CERTIFICATE OF QUALITY

Catalog No: BBVL-048 Lot No: 108073 Expiry: 31OCT2022
Storage: Room temperature

PRODUCT DESCRIPTION:

The Cassette Cover consists of a transparent non-fluorescing plastic window that allows images to be taken by the Growth Direct of the membrane on the enclosed media surface.

MANUFACTURE:

The product was manufactured in an ISO certified facility. The sterilization treatment was performed in an ISO certified facility.

QUALITY RELEASE CRITERIA:

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

PHYSICAL TESTS:

1. Optical background	Pass
2. No fluorescent debris	Pass

This is sterilized as indicated on the product label, packaged and sealed in a Tyvek/poly pouch and stored in a cardboard box.

Released by:
Quality Assurance

Date: 13 NOV 2020

Rapidmicro biosystems
1001 Pawtucket Blvd
Lowell, MA 01854
978-349-3200

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

LOT INSPECTION AND ACCEPTANCE FORM

Catalog #: BBVL-048 Lot Number: 108073 Expiration Date: 31 OCT 2022

Certificate from Manufacturer provided: ☑ Pass ☐ Fail ☐ N/A (N/A if RMB build)

Does the Certificate have the correct information on it according to the notes on the drawing? ☑ Pass ☐ Fail ☐ N/A

Certificate from Sterilizer provided: ☑ Pass ☐ Fail ☐ N/A Sterilization Date: 23 OCT 2020 - 25 OCT 2020

Lot record reviewed ☑ Pass ☐ Fail ☐ N/A (N/A if supplier build)

Sterilization parameters (ETO):

EO Inject Concentration: 454	Specification: 409-461 mg/L	☑ Pass	☐ Fail
EO Inject Pressure: 8.80	Specification: 8.40-8.80 PSIA	☑ Pass	☐ Fail
EO Dwell Concentration: 449.8-454.10	Specification: 408.9-472.0 mg/L	☑ Pass	☐ Fail
EO Dwell Time: 04:01	Specification: 04:00-04:10 (HH:mm)	☑ Pass	☐ Fail

Are parts properly packaged? ☑ Pass ☐ Fail

Are the boxes labeled properly? ☑ Pass ☐ Fail

Are the boxes properly sealed? ☑ Pass ☐ Fail

Are the boxes free of damage? ☑ Pass ☐ Fail

Is Labeling correct per BOM ☑ Pass ☐ Fail

One expiration date per Lot ☑ Pass ☐ Fail

Review and Lot Acceptance

Lot is accepted for use: YES / NO

Associated NCR(s)/Deviation(s): N/A GR 12 NOV 2020

Completed By: Greg Reid **Date:** 12 NOV 2020

Reviewed By: [signature] **Date:** 12 Nov 2020

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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	ADRESSE DU FOURNISSEUR / SUPPLIER'S ADRESS	
Steris Apllied Sterilization 435 Whitney Street, Northborough, MA 01532 USA	Plastiques Moore inc. 22, rue de l'Entreprise St-Damien Bellechasse, Qc, GOR 2Y0	
BULLETIN DE COMMANDE / PURCHASE ORDER	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 QJI 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	
PO-JR00064		
N° DE RELÂCHE (SI REQUIS) / RELEASE NO. ON ORDER (IF REQUIRED)	Jocelyn Lecompte Validation and Documentation Specialist NOM/TITRE DACTYLOGRAPHIÉS - NAME AND TITLE TYPED	Jocelyn Lecompte SIGNATURE (FOURNISSEUR - SUPPLIER) 13/10/2020 DATE (J/M/A) (D/M/Y)
BE-15058		

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
11260	Optical Lids	13779 Rev B	108073	9 984 units
	Date de fabrication / Date of manfacture : 08/10/2020 Date d'expération / Expiration Date : 2022-10 Raw Material Certificate of Analysis : lot no.: 0351113002			

