Taxa Identification

Slashline Name	Species Belonging to the Slashline
C. inconspicua/C. lambica	*Candida inconspicua* *Candida lambica*
Kloeckera spp.	*Kloeckera apiculata* *Kloeckera apis* *Kloeckera japonica*
*Rhodotorula glutinis/mucilaginosa/(Crypto. laurentii)**	*Rhodotorula glutinis* *Rhodotorula mucilaginosa*

*This is also a pseudoslashline.

Certain species may belong to a pseudoslashline (mixed) taxa identification. A pseudoslashline indicates a rare isolate or rare occurrence of the same biopattern. Supplemental tests may be used to separate pseudoslashline taxa. The species in Pseudoslashline Taxa Table belong to the pseudoslashline taxa.

Table 4: Pseudoslashline Taxa

Pseudoslashline name	Species Belonging to Pseudoslashline
Candida sake/(C. famata/C. lipolytica)	*Candida famata* *Candida lipolytica*
*Rhodotorula glutinis/mucilaginosa/(Crypto. laurentii)**	*Cryptococcus laurentii*

*This is also a slashline.

Table 5: 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 6: Notes Associated with Certain Taxa

Taxa	Note		
For 7.01 or Higher Software Users			
Candida krusei	Possibility of *C. inconspicua* or *C. lambica*. Isolates of these infrequent species may be misidentified as *C. krusei*; in order to rule them out, perform the following tests:		
	HYPH/PH	dGLUf	dXYLOSEa
	-	-	-
	+	+	-
	+	+	+
Rhodotorula glutinis/ mucilaginosa *Cryptococcus laurentii*	Possibility of *Cryptococcus albidus*		
Geotrichum klebahnii	Possibility of *Geotrichum candidum*		
Cryptococcus neoformans	Critical pathogen The species identified may have significance to patient or sample outcome and can be stopped for review.		
For 8.01 or Higher Software Users			
Candida glabrata	*Candida nivariensis* and *Candida bracarensi*s have similar morphology and biochemical utilization patterns compared to *Candida glabrata*, and they exhibit similar multi-resistance to anti-fungals. These three species may be differentiated from each other by molecular methods, such as MALDI-TOF, since phenotypic tests do not differentiate them. Retrospective studies of culture collections showed that up to 0.1% of isolates previously identified as *C. glabrata* were strains of *C. nivariensis* and that 0.2-2.2% of isolates previously identified as *C. glabrata* were strains of *C. bracarensis*.[3,9]		

<table>
<tr><th>Taxa</th><th colspan="3">Note</th></tr>
<tr><td colspan="4">For 9.02 or Higher Software Users</td></tr>
<tr><td>Candida parapsilosis</td><td colspan="3">Candida metapsilosis and Candida orthopsilosis have similar morphology and biochemical utilization patterns compared to Candida parapsilosis. Although data are limited, antifungal susceptibility testing of both species show a similar profile to that of C. parapsilosis. These three species may be differentiated from each other by molecular methods, such as MALDI-TOF, since phenotypic tests do not differentiate them. C.orthopsilosis and C. metapsilosis are rare clinical isolates but are reported emerging pathogens associated with candidemia.</td></tr>
<tr><td colspan="4">For 9.04 Software Users</td></tr>
<tr><td rowspan="4">Geotrichum klebahnii</td><td colspan="3">Possibility of Geotrichum candidum.
Isolates of G. klebahnii may be misidentified as G. candidum; in order to rule out G. candidum, ITS sequencing may be performed.
Additionally, the following tests may be performed:</td></tr>
<tr><td></td><td>Growth at 35°C</td><td>Morphology</td></tr>
<tr><td>Geotrichum candidum</td><td>+</td><td>Hyphae fragments into arthroconidia with no specific arrangements</td></tr>
<tr><td>Geotrichum klebahnii</td><td>-</td><td>Rounded conidia occur in long chains at the tip and also as branches from the main hypha</td></tr>
<tr><td rowspan="6">Rhodotorula glutinis / mucilaginosa

Crypto. laurentii</td><td colspan="3">Possibility of Cryptococcus albidus.
Isolates of these species may be misidentified as Cryptococcus albidus; in order to rule them out, perform the following tests:</td></tr>
<tr><td></td><td>INOSITOLa</td><td>NITRATEa</td></tr>
<tr><td>Cryptococcus albidus</td><td>+</td><td>+</td></tr>
<tr><td>Cryptococcus laurentii</td><td>+</td><td>-</td></tr>
<tr><td>Rhodotorula glutinis</td><td>-</td><td>+</td></tr>
<tr><td>Rhodotorula mucilaginosa</td><td>-</td><td>-</td></tr>
<tr><td>Candida duobushaemulonis

Candida haemuloni

Candida haemuloni var. vulneris</td><td colspan="3">Possibility of Candida auris.

