# Rapid Micro Biosystems

## Certificate of Analysis

**Product Name:** **Bioburden Filtration Funnel**
**Catalogue numbers:** ☐ B150-048 ☒ B250-048
**Manufacture Date:** 13Oct2022
**Lot Number:** 134987
**Expiration Date:** 30Apr2024

The above lot has been produced in an ISO9001-certified facility and sterilized in accordance with Rapid Micro Biosystems Quality Systems. Representative samples were tested per Rapid Micro Biosystems protocols and were found to meet the performance and physical characteristics release criteria for this product.

**Storage:** Room temperature

**Product Description:**

The Filtration Kit consists of a black 0.45 micron pore size cellulose ester membrane held in a plastic base below a removable filtration funnel.

**Quality Release Criteria:**

The quality control data given in this document represent the quality of the released lot as tested.

| Physical Test Performed | Test Result |
|---|---|
| Flow Rate | Pass |
| Baseline Signal | Pass |
| **Growth Promotion** | **Test Result** |
| *Bacillus subtilis* - ATCC® 6633[1] | Pass |
| *Pseudomonas aeruginosa* - ATCC® 9027[1] | Pass |
| *Staphylococcus aureus* - ATCC® 6538[1] | Pass |

[1]Or equivalent

**Irradiation:**
This is Gamma Radiation treated product at 15-40kGy, packaged as 8 sets of 6 units in poly sleeves stored in a cardboard box.

Certificate results reported here were obtained at time of release. Product is for exclusive use with Rapid Micro Biosystems Growth Direct system. Not for In Vitro Diagnostic use.

Released by: _____ Release Date 22Nov2022

Quality Representative

**Rapid Micro Biosystems, Inc.**
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www.rapidmicrobio.com

**FUNNEL ASSEMBLY ACCEPTANCE FORM**

Page 1 of 12

Pump Type (selected for use): Gast Measured Vacuum Level, (in-hg): 2.5

Product Description (circle one): B150-048 (B250-048) Lot #: 134987

| | | | |
|---|---|---|---|
| Sterilization certificate and dosage | ☑ Pass | ☐ Fail | |
| Labeled per BOM | ☑ Yes | ☐ No | |
| Correct Expiration Date | ☑ Yes | ☐ No | Enter Exp Date: 30 Apr 2024 |
| Gamma Sticker | ☑ Yes | ☐ No | |
| Gamma Sticker Color | ☑ Red | ☐ Other | |
| Growth Promotion | ☑ Pass | ☐ Fail | |
| Image Analysis | ☑ Pass | ☐ Fail | |
| Leak Test | ☑ Pass | ☐ Fail | |
| Flow Rate | ☑ Pass | ☐ Fail | |
| Visual Inspection (per step 9.7.5.1) | ☑ Pass | ☐ Fail | |

Comments:

N/A AM 22 Nov 2022

Associated NCR(s): _____

Overall Lot Disposition: ☑ PASS ☐ FAIL

Analyst Signature: _____ Date: 22 Nov 2022

Review Signature: _____ Date: 22 Nov 2022


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**Flow Rate** Lot #: 134987 

| Funnel Assembly, Sample # | " Hg reading, before commencement of filtration | Filtration Time (sec) |
|---|---|---|
| Sample #1 | 11.5 | 15 |
| Sample #2 | 11.6 | 16 |
| Sample #3 | 11.5 | 15 |
| Sample #4 | 11.8 | 17 |
| Sample #5 | 11.7 | 17 |
| Sample #6 | 11.6 | 17 |

**Pass** = All filtrations take between 8 and 23 seconds.

Tested By: _____ Date: 16 Nov 2022

**Leak Test**

| Sample | Turbidity (+/-) | *E. coli* Confirmed/method used | Sample | Turbidity (+/-) | *E. coli* Confirmed/method used |
|---|---|---|---|---|---|
| 1 | - | | 9 | - | |
| 2 | - | | 10 | - | |
| 3 | - | (1) | 11 | - | (1) |
| 4 | - | | 12 | - | |
| 5 | - | | 13 | - | |
| 6 | - | | 14 | - | |
| 7 | - | | Neg. Control TSB | - | |
| 8 | - | | Neg. Control Plate | - | |
| | | | Pos. Control *E. coli* | + | confirmed by eye |

**Pass** = No turbidity in test replicates. Positive control has turbidity confirmed as *E. coli*. Negative control has no turbidity or growth on TSA.