Certificate of Processing

Prepared for **RAPID MICRO BIOSYSTEMS**

Ethylene Oxide Load Number **30709**

STERIS

Product Code	Lot Number	Quantity
Customer Load ID: EL00016		
Cycle 3 Item	106262	1 PL
Cycle 3 Item	106264	1 PL
Cycle 3 Item	106266	1 PL
Cycle 3 Item	108073	1 PL
Cycle 3 Item	108087	1 PL
Cycle 3 Item	108089	1 PL

Preconditioning

Equipment Name	Start Date/Time	End Date/Time	Duration (hrs)
Preconditioning Room	23-Oct-2020 10:00	23-Oct-2020 22:40	12.68

		Min	Max
Relative Humidity (%RH):	Spec:	40.0	80.0
	Actual:	54.3	69.0
Temperature (°F):	Spec:	100.0	120.0
	Actual:	108.6	113.5

Vessel Processing

Equipment Name	Start Date/Time	End Date/Time	Duration (hrs)
Chamber 5	23-Oct-2020 23:10	24-Oct-2020 10:28	11.30

Drum ID	EO Drum Serial Number	EO Lot Number	EO Usage (lbs)
5245	E004776	UTLX903007H20	28.0

Aeration

Equipment Name	Start Date/Time	End Date/Time	Duration (hrs)
Aeration Room	24-Oct-2020 12:09	25-Oct-2020 11:04	22.93

		Min	Max
Aeration Temperature (°F):	Spec:	100.0	120.0
	Actual:	104.6	115.7

Customer Specification ID: Cycle 3 - Test/Study Cycle

Product meets Customer specifications; zero nonconformities occurred during this EO load.

Signature Manifest

Reviewed and E-Signed By

Ludmila O'mara (QS/RC Tech)

Document Content Revision: 1

Signed On 10/26/2020 at 9:40 AM

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

Processing Location:
STERIS
3459 South Clinton Ave
South Plainfield, NJ
Phone: 908-757-3727
Fax: 908-757-2926

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 EN ANSI/AAMI/ISO 11135.

*** End of Ethylene Oxide Certificate of Processing Document ***

STERIS - Receiving Report

Receipt ID: **56418**

RAPID MICRO BIOSYSTEMS (4764)
Product received from:
RAPID MICRO BIOSYSTEMS
1001 PAWTUCKET BLVD WEST
LOWELL, MA 01854
US

Frt Carrier: **New Penn**
Trailer #: **NA**
Bill of Lading: **20609355**
Seal: **None**
PO Number: **EL00016**
Product counts verified by STERIS

Receipt Date/Time: **10/21/20 13:57**
ETA:
Pallet Count 6

Container Unload

Ethylene Oxide Item/Lot Summary

Item ID	Pkg	Lot Number	Cust Qty	STERIS Qty	UOM	CD	Dmg Qty	Wh Loc
Cycle 3 Item	1	106262	1	1	PL		0	SPLD
Other Info: EL00016								
Cycle 3 Item	1	106264	1	1	PL		0	SPLD
Other Info: EL00016								
Cycle 3 Item	1	106266	1	1	PL		0	SPLD
Other Info: EL00016								
Cycle 3 Item	1	108073	1	1	PL		0	SPLD
Other Info: EL00016								
Cycle 3 Item	1	108087	1	1	PL		0	SPLD
Other Info: EL00016								
Cycle 3 Item	1	108089	1	1	PL		0	SPLD
Other Info: EL00016								
Totals:			6	6				

Pallet Detail

Pallet ID	Item ID / Customer Item ID (if different)	Pkg	Lot Number	STERIS Quantity	UOM	Pallet Running Total	Pallet Serial Number
1	Cycle 3 Item	1	108073	1	PL	1	7200508
2	Cycle 3 Item	1	106262	1	PL	1	7200509
3	Cycle 3 Item	1	106264	1	PL	1	7200510
4	Cycle 3 Item	1	106266	1	PL	1	7200511
5	Cycle 3 Item	1	108087	1	PL	1	7200512
6	Cycle 3 Item	1	108089	1	PL	1	7200513