Isolates of C. auris may be misidentified as C. duobushaemulonis, C. haemuloni, and C. haemuloni var. vulneris; in order to rule out C. auris, ITS sequencing may be performed.</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.”

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

- *Candida sake*
- *Candida zeylanoides*
- *Malassezia furfur*
- *Malassezia pachydermatis*

For 7.01 Software Users

- *Zygosaccharomyces bailii*

For 8.01 or Higher Software Users

- *Zygosaccharomyces* species

Quality Control

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

Note: *Staphylococcus epidermidis* ATCC® 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. 1.80 to 2.20.

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. Yeast: Streak onto Sabouraud dextrose agar (SDA) or SDA (Emmons) and incubate aerobically at 35°C to 37°C for 18 to 24 hours, or until sufficient growth is achieved, except for:
   - *Prototheca wickerhamii* ATCC® 16529™, *Zygosaccharomyces parabailii* ATCC® MYA-4549™, and *Kloeckera japonica* ATCC® 58370™,which are incubated at 28°C to 30°C.
   - *Sporobolomyces salmonicolor* ATCC® MYA-4550™, which is incubated at 25°C to 27°C.
3. Bacteria: Use trypticase soy agar with 5% sheep blood (TSAB). Incubate aerobically at 35°C to 37°C for 18 to 24 hours.
4. Check for purity. Perform second subculture for testing.
5. Yeast: Streak onto SDA or SDA (Emmons) and incubate aerobically at 35°C to 37°C for 18 to 24 hours, or until sufficient growth is achieved, except for:
   - *Prototheca wickerhamii* ATCC® 16529™, *Zygosaccharomyces parabailii* ATCC® MYA-4549™, and *Kloeckera japonica* ATCC® 58370™, which are incubated at 28°C to 30°C.
   - *Sporobolomyces salmonicolor* ATCC® MYA-4550™, which is incubated at 25°C to 27°C.
6. Bacteria: Use trypticase soy agar with 5% sheep blood (TSAB). Incubate aerobically at 35°C to 37°C for 18 to 24 hours.

Short-Term Storage Conditions

1. Streak to a SDA or SDA (Emmons) plate or slant for yeast QC organisms and TSAB for bacteria QC organisms.
2. Incubate for 24 hours at the appropriate temperature.
3. Refrigerate at 2°C to 8°C for up to one week.
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 appropriate medium twice before running QC.

Note: Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.

Streamlined Quality Control

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

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

Testing may be conducted using *Candida albicans* ATCC® 14053™ and evaluating the performance of the NAGA1 well. Testing at bioMérieux, Inc. has shown that the NAGA1 well is the most labile well on the YST card and *Candida albicans* ATCC® 14053™ is the most sensitive strain for detecting degradation of this well with a false negative reaction. (See YST 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.[5]

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:[4]

- 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.

YST Quality Control Tables:

***Candida albicans* ATCC® 14053™** (for streamlined or comprehensive quality control)

***Candida glabrata* ATCC® MYA-2950™** (for comprehensive quality control)

***Candida lusitaniae* ATCC® 34449™** (for comprehensive quality control)

***Candida utilis* ATCC® 9950™** (for comprehensive quality control)

***Kloeckera japonica* ATCC® 58370™** (for comprehensive quality control)

***Prototheca wickerhamii* ATCC® 16529™** (for comprehensive quality control)

***Sporobolomyces salmonicolor* ATCC® MYA-4550™** (for comprehensive quality control)

***Trichosporon mucoides* ATCC® 204094™** (for comprehensive quality control)

***Oligella ureolytica* ATCC® 43534™** (for comprehensive quality control)

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

***Zygosaccharomyces parabailii* ATCC® MYA-4549™** (for comprehensive quality control)

Note: The comprehensive quality control strain *Zygosaccharomyces bailii* ATCC® MYA-4549™ had a taxonomic update to *Zygosaccharomyces parabailii* ATCC® MYA-4549™. This strain identifies as *Zygosaccharomyces bailii* in the 7.01 software and as *Zygosaccharomyces* species in the 8.01 or higher software.

