Rapid Micro Biosystems

Certificate of Analysis

Product Name: **Bioburden Filtration Funnel**

Catalogue numbers:
☐ B150-048
☒ B250-048

Manufacture Date: 11Oct2022

Lot Number: 134982

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.
1001 Pawtucket Blvd West, Suite 280, Lowell, MA 01854
Phone: +1 978-349-3200 Fax: +1 978-349-2065
www.rapidmicrobio.com
Email:support@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 #: 134982

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: [signature] Date: 22 Nov 2022

Review Signature: [signature] Date: 22 Nov 2022

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Flow Rate Lot #: 134982 Page 2 of 12

Funnel Assembly, Sample #	" Hg reading, before commencement of filtration	Filtration Time (sec)
Sample #1	11.6	14
Sample #2	11.6	14
Sample #3	11.4	15
Sample #4	11.4	14
Sample #5	11.4	14
Sample #6	11.4	13

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 N/A AM 15 Nov 2022

Growth Promotion – Growth Direct Incubation Lot # 134982 Page 3 of 12

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	59	②~~49~~ 50	②~~50~~ 49
% Recovery	111%	②~~94%~~ 96%	②~~109%~~ 107%

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 temp. out of specification on 17 Nov 2022 @ 06:14 pm. Test within QCP0006 Time and temperature specifications. Disregard all claims on Batch report. AM 22 Nov 2022

② AM 22 Nov 2022

On Test By: _____ Date: 16 Nov 2022

Off Test By: _____ Date: 17 Nov 2024

Review Signature: _____ Date: 22 Nov 2022

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Background Check Lot #: 134482 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)
130298	NO			
130299	NO			
130300	NO		(1)	
130313	NO			
130314	NO			
130315	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.

Background check result: ☑ PASS ☐ FAIL

Analyst Signature: _____ Date: 22 Nov 2022

Review Signature: _____ Date: 22 Nov 2022

0 NA AM 22 Nov 2022

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Master Materials/Equipment List Lot #: ~~B3487~~ 134982 AM 22 Nov 2022 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 ☑ NCTC 12923*	B7033	11 Nov 2023
P. aeruginosa	☐ ATCC 9027 ☑ 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:	134982_B250	Sample ID:	TSA B. subtilis 1	Count:	57
Serial Number:	00069C53	Incubation Start:	11/16/2022 08:53	Media Type:	TSA
Loaded On:	11/16/2022 08:53	Incubation End:	11/18/2022 09:04	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:	134982_B250	Sample ID:	TSA B. subtilis 1	Count:	57
Serial Number:	00069C53	Incubation Start:	11/16/2022 08:53	Media Type:	TSA
Loaded On:	11/16/2022 08:53	Incubation End:	11/18/2022 09:04 (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, 51 Minutes, 2 Seconds				

Lot/Batch:	134982_B250	Sample ID:	TSA B. subtilis 2	Count:	71
Serial Number:	00069C52	Incubation Start:	11/16/2022 08:54	Media Type:	TSA
Loaded On:	11/16/2022 08:54	Incubation End:	11/18/2022 09:06	Media Lot:	24922L2
Loaded By:	es			Expiration:	03/07/2023
Alarms:					

Lot/Batch:	134982_B250	Sample ID:	TSA B. subtilis 3	Count:	45
Serial Number:	00069C51	Incubation Start:	11/16/2022 08:54	Media Type:	TSA
Loaded On:	11/16/2022 08:54	Incubation End:	11/18/2022 09:03 (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, 51 Minutes, 1 Seconds				

Lot/Batch:	134982_B250	Sample ID:	TSA B. subtilis 3	Count:	45
Serial Number:	00069C51	Incubation Start:	11/16/2022 08:54	Media Type:	TSA
Loaded On:	11/16/2022 08:54	Incubation End:	11/18/2022 09:03	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:	134982_B250	Sample ID:	TSA S. aureus 1	Count:	36
Serial Number:	00069BDY	Incubation Start:	11/16/2022 09:22	Media Type:	TSA
Loaded On:	11/16/2022 09:22	Incubation End:	11/18/2022 09:40	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:	134982_B250	Sample ID:	TSA S. aureus 1	Count:	36
Serial Number:	00069BDY	Incubation Start:	11/16/2022 09:22 (1)	Media Type:	TSA
Loaded On:	11/16/2022 09:22	Incubation End:	11/18/2022 09:40	Media Lot:	24922L2
Loaded By:	es			Expiration:	03/07/2023

