CERTIFICATE OF QUALITY

Filtration Kit for Growth Cassette

Part No: B150-048 Lot No: 106278 Expiry: 28Feb2022

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.

MANUFACTURE:

The product was manufactured in an ISO qualified facility. The Gamma treatment was performed in an ISO qualified facility.

QUALITY RELEASE CRITERIA:

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

PHYSICAL TESTS:

1. Flow rate	Pass
2. Baseline signal	Pass

BIOLOGICAL TESTS:

Growth Promotion:

Organisms from the following panel were shown to be retained by the membrane and give good growth when placed on qualified media.

Bacillus subtilis	[1]ATCC® 6633	Pass
Psuedomonas aeruginosa	[1]ATCC® 9027	Pass
Staphylococcus aureus	[1]ATCC® 6538	Pass

[1]Or equivalent

This is Gamma Radiation treated product, packaged as 8 sets of 6 units in tyvek/poly sleeves stored in a cardboard box.

Released by:
Quality Assurance

Date: 26 JAN 2021

Rapidmicro biosystems

1001 Pawtucket Blvd.
Lowell, MA 01854
978-349-3200

This product is not for In Vitro diagnostic use.
Country of origin- USA

FUNNEL ASSEMBLY ACCEPTANCE FORM

Page 1 of 1 of 7

ES29OCT2020

Pump Type (selected for use): Sartorius Measured Vacuum Level, (in-hg): 2.4

Cat #: BISO-0118 Lot #: 106278 Date Sterilized: 14OCT2020

Sterilization certificate and dosage	☑ Pass	☐ Fail
Labeled per BOM	☑ Yes	☐ No
Correct Expiration Date	☑ Yes	☐ No Enter Exp Date: 28FEB2022
Gamma Sticker	☑ Yes	☐ No
Gamma Sticker Color	☑ Red	☐ Other
Growth Promotion	☑ Pass	☐ Fail
Image Analysis	☐ Pass	(1) ☑ Fail
Leak Test	☑ Pass	☐ Fail
Flow Rate	☑ Pass	☐ Fail
Visual Inspection (per steps 9.8.5 and 9.8.8)	☑ Pass	☐ Fail

Comments:

N/A

ES02Dec2020

Associated NCR(s): (1) 2829

Overall Lot Disposition ☑ PASS ☐ FAIL

Analyst Signature: [signature] Date: 02Dec2020

Reviewer Signature: [signature] Date: 26Jan2021

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Flow Rate Lot #: 106078 Page 2 of 7

Funnel Assembly, Sample #	" Hg reading, before commencement of filtration	Filtration Time (sec)
Sample #1	11.6	16
Sample #2	10.6	16
Sample #3	11.1	18
Sample #4	11.7	17
Sample #5	11.2	18
Sample #6	11.5	17

Pass = all filtrations take between 8 and 23 seconds

(1) Tested By: _____ Date: 05 Nov 2020

Leak Test

Sample	Turbidity (+/-)	*E. coli* Confirmed/method used	Sample	Turbidity (+/-)	*E. coli* Confirmed/method used
1	–		9	–	
2	–		10	–	
3	–		11	–	N/A
4	–	N/A	12	–	
5	–		13	–	
6	–	E529OCT2020	14	–	
7	–		Neg. Control TSB	–	E529OCT2020
8	–		Neg. Control Plate	–	
			Pos. Control *E. coli*	+	Confirmed, TSA Streak

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: 28OCT2020

Read By: _____ Date: 29OCT2020

Reviewer Signature: _____ Date: 03Dec2020

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(1) Training by: _____ 10NOV2020

Growth Promotion/Background Check Lot #: 106278 Page 3 of 7

Growth Promotion % recovery must be ≥70% control growth (average control count is from 20-200 CFU)

Organism		*B. subtilis*	*P. aeruginosa*	*S. aureus*
Controls				
Replicates (CFU)	1	75	50	47
	2	67	47	45
	3	57	46	39
	4	46	60	46
	5	54	54	40
	6	80	40	44
Average CFU		63	50	44
Test Samples				
Replicates (CFU)	1	84	47	40
	2	83	64	52
	3	71	53	35
	4	63	64	35
	5	71	45	36
	6	71	62	50
Average CFU		74	56	41
% Recovery		118%	112%	93%

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)
64832	N/A			ES06NOV2020
64833	Yes	30483.459	28267.099	8%
64834	N/A			ES06NOV2020
64835	Yes	27032.446	26006.220	6%
64836			ES06NOV2020	
64837		N/A		

Background check result (Pass= No samples with >5% difference.) ☐ Pass ☑ Fail (3)

On Test By: [signature] Date: 29 OCT 2020

Off Test By: [signature] Date: 30 OCT 2020

(2) Training by: ES10NOV2020

Reviewer Signature: [signature] Date: 26 Jan 2021

(3) NUR2529 ES02DEC2020

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(1) Retested since minimum pressure of 2.5 Hg was not achieved, Per QCP0006. Performed ES10NOV2020.
Results: Cassette ID's 65550, 65551, 65552, 65553, and 65555 = No uneven background
Cassette ID 65554 = uneven, bright = 26731.531, dark = 25322.468 % diff = 6% FAIL

Master Materials/Equipment List Lot #(s): 106278 Page 4 of 7

Note: The Master Equipment/Material list may be photocopied and shared between multiple lots, given that the equipment & materials listed are the same between lots.