The YST 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.

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

Table 7: QC Organism: *Candida albicans* ATCC® 14053™ (for streamlined or comprehensive quality control)

LysA	-	ARBa	-	GGT	v	IRHAa	-	NO3a	-	CITa	+
IMLTa	+	AMYa	v	dMALa	+	XLTa	+	IARAa	v	GRTas	v

LeuA	+	dGALa	+	dRAFa	-	dSORa	+	dGATa	v	IPROa	+
ARG	+	GENa	-	NAGA1	+	SACa	+	ESC	-	2KGa	+
ERYa	-	dGLUa	+	dMNEa	+	URE	-	IGLTa	+	NAGa	+
GLYLa	v	LACa	-	dMELa	-	AGLU	+	dXYLa	+	dGNTa	+
TyrA	v	MAdGa	+	dMLZa	-	dTURa	+	LATa	+		
BNAG	-	dCELa	-	ISBEa	-	dTREa	+	ACEa	+		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Note: The NAGA1 well is used for streamlined quality control.

Table 8: QC Organism: *Candida glabrata* ATCC® MYA-2950™ (for comprehensive quality control)

LysA	–	ARBa	–	GGT	–	IRHAa	–	NO3a	v	CITa	–
lMLTa	–	AMYa	v	dMALa	–	XLTa	v	lARAa	–	GRTas	–
LeuA	v	dGALa	–	dRAFa	v	dSORa	–	dGATa	–	IPROa	v
ARG	–	GENa	v	NAGA1	–	SACa	–	ESC	–	2KGa	–
ERYa	–	dGLUa	v	dMNEa	v	URE	–	lGLTa	v	NAGa	–
GLYLa	–	LACa	–	dMELa	–	AGLU	–	dXYLa	–	dGNTa	v
TyrA	–	MAdGa	–	dMLZa	v	dTURa	–	LATa	–		
BNAG	v	dCELa	v	ISBEa	–	dTREa	+	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 9: QC Organism: *Candida lusitaniae* ATCC® 34449™ (for comprehensive quality control)

LysA	v	ARBa	+	GGT	v	IRHAa	+	NO3a	v	CITa	+
lMLTa	+	AMYa	+	dMALa	v	XLTa	v	lARAa	–	GRTas	v
LeuA	+	dGALa	v	dRAFa	–	dSORa	+	dGATa	v	IPROa	+
ARG	v	GENa	+	NAGA1	v	SACa	v	ESC	+	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	+	NAGa	+
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	+	LATa	v		
BNAG	v	dCELa	+	ISBEa	+	dTREa	v	ACEa	+		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 10: QC Organism: QC Organism *Candida utilis* ATCC® 9950™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	IRHAa	v	NO3a	+	CITa	v
lMLTa	v	AMYa	+	dMALa	v	XLTa	–	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	+	dSORa	–	dGATa	v	IPROa	v
ARG	v	GENa	v	NAGA1	–	SACa	+	ESC	v	2KGa	–
ERYa	v	dGLUa	+	dMNEa	+	URE	v	lGLTa	v	NAGa	–
GLYLa	+	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	+	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 11: QC Organism: *Kloeckera japonica* ATCC® 58370™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	IRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	–	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	–		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 12: QC Organism: *Prototheca wickerhamii* ATCC® 16529™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	–	IRHAa	v	NO3a	–	CITa	–
lMLTa	–	AMYa	–	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	–	NAGA1	v	SACa	–	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	+	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	–	MAdGa	–	dMLZa	–	dTURa	–	LATa	v		
BNAG	–	dCELa	–	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 13: QC Organism: *Sporobolomyces salmonicolor* ATCC® MYA-4550™ (for comprehensive quality control)

LysA	+	ARBa	v	GGT	v	IRHAa	v	NO3a	v	CITa	v
lMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 14: QC Organism: *Trichosporon mucoides* ATCC® 204094™ (for comprehensive quality control)