STERIS - Receiving Report

Receipt ID: **56418**

RAPID MICRO BIOSYSTEMS (4764)
Product received from:
RAPID MICRO BIOSYSTEMS
1001 PAWTUCKET BLVD WEST
LOWELL, MA 01854
US

Frt Carrier: **New Penn**
Trailer #: **NA**
Bill of Lading: **20609355**
Seal: **None**
PO Number: **EL00016**
Product counts verified by STERIS

Receipt Date/Time: **10/21/20 13:57**
ETA:
Pallet Count 6

Container Unload

Signature Manifest

Reviewed By:
Brown, Katherine (Production Assistant I)
Document Content Revision: 1

Signed On 10/22/2020 at 11:33 AM
UTC / GMT Offset (hh:mm): -4:00

Stage Cmd:

Stage
1. Scan Stage Cmd
2. Scan Receipt ID
3. Select Destination

Confirm Cmd:

Confirm
1. Scan Confirm Cmd
2. Scan Pallet
3. Move to destination
4. Scan destination

EO Processing Results

Customer Load ID: EL00016

Specifications assigned to Load 30709

Spec Type	Spec ID	Rev	Validation Spec	Cust Spec ID
Process	3	5	No	Cycle 3 - Test/Study Cycle

Process Spec Other Info: Cycle 3 - Test/Study Cycle: No BI's required. Non-Validated Process.
Transfer time into chamber less than 1 hour.
Extend Precon & Aeration times to compensate for below spec conditions.

Results Summary	Collected / Confirmed	Missing	Out of Spec
Parameters:	86	0	0
Sensors:	0	0	N/A
Equipment:	3	0	N/A
EO Usage:	1	0	N/A
Actions:	0	0	N/A
Documents:	1	0	N/A

Approved Equipment

Stage Name	Equipment Name	Capacity	Cycle ID	Cycle Rev	Check Value	Cycle Comments
Preconditioning	Preconditioning Room	2925 SF	N/A	N/A	N/A	N/A
Preconditioning	Preconditioning Room 2	750 SF	N/A	N/A	N/A	N/A
Vessel Processing	Chamber 3	12 PL	N/A	N/A	N/A	N/A
Vessel Processing	Chamber 4	6 PL	N/A	N/A	N/A	N/A
Vessel Processing	Chamber 5	6 PL	N/A	N/A	N/A	N/A
Vessel Processing	Chamber 6	8 PL	N/A	N/A	N/A	N/A
Vessel Processing	Chamber 7	1 PL	N/A	N/A	N/A	N/A
Aeration	Aeration Room	3923 SF	N/A	N/A	N/A	N/A

Customer Inventory associated with Load ID 30709

STERIS Item ID	Lot Number	Cust Item ID	PO Number	Cust Load ID	Receipt ID	Qty	UOM
Cycle 3 Item	106264	Cycle 3 Item	EL00016	EL00016	56418	1	PL
Cycle 3 Item	108073	Cycle 3 Item	EL00016	EL00016	56418	1	PL
Cycle 3 Item	106262	Cycle 3 Item	EL00016	EL00016	56418	1	PL
Cycle 3 Item	106266	Cycle 3 Item	EL00016	EL00016	56418	1	PL
Cycle 3 Item	108087	Cycle 3 Item	EL00016	EL00016	56418	1	PL
Cycle 3 Item	108089	Cycle 3 Item	EL00016	EL00016	56418	1	PL
					Total Quantity:	**6**	

EO Processing Results

STERIS Load ID **30709**

Equipment Processing Times

Stage / Equipment	Entry / Exit		--- Duration --- Minutes	Hours
Preconditioning	23-Oct-2020 10:00		760	12.67
Preconditioning Room	23-Oct-2020 22:40			
		Total	760	12.67
Vessel Processing	23-Oct-2020 23:10		678	11.30
Chamber 5	24-Oct-2020 10:28			
		Total	678	11.30
Aeration	24-Oct-2020 12:09		1375	22.92
Aeration Room	25-Oct-2020 11:04			
		Aeration Total	1375	22.92
		Total	1375	22.92

