

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Staphylococcus aureus subsp. aureus

Catalog Number: 0827 Lot Number: 827-200

Reference Number: ATCC® 6538P™*

See attached ID System results document.

Purity: Pure

Passage from Reference: 2

Expiration Date: 2019/1/31

Release Information:

Quality Control Technologist: Mary L Bowman

Release Date: 2017/3/31

Performance

Medium: **Macroscopic Features:**

Medium to large, convex, pale yellow and some gold, creamy, opaque, beta SBAP

Method: Microscopic Features:

Gram positive cocci occurring singly, in pairs and in irregular clusters. Gram Stain (1)

ID System: MALDI-TOF Other Features/ Challenges: Results

(1) Catalase(3% Hydrogen Peroxide): positive

(1) Coagulase(rabbit plasma-tube): positive

(1) Beta Lactamase (Cefinase Disk): negative

Amanda Kuperus **Quality Control Manager AUTHORIZED SIGNATURE**

Disclaimer: The last digit(s) of the lot number appearing on the product label and packing slip are merely a packaging event number. The lot number displayed on this certificate is the actual base lot

Note for Vitek®: Although the Vitek® panel uses many conventional tests, the unique environment of the card, combined with the short incubation period, may produce results that differ from published results obtained by other methods.

Refer to the enclosed product insert for instructions, intended use and hazard/safety information.

Individual products are traceable to a recognized culture collection.



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(1) These tests are accredited to ISO/IEC 17025:2005.

TESTING CERT #2655.01

Bruker Daltonik MALDI Biotyper Classification Results





| Range | Interpretation | Symbols | Color |
|-------------|-------------------------------------|---------|--------|
| 2.00 - 3.00 | High-confidence identification | (+++) | green |
| 1.70 - 1.99 | Low-confidence identification | (+) | yellow |
| 0.00 - 1.69 | No Organism Identification Possible | (-) | red |

Meaning of Consistency Categories (A - C)

| Category | Interpretation |
|----------|--|
| | High consistency: The best match is a high-confidence identification. The second-best match is (1) a high-confidence identification in which the species is identical to the best match, (2) a low-confidence identification in which the species or genus is identical to the best match, or (3) a non-identification. |
| (B) | Low consistency: The requirements for high consistency are not met. The best match is a high- or low-confidence identification. The second-best match is (1) a high- or low-confidence identification in which the genus is identical to the best match or (2) a non-identification. |
| (C) | No consistency: The requirements for high or low consistency are not met. |

Sample Name: Staphylococcus aureus subsp. aureus

Sample Description: 0827 Sample ID: 827-200

Sample Creation Date/Time: 2017-03-22T13:57:43.640 MB

Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

| Sample Name | Sample ID | Organism (best match) | Score Value | | |
|------------------|-----------|-----------------------|-------------|--|--|
| B11 (+++) (A) | 827-200 | Staphylococcus aureus | 2.44 | | |

Comments:

| N/A | | |
|-----|--|--|
| | | |



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Candida glabrata

Catalog Number: 0122

Lot Number: 122-27

Reference Number: ATCC® MYA-2950™*

Purity: Pure

Passage from Reference: 2

Expiration Date: 2019/7/31

Release Information:

Quality Control Technologist: Kieshia L Negen

Release Date: 2017/10/11

Performance

Macroscopic Features:

Large, circular, convex, entire edge, white, glistening

Microscopic Features:

Gram positive, oval, budding yeast cells

Medium:

SAB DEX EMMONS

Method:

Gram Stain (1)

ID System: Vitek YST (1)

See attached ID System results document.

Amanda Kuperus

Quality Control Manager

AUTHORIZED SIGNATURE

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TESTING CERT #2655.01

Laboratory Report

bioMerieux Customer: 1012555

System #: 521711

Printed Oct 10, 2017 17:05 CDT Printed by: kln

Isolate Group: 122-27 Bench: TB

Card Type: YST Testing Instrument: 000017919CE3 (15220)

Bionumber: 4000104000201110 Organism Quantity:

| organioni Quantity: | |
|---------------------|--|
| | |
| Comments: | |
| Comments. | |
| | |

| Identification | Card: | Oct 7, 2017, 03:21 | | 243397610 | Expires: | Nov 2, 2017 13:00 CDT | | | |
|--|------------------|--------------------|-------------|-----------|-------------------|--------------------------|--|--|--|
| Information | Completed: | | | Final | Analysis Time: | 18.25 hours | | | |
| | 99% Probabil | lity | Candida gla | abrata | | | | | |
| Selected Organism | Bionumber: | 4000104000201110 | | | Confidence: | Excellent identification | | | |
| SRF Organism | • | | | | | | | | |
| Analysis Organisms and Te | ests to Separate | : : | | | | | | | |
| Analysis Messages: | | | | | | | | | |
| Contraindicating Typical Biopattern(s) | | | | | | | | | |