LysA	v	ARBa	+	GGT	+	IRHAa	+	NO3a	v	CITa	v
lMLTa	v	AMYa	–	dMALa	+	XLTa	+	lARAa	+	GRTas	+
LeuA	v	dGALa	+	dRAFa	+	dSORa	v	dGATa	+	lPROa	v
ARG	+	GENa	+	NAGA1	+	SACa	v	ESC	+	2KGa	+
ERYa	+	dGLUa	v	dMNEa	v	URE	+	lGLTa	v	NAGa	v
GLYLa	v	LACa	+	dMELa	+	AGLU	+	dXYLa	+	dGNTa	+
TyrA	+	MAdGa	+	dMLZa	+	dTURa	v	LATa	+		
BNAG	+	dCELa	+	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 15: QC Organism: *Oligella ureolytica* ATCC® 43534™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	IRHAa	v	NO3a	v	CITa	v
IMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	–	dMNEa	–	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Note: *Oligella ureolytica* is an unclaimed taxa for the YST card.

Table 16: QC Organism: *Staphylococcus epidermidis* ATCC® 12228™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	IRHAa	v	NO3a	v	CITa	v
IMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	–	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	v
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	v	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	v
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	v	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

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

Table 17: QC Organism: *Zygosaccharomyces parabailii* ATCC® MYA-4549™ (for comprehensive quality control)

LysA	v	ARBa	v	GGT	v	IRHAa	v	NO3a	v	CITa	v
IMLTa	v	AMYa	v	dMALa	v	XLTa	v	lARAa	v	GRTas	v
LeuA	v	dGALa	v	dRAFa	v	dSORa	v	dGATa	v	lPROa	–
ARG	v	GENa	v	NAGA1	v	SACa	v	ESC	v	2KGa	v
ERYa	v	dGLUa	v	dMNEa	v	URE	v	lGLTa	–	NAGa	v
GLYLa	v	LACa	v	dMELa	v	AGLU	v	dXYLa	v	dGNTa	–
TyrA	v	MAdGa	v	dMLZa	v	dTURa	v	LATa	v		
BNAG	v	dCELa	v	ISBEa	v	dTREa	–	ACEa	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

For 7.01 Software Users

Zygosaccharomyces parabailii ATCC® MYA-4549™ identifies as *Zygosaccharomyces bailii*.

For 8.01 or Higher Software Users
Zygosaccharomyces parabailii ATCC® MYA-4549™ identifies as *Zygosaccharomyces* species.

Limitations

The VITEK® 2 YST card cannot be used with a direct clinical specimen, sample, or another source 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 YST 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 YST identification card was evaluated using 623 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with API® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 98.2% of the isolates, including 8.1% low discrimination with the correct species listed. Misidentifications occurred at 1.5% and no identifications occurred at 0.3%.

For 8.01 and 9.01 Software Users

In a multi-site clinical study*, the performance of the VITEK® 2 YST identification card was evaluated using 621 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with API® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 97.9% of the isolates, including 7.2% low discrimination with the correct species listed. Misidentifications occurred at 1.8% and no identifications occurred at 0.5%.

For 9.02 Software Users or Higher

In a multi-site clinical study*, the performance of the VITEK® 2 YST identification card was evaluated using 621 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with API® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 97.6% of the isolates, including 6.0% low discrimination with the correct species listed. Misidentifications occurred at 1.9% and no identifications occurred at 0.5%.

*Data on file at bioMérieux, Inc.

Organisms Identified

Claims are for all software users unless otherwise stated.

- *Candida albicans*
- *Candida boidinii*
- *Candida catenulata*
- *Candida colliculosa*
- *Candida dubliniensis*
- *Candida famata*
- *Candida freyschussii*
- *Candida glabrata*
- *Candida guilliermondii*
- *Candida haemulonii*
- *Candida inconspicua/Candida lambica*
- *Candida intermedia*
- *Candida kefyr*
- *Candida krusei*
- *Candida lipolytica*
- *Candida lusitaniae*