Material	Lot Number	Expiration
1x TSB (overnight)	0056121	23 Feb 2021
2x TSB (autoclaved)	J-4-20 / K-2-20 (1)	24 Jun 2023
BTSA-048	189201	05JAN2021
Fluid A	462338	30 NOV 2020
PBS	ES29OCT2020 ~~0210~~ 464945	09JUL2022
Sterile Water	833NOV20	03 May 2021
TSA Plate	0163419 / 0210537 (Leak Test / Growth Promotion)	24 NOV 2020 / 08JAN2021 (Leak Test / Growth Promotion)

Organism	Strain	Lot Number	Expiration
B. subtilis	ATCC 6633	486-1070-1	28Feb2022
E. coli	☐ ATCC 8739 ☑ NCTC 12923*	B5480	08JUN2021
P. aeruginosa	☐ ATCC 9027 ☑ NCTC 12924*	B5677	28NOV2021
S. aureus	ATCC 6538	485-920-1	28Feb2022

*Equivalent strain to spec ATCC

Equipment	
Pipettor Calibration ID/Cal. Due Date	CAL-1088 / 07OCT2021
Growth Direct Equipment Identification Number	E17514181
Growth Direct Vision Server Version	3.1.1.12

(1) Lot 104148 only. ES07Dec2020

Analyst Signature: _____ Date: 02Dec2020

Reviewer Signature: _____ Date: 26Jan2021

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PLASTIQUES MOORE
Technologies d'injection

CERTIFICAT DE CONFORMITÉ / CERTIFICATE OF CONFORMITY

RESTREINT (Plastiques Moore inc.) / RESTRICTED (Plastiques Moore inc.)

IDENTIFICATION DU CLIENT / CUSTOMER IDENTIFICATION	IDENTIFICATION DU FOURNISSEUR - SUPPLIER IDENTIFICATION	NOM DE L'ACHETEUR / BUYER'S NAME
Rapid Medical Biosystems		Lindsey Dyer qualitycontrol@rapidmicrobio.com
ADRESSE DE LIVRAISON / SHIPPING ADRESS Steris Apllied Sterilization 435 Whitney Street, Northborough, MA 01532 USA	ADRESSE DU FOURNISSEUR / SUPPLIER'S ADRESS Plastiques Moore inc. 22, rue de l'Entreprise St-Damien Bellechasse, Qc, GOR 2Y0	
BULLETIN DE COMMANDE / PURCHASE ORDER PO JR00061	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 ALX 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-14983	Jocelyn Lecompte Validation and Documentation Specialist NOM/TITRE DACTYLOGRAPHIÉS - NAME AND TITLE TYPED Jocelyn Lecompte SIGNATURE (FOURNISSEUR - SUPPLIER) 16/09/2020 DATE (J/M/A) (D/M/Y)	

N° DE L'ARTICLE ITEM NO.	DESCRIPTION DE L'ITEM ITEM DESCRIPTION	DESSIN (AVEC REVISION) DRAWING (WITH REVISION)	NUMÉRO DU LOT * LOT NUMBER *	QUANTITÉ QUANTITY
12610	B150-048, 150 ML FUNNEL Date de fabrication / Manufacturing date : Funnel 150 ml Date d'expériation / Expiration date :	 30/08/2020 2022-02	106278	1 920 unités
	Raw Material Certificate of Analysis: ZA31BCC03			

K529057/2020

Page 5 of 7

Certificate Of Processing

Prepared for **RAPID MICRO BIOSYSTEMS**

STERIS

Gamma Process Run ID **127414A**

Product Code	Product Lot Number	Quantity	UOM
B150-048	106278	40	CS
B250-048	106691	40	CS
B250-048	106694	2	CS
B250-048	108146	40	CS
B250-048	108148	40	CS

Processing Run Start Date/Time:	14-Oct-2020 03:17:00 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	14-Oct-2020 04:06:00 pm		

Minimum Specified Dose (kGy):	**15.0**	**Minimum Delivered Dose (kGy):**	**16.4**
Maximum Specified Dose (kGy):	**25.0**	**Maximum Delivered Dose (kGy):**	**21.3**

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

Signature Manifest

Reviewed and E-Signed By

Robin Hinckley (QS/RC Analyst)

Document Content Revision: 1

Signed On 10/15/2020 at 2:40 PM

UTC / GMT Offset (hh:mm): -4:00

Processing Location:

STERIS
435 Whitney Street
Northborough, MA 01532
Phone: 508-393-9323
Fax: 844-698-9776

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 FDA QSR, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for RAPID MICRO BIOSYSTEMS
Process Run ID 127414A
Date Prepared: 10/15/2020 2:39:42PM

Processing Location: **Northborough**

Irradiator / Method: **126, Nordion Cobalt-60 Irradiator #126, ON-STD**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	0C1	0CA600166921	TH0119	0528	16.8	16.8
1	2	13A5	0CA600010840	TH0119	0528	21.3	21.3
1	3	13E5	0CA600166949	TH0119	0528	20.6	20.6
9	1	0C1	0CA600166901	TH0119	0528	16.4	16.4
9	2	13A5	0CA600166700	TH0119	0528	21.2	21.2
9	3	13E5	0CA600166865	TH0119	0528	21.1	21.1

Minimum Dose for Record (kGy): **16.4**

Maximum Dose for Record (kGy): **21.3**

Signature Manifest

Prepared By:
Hung Vuong (Operator)
Signed On 10/14/2020 at 5:24 PM
UTC / GMT Offset (hh:mm): -4:00

Approved By:
Robin Hinckley (QS/RC Analyst)
Signed On 10/15/2020 at 2:39 PM
UTC / GMT Offset (hh:mm): -4:00

Document Content Revision: 1

Page 7 of 7