EO Usage Summary

Drum ID / SN / Lot#	Equip / Scale	Drum Weight Start / End	EO Usage	UOM	Reported By / Date
5245					
E004776	Chamber 5	587.5	28.0	lbs	PLCONTROLS
UTLX903007H20		559.5			10/24/2020 6:22:23AM
		Total EO Usage	28.0		

Processing Results

Stage: Load Generation **Phase: Load Information**

Pallet Count - Tolerance	Spec: Min= 1; Max= 12			Check for Release
	Actual: 8			

Stage: Preconditioning **Phase: PCR**

Length of Time (hr) - Tolerance	Spec: Min= 8.00; Max= 48.00	Start:	23-Oct 10:00:03	Check for Release
	Actual: 12.68	End:	23-Oct 22:40:44	
Relative Humidity (%RH) - Tolerance	Spec: Min= 40.0; Max= 80.0			Check for Release
	Actual: Min= 54.3; Max= 69.0			
Temperature (°F) - Tolerance	Spec: Min= 100.0; Max= 120.0			Check for Release
	Actual: Min= 108.6; Max= 113.5			

Stage: Preconditioning **Phase: PCR Transfer**

Transfer Time from PCR to Vessel (min) - Tolerance	Spec: Min= N/A; Max= 60	Start:	23-Oct 22:40:44	Check for Release
	Actual: 30	End:	23-Oct 23:10:56	

Stage: Vessel Processing **Phase: Evacuation**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:15; Max= 00:45	Start:	23-Oct 23:11:07	Check for Release
	Actual: 00:32	End:	23-Oct 23:43:30	
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0			Check for Release
	Actual: Min= 110.8; Max= 118.1			
Final Pressure (PSIA) - Tolerance	Spec: Min= 0.7; Max= 1.2			Check for Release
	Actual: 1.0			

Stage: Vessel Processing **Phase: Leak Check**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:04; Max= 00:10	Start:	23-Oct 23:43:31	Check for Release
	Actual: 00:05	End:	23-Oct 23:48:39	
Pressure (PSIA) - Tolerance	Spec: Min= 0.7; Max= 1.2			Check for Release
	Actual: Min= 1.0; Max= 1.1			
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0			Check for Release
	Actual: Min= 118.2; Max= 119.3			

Final Pressure (PSIA) - Tolerance	Spec: Min= 0.7; Max= 1.2 Actual: 1.1		Check for Release
Stage: Vessel Processing Phase: Steam Inject			
Length of Time (d HH mm) - Tolerance	Spec: Min= 00:05; Max= 00:30 Actual: 00:20	Start: 23-Oct 23:48:40 End: 24-Oct 00:08:55	Check for Release
Relative Humidity (%RH) - Tolerance	Spec: Min= 20.0; Max= 46.0 Actual: Min= N/A; Max= 34.6		Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 119.3; Max= 123.2		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 1.5; Max= 1.9 Actual: 1.7		Check for Release
Relative Humidity (%RH) - Tolerance	Spec: Min= 20.0; Max= 46.0 Actual: 34 6		Check for Release
Stage: Vessel Processing Phase: Conditioning Dwell			
Length of Time (d HH mm) - Tolerance	Spec: Min= 01:05; Max= 01:15 Actual: 01:06	Start: 24-Oct 00:08:56 End: 24-Oct 01:15:04	Check for Release
Relative Humidity (%RH) - Tolerance	Spec: Min= 20.0; Max= 46.0 Actual: Min= 29.5; Max= 34.6		Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 123.2; Max= 127.9		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 1.5; Max= 1.9 Actual: 1.7		Check for Release
Relative Humidity (%RH) - Tolerance	Spec: Min= 20.0; Max= 46.0 Actual: 29.8		Check for Release
Stage: Vessel Processing Phase: Nitrogen Inject			
Length of Time (d HH mm) - Tolerance	Spec: Min= 00:10; Max= 00:30 Actual: 00:20	Start: 24-Oct 01:15:05 End: 24-Oct 01:35:15	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 127.8; Max= 127.9		Check for Release