Leak Test Meets Acceptance Criteria: ☑ PASS ☐ FAIL

Performed By: _____ Date: 14 Nov 2022

Read By: _____ Date: 15 Nov 2022

Reviewer Signature: _____ Date: 22 Nov 2022

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(1) NIA AM 15 Nov 2022

**Growth Promotion – Growth Direct Incubation** Lot # 134987 Page 3 of 17

Growth Promotion % recovery must be 50-200% control growth (average control count is from 20-200 CFU)

| Organism | *B. subtilis* | *P. aeruginosa* | *S. aureus* |
|---|---|---|---|
| **Controls** | | | |
| Average CFU | 53 | 52 | 46 |
| **Test Samples** | | | |
| Average CFU | 62 | 53 | 47 |
| **% Recovery** | 117% | 102% | 102% |

(1) ☒ Report from Growth Direct for Test and Control Sample Results Attached

(1) Reference attachment 1 for control rep results. AM 22 Nov 2022

(1) Top incubator temperature went out of spec on 17 Nov 2022 @ 08:14pm. Test is within Time and temp specs per QCP0006. Disregard all alarms on Batch report. AM 22 Nov 2022

On Test By: _____ Date: 16 Nov 2022

Off Test By: _____ Date: 17 Nov 2022

Review Signature: _____ Date: 22 Nov 2022


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**Background Check** Lot #: 134987 Page 4 of 12

| Background Check | | | | |
|---|---|---|---|---|
| Cassette ID | Uneven Background Yes/No | Relative mean intensity of bright area (N/A if background is uniform) | Relative mean intensity of dark area (N/A if background is uniform) | Percent Difference (N/A if background is uniform) |
| 130334 | NO | | | |
| 130335 | NO | | | |
| 130336 | NO | | (1) | |
| 130349 | NO | | | |
| 130350 | NO | | | |
| 130351 | NO | | | |
| Use table below if Alert triggered (N/A if all six original samples pass) | | | | |
| | | | | |
| | | | | |
| | | | (1) | |
| | | | | |
| | | | | |
| | | | | |

**Pass =** no samples have uneven background, defined as >10% difference.

**Alert =** one sample >10%, process 6 more samples per 9.9. Alert cleared if additional 6 samples pass - if any are >10%, trigger action.

**Action =** two or more samples >10%, initiate NCR.

The bright annular ring between the OD of the Porex Pad and the ROI shall be excluded from this analysis.

(1) N/A AM 22 Nov 2022

Background check result: ☑ PASS ☐ FAIL

Analyst Signature: _____ Date: 22 Nov 2022

Review Signature: _____ Date: 22 Nov 2022


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**Master Materials/Equipment List** Lot #: 134987 Page 5 of 12

**Note:** The Master Equipment/Material list may be photocopied & shared between multiple lots, given that the equipment & materials listed are the same between lots. Leave lot # and signatures blank when photocopying – these lines must be lot specific.

| Material | Lot Number | Expiration |
|---|---|---|
| 1x TSB (overnight) | 2011978 | 21 Jan 2023 |
| 2x TSB (autoclaved) | K-2-22 | 10 May 2023 |
| Control Funnels | 132852 | 31 Dec 2023 |
| BTSA-048 | 2492222 | 07 Mar 2023 |
| Fluid A | 144938 | 09 Jan 2023 |
| PBS | 963AUG2022 | 22 Feb 2023 |
| Sterile Water | 26521007 | 30 Sep 2024 |
| TSA Plate (if applicable) | ☐ N/A 2270849 | ☐ N/A 27 Jan 2023 |

| Organism | Strain | Lot Number | Expiration |
|---|---|---|---|
| *B. subtilis* | ATCC 6633 | 486-1268-4 | 30 Sep 2023 |
| *E. coli* | ☐ ATCC 8739<br>☑ NCTC 12923* | B7033 | 11 Nov 2023 |
| *P. aeruginosa* | ☐ ATCC 9027<br>☑ NCTC 12924* | B7118 | 21 Dec 2023 |
| *S. aureus* | ATCC 6538 | 485-1074-1 | 30 Nov 2023 |