(1) Duplicate Sample. AM 22 Nov 2022

Batch Report

Confidential

Alarms: Top incubator's temperature: 35 alarm ended, maximum temperature out of range was: 47 event duration was: 17 Hours, 50 Minutes, 57 Seconds

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA S. aureus 2**	**Count:**	**52**
Serial Number:	00069BDZ	**Incubation Start:**	11/16/2022 09:21	**Media Type:**	TSA
Loaded On:	11/16/2022 09:21	**Incubation End:**	11/18/2022 09:45	**Media Lot:**	24922L2
Loaded By:	es			**Expiration:**	03/07/2023
Alarms:					

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA S. aureus 3**	**Count:**	**63**
Serial Number:	00069BE0	**Incubation Start:**	11/16/2022 09:21	**Media Type:**	TSA
Loaded On:	11/16/2022 09:21	**Incubation End:**	11/18/2022 09:46	**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, 57 Seconds				

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA S. aureus 3**	**Count:**	**63**
Serial Number:	00069BE0	**Incubation Start:**	11/16/2022 09:21	**Media Type:**	TSA
Loaded On:	11/16/2022 09:21	**Incubation End:**	11/18/2022 09:46	**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:	**134982_B250**	**Sample ID:**	**TSA P. aeruginosa 1**	**Count:**	**60**
Serial Number:	00069BVM	**Incubation Start:**	11/16/2022 09:35	**Media Type:**	TSA
Loaded On:	11/16/2022 09:35	**Incubation End:**	11/18/2022 09:51	**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:	**134982_B250**	**Sample ID:**	**TSA P. aeruginosa 1**	**Count:**	**60**
Serial Number:	00069BVM	**Incubation Start:**	11/16/2022 09:35	**Media Type:**	TSA
Loaded On:	11/16/2022 09:35	**Incubation End:**	11/18/2022 09:51	**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, 59 Seconds				

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA P. aeruginosa 2**	**Count:**	**41**
Serial Number:	00069BVN	**Incubation Start:**	11/16/2022 09:35	**Media Type:**	TSA
Loaded On:	11/16/2022 09:35	**Incubation End:**	11/18/2022 09:55	**Media Lot:**	24922L2
Loaded By:	es			**Expiration:**	03/07/2023
Alarms:					

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA P. aeruginosa 3**	**Count:**	**52**
Serial Number:	00069BVO	**Incubation Start:**	11/16/2022 08:51	**Media Type:**	TSA

① Duplicate sample. AM 22 Nov 2022

Batch Report

Confidential

Loaded On:	11/16/2022 08:51	**Incubation End:**	11/18/2022 09:01	**Media Lot:**	24922L2
Loaded By:	es			**Expiration:**	03/07/2023
Alarms:					

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA B subtilis 4**	**Count:**	**70**
Serial Number:	00069C50	**Incubation Start:**	11/16/2022 08:52	**Media Type:**	TSA
Loaded On:	11/16/2022 08:52	**Incubation End:**	11/18/2022 09:05	**Media Lot:**	24922L2
Loaded By:	es			**Expiration:**	03/07/2023
Alarms:					

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA B subtilis 5**	**Count:**	**54**
Serial Number:	00069C4Z	**Incubation Start:**	11/16/2022 08:53	**Media Type:**	TSA
Loaded On:	11/16/2022 08:53	**Incubation End:**	11/18/2022 09:03	**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, 51 Minutes, 0 Seconds				

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA B subtilis 5**	**Count:**	**54**
Serial Number:	00069C4Z	**Incubation Start:**	11/16/2022 08:53	**Media Type:**	TSA
Loaded On:	11/16/2022 08:53	**Incubation End:**	11/18/2022 09:03	**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:	**134982_B250**	**Sample ID:**	**TSA B subtilis 6**	**Count:**	**55**
Serial Number:	00069C4Y	**Incubation Start:**	11/16/2022 08:53	**Media Type:**	TSA
Loaded On:	11/16/2022 08:53	**Incubation End:**	11/18/2022 09:05	**Media Lot:**	24922L2
Loaded By:	es			**Expiration:**	03/07/2023
Alarms:					