| Bio | Biochemical Details | | | | | | | | | | | | | | | | |
|-----|---------------------|---|----|-------|---|----|-------|---|----|-------|---|----|-------|---|----|-------|----------|
| 3 | LysA | - | 4 | IMLTa | - | 5 | LeuA | + | 7 | ARG | - | 10 | ERYa | - | 12 | GLYLa | - |
| 13 | TyrA | - | 14 | BNAG | - | 15 | ARBa | - | 18 | AMYa | - | 19 | dGALa | - | 20 | GENa | Ţ- |
| 21 | dGLUa | + | 23 | LACa | - | 24 | MAdGa | - | 26 | dCELa | - | 27 | GGT | - | 28 | dMALa | - |
| 29 | dRAFa | - | 30 | NAGA1 | - | 32 | dMNEa | + | 33 | dMELa | - | 34 | dMLZa | - | 38 | ISBEa | - |
| 39 | IRHAa | - | 40 | XLTa | - | 42 | dSORa | - | 44 | SACa | - | 45 | URE | - | 46 | AGLU | <u> </u> |
| 47 | dTURa | - | 48 | dTREa | + | 49 | NO3a | - | 51 | IARAa | - | 52 | dGATa | - | 53 | ESC | - |
| 54 | IGLTa | + | 55 | dXYLa | - | 56 | LATa | - | 58 | ACEa | + | 59 | CITa | - | 60 | GRTas | - |
| 61 | IPROa | + | 62 | 2KGa | - | 63 | NAGa | - | 64 | dGNTa | - | | | | | | |



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Mycoplasma bovis

Catalog Number: 01053 Lot Number: 1053-10

Reference Number: ATCC® 25025™* Purity: > 99.9% of Total Pellet CFU Passage from Reference: 3

Expiration Date: 2019/2/28

Release Information:

Medium:

Quality Control Technologist: Carol J Stanoch

Release Date: 2017/5/4

Performance

Macroscopic Features:

Growth can be noted macroscopically. Microscopically, colonies are circular, Mycoplasma Agar granular, and approximately 100-250 microns in diameter

Microscopic Features: Method:

ID System: MEI None Other Features/ Challenges: Results

Mycoplasma Broth: growth evident as slight turbidity in the broth - growth upon subculture to Mycoplasma Agar See attached ID System results document.

> Amanda Kuperus **Quality Control Manager AUTHORIZED SIGNATURE**

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Molecular Epidemiology, Inc. Sample Analysis Report



F09/MB450/09

| Customer ID Number | 4081 | 1-3201 Sample 04/19/20 | | 04/19/2017 | MEI Re | port # | R17050 | 0230592-01 | Date Reported | d | 05/03/2017 | | |
|---|----------------------------------|------------------------|-------------------|--------------------|--------------------------|---|--------|---------------------|---------------------------------------|--------|------------|--|--|
| Customer Sar | nple # | 1053-1 | 10 | | | Job ID 103552- | | | | | | | |
| Sample | е Туре | Agar p | late | | | | | | J3332-4061-3201 | | | | |
| Sample S | | n/a | | | Requested Service(s) Phe | | | Phenotyp | Phenotypic and Genetic Identification | | | | |
| Customer Com | ments | n/a | | | ١ . | Test Method(s) MB450, MB457, MB473 | | | | | | | |
| MEI Sar | nple # | 10638 | 4-1 | | ı ı | est wetr | 10a(S) | MB450, MB457, MB473 | | | | | |
| Test | | | T | est Results | | | ğ | • | | | | | |
| Basic ID Bacterium | | | | | | | | | | | | | |
| Acridine Orange | e Stain | Positiv | e | | | | | | | | | | |
| Genetic ID Comparisons to g | enetical | ly simila | ar microorganisms | | | Notes: | | • • | 65 | A | • | | |
| Genetic Distance | | | enus | Species | | None | | | | | | | |
| 0.0000 | · | | | | | | | | | | | | |
| 0.0057 | | coplasm | | alactiae | | | | | | | | | |
| 0.0529 | 1 1 | coplasn | | matum | | | | | | | | | |
| 0.0744 | 1 1 | coplasm | · | alescens | | | | | | | | | |
| 0.0801 | 1 1 | - | | iculosum | | | | | | | | | |
| 0.0824 | | coplasm | | | | | | | | | | | |
| | 1 - | coplasm | | pharyngis | | | | | | | | | |
| 0.0866 | 1 - | coplasm , | I - | ofaciens ······ | | | | | | | | | |
| 0.0881 | | coplasm | na teli | faucium | | | | | | | | | |
| Deviations | None | | | | | | | | | | | | |
| Microbial ID Conclusion | Мусор | olasma | bovis | | | | | | | | | | |
| Microbiology R | Review | | | Ali F | azeli | | | | Date: | 05/0 | 03/2017 | | |
| Genetics Review Song | | | | Songha | i Shen | | | | Date: | 05/0 | 03/2017 | | |
| QC Ap | | Seth | Farb | | | | Date: | 05/0 | 03/2017 | | | | |
| QA Approval Fatel | | | | | amadpour | | | | Date: | 05/0 | 03/2017 | | |
| Reported By: | | | Mole | cular Ep | idemiology, I | nc. | | | | | | | |
| Reported By: Gregory J. Ma, SM(AAM), MSPH Phone: 206-306-8882 | | | | | | | - | | | | | | |
| Fax: 206-306-8883 | | | | | | 15300 Bothell Way NE, Lake Forest Park, WA 98155 | | | | | | | |
| | e-Mail: gregory@molecularepi.com | | | | | | | | /ww.moleculare | pi,con | n | | |
| This laboratory report relates only to the portion of the sample which was tested in this report. | | | | | | | | | | - | | | |