*Equivalent strain to spec ATCC

| Equipment | |
|---|---|
| Pipettor Calibration ID/Cal. Due Date | Cal-1157 \| 28 Feb 2023 |
| Growth Direct Equipment Identification Number | E17514181 \| 12 Jan 2023 |

Analyst Signature: _____ Date: 22 Nov 2022

Reviewer Signature: _____ Date: 22 Nov 2022

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# Batch Report

Confidential

| Lot/Batch: | 134987_B250 | Sample ID: | TSA B. subtilis 1 | Count: | 82 |
|---|---|---|---|---|---|
| Serial Number: | 00069C6F | Incubation Start: | 11/16/2022 09:02 | Media Type: | TSA |
| Loaded On: | 11/16/2022 09:02 | Incubation End: | 11/18/2022 09:13 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA B. subtilis 1 | Count: | 82 |
|---|---|---|---|---|---|
| Serial Number: | 00069C6F | Incubation Start: | 11/16/2022 09:02 | Media Type: | TSA |
| Loaded On: | 11/16/2022 09:02 | Incubation End: | 11/18/2022 09:13 (1) | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 50 Minutes, 50 Seconds | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA B. subtilis 2 | Count: | 64 |
|---|---|---|---|---|---|
| Serial Number: | 00069C6E | Incubation Start: | 11/16/2022 09:02 | Media Type: | TSA |
| Loaded On: | 11/16/2022 09:02 | Incubation End: | 11/18/2022 09:20 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA B. subtilis 3 | Count: | 55 |
|---|---|---|---|---|---|
| Serial Number: | 00069C6D | Incubation Start: | 11/16/2022 09:01 | Media Type: | TSA |
| Loaded On: | 11/16/2022 09:01 | Incubation End: | 11/18/2022 09:16 (1) | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 50 Minutes, 49 Seconds | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA B. subtilis 3 | Count: | 55 |
|---|---|---|---|---|---|
| Serial Number: | 00069C6D | Incubation Start: | 11/16/2022 09:01 | Media Type: | TSA |
| Loaded On: | 11/16/2022 09:01 | Incubation End: | 11/18/2022 09:16 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S. aureus 1 | Count: | 58 |
|---|---|---|---|---|---|
| Serial Number: | 00069C36 | Incubation Start: | 11/16/2022 08:56 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:56 | Incubation End: | 11/18/2022 09:13 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S. aureus 2 | Count: | 45 |
|---|---|---|---|---|---|
| Serial Number: | 00069C35 | Incubation Start: | 11/16/2022 08:55 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:55 | Incubation End: | 11/18/2022 09:06 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |



(1) Duplicate sample. AM 22 Nov 2022

# Batch Report

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**Alarms:** Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA S. aureus 2** | **Count:** | **45** |
| **Serial Number:** | 00069C35 | **Incubation Start:** | 11/16/2022 08:55 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 08:55 | **Incubation End:** | 11/18/2022 09:06 (1) | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 50 Minutes, 45 Seconds | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA S. aureus 3** | **Count:** | **34** |
| **Serial Number:** | 00069C34 | **Incubation Start:** | 11/16/2022 08:55 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 08:55 | **Incubation End:** | 11/18/2022 09:07 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P. aeruginosa 1** | **Count:** | **52** |
| **Serial Number:** | 00069C2S | **Incubation Start:** | 11/16/2022 08:59 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 08:59 | **Incubation End:** | 11/18/2022 09:10 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P. aeruginosa 2** | **Count:** | **52** |
| **Serial Number:** | 00069C2T | **Incubation Start:** | 11/16/2022 08:57 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 08:57 | **Incubation End:** | 11/18/2022 09:09 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P. aeruginosa 2** | **Count:** | **52** |
| **Serial Number:** | 00069C2T | **Incubation Start:** | 11/16/2022 08:57 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 08:57 | **Incubation End:** | 11/18/2022 09:09 (1) | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 50 Minutes, 47 Seconds | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P. aeruginosa 3** | **Count:** | **53** |
| **Serial Number:** | 00069C2U | **Incubation Start:** | 11/16/2022 08:57 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 08:57 | **Incubation End:** | 11/18/2022 09:09 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA B subtilis 4** | **Count:** | **62** |
| **Serial Number:** | 00069C6C | **Incubation Start:** | 11/16/2022 09:01 | **Media Type:** | TSA |