- *Candida magnoliae*
- *Candida norvegensis*
- *Candida parapsilosis*
- *Candida pelliculosa*
- *Candida pulcherrima*
- *Candida rugosa*
- *Candida sake*
- *Candida spherica*
- *Candida tropicalis*
- *Candida utilis*
- *Candida zeylanoides*
- *Cryptococcus albidus*
- *Cryptococcus laurentii*
- *Cryptococcus neoformans*
- *Cryptococcus terreus*
- *Cryptococcus uniguttulatus*
- *Geotrichum klebahnii*
- *Kloeckera* spp.
- *Kodamaea ohmeri*
- *Malassezia furfur*
- *Malassezia pachydermatis*
- *Millerozyma farinosa* (formerly known as *Pichia farinosa*)
- *Prototheca wickerhamii*
- *Prototheca zopfii*
- *Rhodotorula glutinis/Rhodotorula mucilaginosa*
- *Rhodotorula minuta*
- *Saccharomyces cerevisiae*
- *Saprochaete capitata* (formerly known as *Geotrichum capitatum*)
- *Sporobolomyces salmonicolor*
- *Stephanoascus ciferrii*
- *Trichosporon asahii*
- *Trichosporon inkin*
- *Trichosporon mucoides*
- *Zygosaccharomyces bailii*

Additional Claims For 8.01 or Higher Software Users

- *Candida auris*
- *Candida ciferrii* (formerly known as *Stephanoascus ciferrii*)
- *Candida duobushaemulonii*
- *Candida haemulonii* var *vulnera*
- *Cryptococcus gattii*
- *Zygosaccharomyces* species (includes *Zygosaccharomyces bailii*; *Zygosaccharomyces bailii* is no longer a single species claim)

Taxonomy Changes For 9.04 Software Users

- *Candida duobushaemulonis* (formerly known as *Candida duobushaemulonii*)
- *Candida haemuloni* (formerly known as *Candida haemulonii*)
- *Candida haemuloni* var. *vulnera* (formerly known as *Candida haemulonii* var. *vulnera*)
- *Candida sphaerica* (formerly known as *Candida spherica*)

Supplemental Tests

Table 18: YST Supplemental Tests

Abbreviation	Test Name	Description	Comment	Reference
For 7.01 or Higher Software Users				
2KG	2-KETO-D-GLUCONATE	Ability to use 2-keto-D-gluconate as a sole carbon source.	N/A	2, 6, 10
4ASCOSPOR.	4 Ascospores	Microscopic examination for the presence of four ascospores per ascus.	N/A	2, 6, 10
Apic.CELLS	APICULATE CELLS	Microscopic examination for the presence of apiculate (lemon-drop shaped) cells.	N/A	2, 6, 10
Arthro.	Arthroconidia	Microscopic examination for the presence of arthroconidia (fragmentation of hyphae into rectangular cells) on morphology agar (e.g., cornmeal agar).	N/A	2, 6, 10
CAROTENOID	CAROTENOID PIGMENT	Presence of red, pink, or orange pigment on Sabouraud dextrose agar.	N/A	2, 6, 7, 10, 15, 16
dCELLOB.a	D-CELLOBIOSE Assimilation	Ability to use cellobiose as the sole carbon source.	N/A	2, 6, 7, 10, 15, 16
CHLS	Chlamydospores	Microscopic examination for the presence of chlamydospores on morphology agar (e.g., cornmeal agar).	N/A	2, 6, 10
DULCITOLa	DULCITOL Assimilation	Ability to use dulcitol (galactitol) as the sole carbon source.	N/A	2, 6, 10
ERYTHRIT.a	ERYTHRITOL Assimilation	Ability to use erythritol as the sole carbon source.	N/A	2, 6, 10
dGALACT.a	D-GALACTOSE Assimilation	Ability to use galactose as the sole carbon source.	N/A	2, 6, 10, 15