Final Pressure (PSIA) - Tolerance	Spec: Min= 4.5; Max= 4.9 Actual: 4.7		Check for Release
Stage: Vessel Processing Phase: EO Inject			
Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:05; Max= 00:45 Actual: 00:20	Start: 24-Oct 01:35:16 End: 24-Oct 01:55:50	Check for Release
EO Gas Usage (lbs) - Tolerance	Spec: Min= 0.5; Max= 200.0 Actual: 28.0		Check for Release
Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 127.7; Max= 127.8		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 8.4; Max= 8.8 Actual: 8.8		Check for Release
EO Concentration (mg/l) - Tolerance	Spec: Min= 409; Max= 461 Actual: 454		Check for Release
Stage: Vessel Processing Phase: Nitrogen Inject			
Length of Time (d HH mm) - Tolerance	Spec: Min= 00:15; Max= 00:45 Actual: 00:25	Start: 24-Oct 01:55:51 End: 24-Oct 02:21:05	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 127.7; Max= 127.9		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 14.0; Max= 14.4 Actual: 14.2		Check for Release
Stage: Vessel Processing Phase: EO Dwell			
Length of Time (d HH:mm) - Tolerance	Spec: Min= 04:00; Max= 04:10 Actual: 04:01	Start: 24-Oct 02:21:06 End: 24-Oct 06:22:30	Check for Release
EO Concentration (mg/l) - Tolerance	Spec: Min= 408.9; Max= 472.0 Actual: Min= 449.8; Max= 454.1		Check for Release
Pressure (PSIA) - Tolerance	Spec: Min= 14.0; Max= 14.5 Actual: Min= 14.2; Max= 14.2		Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 125.0; Max= 135.0 Actual: Min= 127.9; Max= 129.1		Check for Release

Stage: Vessel Processing **Phase: Evacuation**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:31	Start: 24-Oct 06:22:30 End: 24-Oct 06:54:27	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 127.2; Max= 129.1		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 1.0; Max= 1.4 Actual: 1.2		Check for Release

Stage: Vessel Processing **Phase: Nitrogen Inject**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:30	Start: 24-Oct 06:54:28 End: 24-Oct 07:24:39	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 126.7; Max= 127.2		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 14.0; Max= 14.4 Actual: 14.2		Check for Release

Stage: Vessel Processing **Phase: Evacuation**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:31	Start: 24-Oct 07:24:40 End: 24-Oct 07:56:09	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 126.3; Max= 126.9		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 1.0; Max= 1.4 Actual: 1.2		Check for Release

Stage: Vessel Processing **Phase: Nitrogen Inject**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:30	Start: 24-Oct 07:56:09 End: 24-Oct 08:26:20	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 126.2; Max= 126.3		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 14.0; Max= 14.4 Actual: 14.2		Check for Release

Stage: Vessel Processing **Phase: Evacuation**

Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:31	Start: 24-Oct 08:26:21 End: 24-Oct 08:57:40	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 126.0; Max= 126.4		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 1.0; Max= 1.4 Actual: 1.2		Check for Release
Stage: Vessel Processing Phase: Nitrogen Inject			
Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:30	Start: 24-Oct 08:57:41 End: 24-Oct 09:27:50	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 125.9; Max= 126.1		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 14.0; Max= 14.4 Actual: 14.2		Check for Release
Stage: Vessel Processing Phase: Evacuation			
Length of Time (d HH mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:31	Start: 24-Oct 09:27:51 End: 24-Oct 09:59:06	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 125.8; Max= 126.1		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 1.0; Max= 1.4 Actual: 1.2		Check for Release
Stage: Vessel Processing Phase: Air Inbleed			
Length of Time (d HH:mm) - Tolerance	Spec: Min= 00:10; Max= 00:45 Actual: 00:29	Start: 24-Oct 09:59:07 End: 24-Oct 10:28:49	Check for Release
Chamber Temperature (°F) - Tolerance	Spec: Min= 0.0; Max= 135.0 Actual: Min= 125.5; Max= 125.8		Check for Release
Final Pressure (PSIA) - Tolerance	Spec: Min= 14.0; Max= 15.0 Actual: 14.2		Check for Release
Stage: Aeration Phase: Aeration Room			