Lot/Batch:	**134982_B250**	**Sample ID:**	**TSA P aeruginosa 4**	**Count:**	**46**
Serial Number:	00069BVP	**Incubation Start:**	11/16/2022 08:51	**Media Type:**	TSA
Loaded On:	11/16/2022 08:51	**Incubation End:**	11/18/2022 09:05	**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:	**134982_B250**	**Sample ID:**	**TSA P aeruginosa 4**	**Count:**	**46**
Serial Number:	00069BVP	**Incubation Start:**	11/16/2022 08:51	**Media Type:**	TSA
Loaded On:	11/16/2022 08:51	**Incubation End:**	11/18/2022 09:05	**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, 51 Minutes, 0 Seconds				

6 Duplicate sample. AM 22 Nov 2022

Batch Report

Confidential

Lot/Batch:	134982_B250	Sample ID:	TSA P aeruginosa 5	Count:	53
Serial Number:	00069BVQ	Incubation Start:	11/16/2022 08:52	Media Type:	TSA
Loaded On:	11/16/2022 08:52	Incubation End:	11/18/2022 09:00	Media Lot:	24922L2
Loaded By:	es			Expiration:	03/07/2023
Alarms:					

Lot/Batch:	134982_B250	Sample ID:	TSA P aeruginosa 6	Count:	45
Serial Number:	00069BVR	Incubation Start:	11/16/2022 08:52	Media Type:	TSA
Loaded On:	11/16/2022 08:52	Incubation End:	11/18/2022 09:01 (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, 59 Seconds				

Lot/Batch:	134982_B250	Sample ID:	TSA P aeruginosa 6	Count:	45
Serial Number:	00069BVR	Incubation Start:	11/16/2022 08:52	Media Type:	TSA
Loaded On:	11/16/2022 08:52	Incubation End:	11/18/2022 09:01	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:	134982_B250	Sample ID:	TSA S aureus 4	Count:	50
Serial Number:	00069BE1	Incubation Start:	11/16/2022 09:21	Media Type:	TSA
Loaded On:	11/16/2022 09:21	Incubation End:	11/18/2022 09:40	Media Lot:	24922L2
Loaded By:	es			Expiration:	03/07/2023
Alarms:					

Lot/Batch:	134982_B250	Sample ID:	TSA S aureus 5	Count:	43
Serial Number:	00069BE2	Incubation Start:	11/16/2022 09:34	Media Type:	TSA
Loaded On:	11/16/2022 09:34	Incubation End:	11/18/2022 09:52	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:	134982_B250	Sample ID:	TSA S aureus 5	Count:	43
Serial Number:	00069BE2	Incubation Start:	11/16/2022 09:34	Media Type:	TSA
Loaded On:	11/16/2022 09:34	Incubation End:	11/18/2022 09:52 (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, 58 Minutes, 58 Seconds				

Lot/Batch:	134982_B250	Sample ID:	TSA S aureus 6	Count:	49
Serial Number:	00069BE3	Incubation Start:	11/16/2022 09:34	Media Type:	TSA
Loaded On:	11/16/2022 09:34	Incubation End:	11/18/2022 09:55	Media Lot:	24922L2
Loaded By:	es			Expiration:	03/07/2023

(1) Duplicate sample. AM 22 NOV 2022

Alarms:

Comments:

N/A
AM 22 NOV 2022

AM22Nov2022

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

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.	Lindsey Dyer <qualitycontrol@rapidmicrobio.com> Gregory Reid <greid@rapidmicrobio.com>
ADRESSE DE LIVRAISON / SHIPPING ADDRESS 184 Crown Court Whitby, ON, Canada, L1N 7B1	ADRESSE DU FOURNISSEUR / SUPPLIER'S ADDRESS 22, rue de l'Entreprise St-Damien, Qc, Canada, G0R 2Y0	
BULLETIN DE COMMANDE / PURCHASE ORDER 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. 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) BE-17815	Andre Parent Quality & CI Director NOM/TITRE DACTYLOGRAPHIÉS - NAME AND TITLE TYPED	Andre Parent Signature numérique de Andre Parent Date : 2022.10.21 10:55:01 -04'00' SIGNATURE (FOURNISSEUR - SUPPLIER) 2022-10-21 DATE (J/M/A) (D/M/Y)

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

AN 22 Nov 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