(1) Duplicate sample. AM 22 Nov 2022

# Batch Report

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| | | | | | |
|---|---|---|---|---|---|
| **Loaded On:** | 11/16/2022 09:01 | **Incubation End:** | 11/18/2022 09:25 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA B subtilis 5** | **Count:** | **66** |
| **Serial Number:** | 00069C6B | **Incubation Start:** | 11/16/2022 09:01 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 09:01 | **Incubation End:** | 11/18/2022 09:15 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA B subtilis 5** | **Count:** | **66** |
| **Serial Number:** | 00069C6B | **Incubation Start:** | 11/16/2022 09:01 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 09:01 | **Incubation End:** | 11/18/2022 09:15 (1) | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 56 Minutes, 49 Seconds | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA B subtilis 6** | **Count:** | **41** |
| **Serial Number:** | 00069C6A | **Incubation Start:** | 11/16/2022 09:00 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 09:00 | **Incubation End:** | 11/18/2022 09:20 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P aeruginosa 4** | **Count:** | **50** |
| **Serial Number:** | 00069C2V | **Incubation Start:** | 11/16/2022 09:00 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 09:00 | **Incubation End:** | 11/18/2022 09:11 (1) | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 56 Minutes, 48 Seconds | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P aeruginosa 4** | **Count:** | **50** |
| **Serial Number:** | 00069C2V | **Incubation Start:** | 11/16/2022 09:00 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 09:00 | **Incubation End:** | 11/18/2022 09:11 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Lot/Batch:** | **134987_B250** | **Sample ID:** | **TSA P aeruginosa 5** | **Count:** | **44** |
| **Serial Number:** | 00069C2W | **Incubation Start:** | 11/16/2022 09:00 | **Media Type:** | TSA |
| **Loaded On:** | 11/16/2022 09:00 | **Incubation End:** | 11/18/2022 09:11 | **Media Lot:** | 24922L2 |
| **Loaded By:** | es | | | **Expiration:** | 03/07/2023 |
| **Alarms:** | | | | | |



(1) Duplicate Sample. AM 22 Nov 2022

# Batch Report

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| Lot/Batch: | 134987_B250 | Sample ID: | TSA P aeruginosa 6 | Count: | 67 |
|---|---|---|---|---|---|
| Serial Number: | 00069C2X | Incubation Start: | 11/16/2022 08:59 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:59 | Incubation End: | 11/18/2022 09:10 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA P aeruginosa 6 | Count: | 67 |
|---|---|---|---|---|---|
| Serial Number: | 00069C2X | Incubation Start: | 11/16/2022 08:59 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:59 | Incubation End: | 11/18/2022 09:10 (1) | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 59 Minutes, 47 Seconds | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S aureus 4 | Count: | 44 |
|---|---|---|---|---|---|
| Serial Number: | 00069C39 | Incubation Start: | 11/16/2022 08:57 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:57 | Incubation End: | 11/18/2022 09:07 (1) | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 59 Minutes, 46 Seconds | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S aureus 4 | Count: | 44 |
|---|---|---|---|---|---|
| Serial Number: | 00069C39 | Incubation Start: | 11/16/2022 08:57 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:57 | Incubation End: | 11/18/2022 09:07 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S aureus 5 | Count: | 45 |
|---|---|---|---|---|---|
| Serial Number: | 00069C38 | Incubation Start: | 11/16/2022 08:56 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:56 | Incubation End: | 11/18/2022 09:08 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S aureus 6 | Count: | 55 |
|---|---|---|---|---|---|
| Serial Number: | 00069C37 | Incubation Start: | 11/16/2022 08:56 | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:56 | Incubation End: | 11/18/2022 09:06 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |
| Alarms: | Top incubator's temperature: 35.1 is greater than upper alarm: 35, alert start time: 2022-11-17 18:14 | | | | |