Abbreviation	Test Name	Description	Comment	Reference
dGALf	D-GALACTOSE Fermentation	Production of gas from fermentation of galactose.	N/A	2, 6, 10
dGLUf	D-GLUCOSE Fermentation	Production of gas from fermentation of glucose.	N/A	2, 6, 10
w/o OIL	GROWTH WITHOUT OIL	Ability to grow on Sabouraud dextrose agar without the addition of a fatty acid source (e.g., olive oil).	N/A	2, 6, 7, 10, 16
HYPH/PH	HYPHAE/ PSEUDOHYHPAE	Microscopic examination for the presence of filaments on morphology agar (e.g., cornmeal agar).	N/A	2, 6, 7, 10, 16
INOSITOLa	myo-INOSITOL Assimilation	Ability to use inositol as the sole carbon source.	N/A	2, 6, 10, 15
NITRATEa	NITRATE Assimilation	Ability to use potassium nitrate as the sole nitrogen source.	N/A	2, 6, 7, 10, 14, 16
LACTOSEa	LACTOSE Assimilation	Ability to use lactose as the sole carbon source.	N/A	2, 6, 10
lARABIN.a	L-ARABINOSE Assimilation	Ability to use arabinose as the sole carbon source.	N/A	2, 6, 10
dMALTOSEa	D-MALTOSE Assimilation	Ability to use maltose as the sole carbon source.	N/A	2, 6, 10
dMALf	D-MALTOSE Fermentation	Production of gas from fermentation of maltose.	N/A	2, 6, 10
dMELIBIO.a	D-MELIBIOSE Assimilation	Ability to use melibiose as the sole carbon source.	N/A	2, 6, 10
OX_Phe	Phenol Oxidase	Ability to produce brown to black pigment from phenol oxidase activity on phenolic substrates (e.g., caffeic acid or birdseed agar).	N/A	12
dRAFFIN.a	D-RAFFINOSE Assimilation	Ability to use raffinose as the sole carbon source.	N/A	2, 6, 7, 10, 16
lRHAMNOSEa	L-RHAMNOSE Assimilation	Ability to use rhamnose as the sole carbon source.	N/A	2, 6, 10

Abbreviation	Test Name	Description	Comment	Reference
SACCHAR.a	SACCHAROSE/ SUCROSE Assimilation	Ability to use sucrose as the sole carbon source.	N/A	2, 6, 10
SACf	SACCAROSE/ SUCROSE Fermentation	Production of gas from fermentation of sucrose.	N/A	2, 6, 10
SATELLITE	SATELLITE behavior	Formation of satellite colonies on Sabouraud dextrose agar.	N/A	2, 6, 10
Sphe.CELLS	Spherical CELLS	Microscopic examination for the presence of spherical cells.	*Candida famata* can be differentiated from *Candida guilliermondii* by the shape of the cells. *Candida famata* has mostly spherical cells while *Candida guilliermondii* has mostly ovoid cells.	2, 6, 10
SPORANGE	SPORANGE	Microscopic examination for the presence of sporangia.	N/A	11
dTREHAL.a	D-TREHALOSE Assimilation	Ability to use trehalose as the sole carbon source.	N/A	2, 6, 10
dTREf	D-TREHALOSE Fermentation	Production of gas from fermentation of trehalose.	N/A	2, 6, 10
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	N/A	2, 6, 10
dXYLOSEa	D-XYLOSE Assimilation	Ability to use xylose as the sole carbon source.	N/A	2, 6, 10
For 8.01 or Higher Software Users				
37C	GROWTH AT 37C	Ability to grow at 37°C.	N/A	15
42C	Growth at 42degC	Ability to grow at 42°C.	N/A	2, 15
Cser.AorD	Capsular Serotype A or D	Agglutination tests for capsular serotype A , D or AD.	N/A	18
Cser.BorC	Capsular Serotype B or C	Agglutination tests for capsular serotype B or C.	N/A	18

Abbreviation	Test Name	Description	Comment	Reference
GLYCEROLa	Glycerol assim.	Ability to use glycerol as the sole carbon source.	N/A	2, 15
INUa	INULIN assimilation	Ability to use inulin as the sole carbon source.	N/A	15
RAFf	RAFFINOSE fermentation	Production of gas from fermentation of raffinose.	N/A	2, 15

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Use this Instructions for Use with VITEK® 2 Product No. 21343.

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	043908-04	Technical change	Updated for 9.04 software release. Updated sections: • Specimen Preparation • Procedure • Additional Information on Lab Report • Comprehensive Quality Control • Performance Characteristics • Organisms Identified
2019-03	043908-03	Technical change	Updated for 9.02 software release. Updated sections: • Intended Use • Precautions • Culture Requirements • Additional Information on Lab Report • Testing of QC Organisms • Performance Characteristics • Organisms Identified • References
2016-10	043908-02	Technical change	• Updated content to reflect the 8.01 Product Information Manual

Release Date	Part Number	Change Type	Change Summary
2016-05	043908-01	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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