| Lot/Batch: | 134987_B250 | Sample ID: | TSA S aureus 6 | Count: | 55 |
|---|---|---|---|---|---|
| Serial Number: | 00069C37 | Incubation Start: | 11/16/2022 08:56 (1) | Media Type: | TSA |
| Loaded On: | 11/16/2022 08:56 | Incubation End: | 11/18/2022 09:06 | Media Lot: | 24922L2 |
| Loaded By: | es | | | Expiration: | 03/07/2023 |



(1) Duplicate sample. AM 22 Nov 2022

# Batch Report

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**Alarms:** Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 50 Minutes, 46 Seconds

Comments:

N/A
AM 22 Nov 2022

AM 22 Nov 2022

# STERIS: Certificate Of Processing

**Prepared for:** RAPID MICRO BIOSYSTEMS (4764)

**Gamma Process Run ID** 1193-6636A

| Product Code | Lot Number | Quantity | UOM |
|---|---|---|---|
| B250-048 | 134978 | 40 | Case |
| B250-048 | 134982 | 40 | Case |
| B250-048 | 134984 | 40 | Case |
| B250-048 | 134987 | 40 | Case |
| B250-048 | 134990 | 40 | Case |

**Processing Run Start Date:** 05-Nov-2022 1:50 AM

**Processing Run End Date:** 05-Nov-2022 9:26 AM

| | | | |
|---|---|---|---|
| **Minimum Specified Dose (kGy):** | **15.0** | **Minimum Delivered Dose (kGy):** | **20.8** |
| **Maximum Specified Dose (kGy):** | **40.0** | **Maximum Delivered Dose (kGy):** | **30.0** |

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

**Gamma Process Run Approval authorized by STERIS**

Date/Time E-Signed: 05-Nov-2022 12:05 PM

**Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of Health Canada GMP, FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.**

**Processing Location**

**184 Crown Court**
**Whitby, ON, L1N 7B1**
**Phone: 905-433-1202**

exo-S

# CERTIFICAT DE CONFORMITÉ / CERTIFICATE OF CONFORMITY

RESTREINT / RESTRICTED

| IDENTIFICATION DU CLIENT / CUSTOMER IDENTIFICATION | IDENTIFICATION DU FOURNISSEUR - SUPPLIER IDENTIFICATION | ADRESSÉ À / ADDRESSED TO: |
|---|---|---|
| Steris Whitby | Exo-S St-Damien Inc. | |
| ADRESSE DE LIVRAISON / SHIPPING ADDRESS<br>184 Crown Court<br>Whitby, ON, Canada, L1N 7B1 | ADRESSE DU FOURNISSEUR / SUPPLIER'S ADDRESS<br>22, rue de l'Entreprise<br>St-Damien, Qc, Canada, G0R 2Y0 | Lindsey Dyer <qualitycontrol@rapidmicrobio.com><br>Gregory Reid <greid@rapidmicrobio.com> |
| BULLETIN DE COMMANDE / PURCHASE ORDER<br>4500000637 | IL EST CERTIFIÉ QUE LA TOTALITÉ DES ARTICLES ET(OU) SERVICES ÉNUMÉRÉS CI-DESSOUS SONT CONFORMES EN TOUS POINTS AUX SPÉCIFICATIONS, DESSINS ET À LA COMMANDE QUI S'Y RAPPORTE ET QUE LES ARTICLES ET (OU) LES SERVICES ONT ÉTÉ INSPECTÉS ET SOUMIS AUX ESSAIS CONFORMÉMENT AUX CONDITIONS DE, ET RÉPONDENT AUX EXIGENCES DE LA COMMANDE.<br>IT IS CERTIFIED THAT THE WHOLE OF THE ITEMS AND(OR) SERVICES DETAILED BELOW CONFORM IN ALL RESPECTS TO THE SPECIFICATIONS, DRAWINGS AND ORDER RELATIVE THERE TO AND THAT THE ITEMS AND(OR) SERVICES HAVE BEEN INSPECTED AND TESTED IN ACCORDANCE WITH THE CONDITIONS OF, AND FOUND TO COMPLY WITH THE REQUIREMENTS OF THE ORDER | |
| N° DE RELÂCHE (SI REQUIS) / RELEASE NO. ON ORDER (IF REQUIRED)<br>BE-17815 | Andre Parent<br>Quality & CI Director<br>NOM/TITRE DACTYLOGRAPHIÉS - NAME AND TITLE TYPED | Andre Parent Signature numérique de Andre Parent Date : 2022.10.21 10:55:01 -04'00'<br>SIGNATURE (FOURNISSEUR - SUPPLIER)<br>2022-10-21<br>DATE (J/M/A) (D/M/Y) |

| N° DE L'ARTICLE<br>ITEM NO. | DESCRIPTION DE L'ITEM<br>ITEM DESCRIPTION | DATE DE FABRICATION<br>MANUFACTURING DATE | DATE D'EXPIRATION<br>EXPIRATION DATE | NUMÉRO DU LOT<br>LOT NUMBER | CERTIFICAT D'ANALYSE DE LA MATIÈRE<br>RAW MATERIAL CERTIFICATE OF ANALYSIS | QUANTITÉ<br>QUANTITY |
|---|---|---|---|---|---|---|
| 11157<br>(20519-01) | 250ML FUNNEL F/BB B250-048 | 2022-10-05 | 2024-03 | 134978 | Porex lot# 66267-02, 67187-01<br>Membrane lot# MO1001802<br>PPC-162 (134985) lot# BC13BCC04 | 1920 units |
| 11157<br>(20519-01) | 250ML FUNNEL F/BB B250-048 | 2022-10-11 | 2024-04 | 134982 | Porex lot# 67187-01<br>Membrane lot# MO1001802<br>PPC-162 (134985) lot# BC13BCC04 | 1920 units |
| 11157<br>(20519-01) | 250ML FUNNEL F/BB B250-048 | 2022-10-12 | 2024-04 | 134984 | Porex lot# 67187-01<br>Membrane lot# MO1001802, MO1002185<br>PPC-162 (134985) lot# BC13BCC04 | 1920 units |
| 11157<br>(20519-01) | 250ML FUNNEL F/BB B250-048 | 2022-10-13 | 2024-04 | 134987 | Porex lot# 67187-01<br>Membrane lot# MO1002185<br>PPC-162 (134985) lot# BC13BCC04 | 1920 units |
| 11157<br>(20519-01) | 250ML FUNNEL F/BB B250-048 | 2022-10-17 | 2024-04 | 134990 | Porex lot# 67187-01<br>Membrane lot# MO1002185<br>PPC-162 (134985) lot# BC13BCC04 | 1920 units |
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Annexe 2022

Attachment 1
QCP0006 Growth Promotion Control Results



Control Media: **24922L2**, exp. **07Mar2023**

**Incubation:** (1)
E17514181, exp. 12Jan2023
Incubation Start: 16Nov2022 @ 09:10am
Incubation End: 17Nov2022 @ 06:14pm

**Results:**

| Organism | Rep 1 | Rep 2 | Rep 3 | Rep 4 | Rep 5 | Rep 6 | Average |
|---|---|---|---|---|---|---|---|
| B. subtilis | 58 | 56 | 47 | 57 | 50 | 52 | 53 |
| P. aeruginosa | 55 | 56 | 43 | 48 | 53 | 59 | 52 |
| S. aureus | 47 | 46 | 37 | 54 | 39 | 51 | 46 |

(1) Incubator E17514181 experienced a high temperature alarm starting on 17Nov2022 @ 06:14pm. This alarm caused the control plates to be sent to the output que, ending incubation. Per QCP0006, incubation time for all organism growth is 24-48 hours, which was met by the control lots incubation time. Plates were counted by eye and results are listed above in the table. AM 21Nov2022