Length of Time (hr) - Tolerance	Spec: Min= 8.00; Max= 60.00 Actual: 22.93	Start: 24-Oct 12:09:07 End: 25-Oct 11:04:55	Check for Release
Temperature (°F) - Tolerance	Spec: Min= 100.0; Max= 120.0 Actual: Min= 104.6; Max= 115.7		Check for Release

Signature Manifest

Approved By:

Rosete, Nathaniel (Supervisor, Production I)

Signed On 10/26/2020 at 7:35 AM

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

Document Content Revision: 1

Detailed Run Record

STERIS Isomedix Services
3459 South Clinton Ave.
South Plainfield, NJ 07080
Tel: 908-757-3727
Fax: 908-757-2926

Load #:	30709	Customer Name:	RAPID MICRO BIOSYSTEM
Chamber #:	5	Cust. Load Number:	EL00016
Spec ID:	3	Cust. Spec. ID:	Cycle 3 - Test/Study Cycle
Spec Rev:	5	Date in Vessel:	10/23/2020
	Blowers are Required	Date Processed:	10/24/2020

Evacuation

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
23:11:07	14.7	14.7	110.8					
23:16:06	12.4	12.4	111.2					
23:21:06	10.1	10.1	112.2					
23:26:06	7.8	7.8	113.8					
23:31:06	5.6	5.6	115.2					
23:36:06	3.3	3.3	116.6					
23:41:06	1.4	1.0	117.7					
23:43:30	1.0	1.0	118.1					

Elapsed Time	00:32:24
Final Pressure	1.0 PSIA
Maximum Avg. Temp.	118.1 °F
Minimum Avg. Temp.	110.8 °F

Leak Check

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
23:43:31	1.0	1.0	118.2					
23:48:30	1.1	1.0	119.2					
23:48:39	1.1	1.0	119.3					

Elapsed Time	00:05:09
Final Pressure	1.1 PSIA
Maximum Pressure	1.1 PSIA
Minimum Pressure	1.0 PSIA
Maximum Avg. Temp.	119.3 °F
Minimum Avg. Temp.	118.2 °F

Steam Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
23:48:40	1.1	1.1	119.3	0.0				
23:53:39	1.2	1.2	120.3	10.3				
23:58:39	1.4	1.4	121.2	17.8				
0:03:39	1.5	1.5	122.2	26.7				
0:08:39	1.7	1.7	123.1	34.6				
0:08:55	1.7	1.7	123.2	34.6				

Elapsed Time	00:20:16
Final Pressure	1.7 PSIA
Maximum Avg. Temp.	123.2 °F
Minimum Avg. Temp.	119.3 °F
Final RH	34.6 %
Maximum RH	34.6 %

Conditioning Dwell

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
0:08:56	1.7	1.7	123.2	34.6				
0:13:55	1.7	1.7	123.8	32.8				
0:18:55	1.7	1.7	124.3	32.8				
0:23:55	1.7	1.7	124.8	32.0				
0:28:55	1.7	1.7	125.1	31.9				
0:33:55	1.7	1.7	125.5	31.2				
0:38:55	1.7	1.7	125.9	31.2				
0:43:55	1.7	1.7	126.2	31.1				
0:48:55	1.7	1.7	126.5	31.1				
0:53:55	1.7	1.7	126.8	30.3				
0:58:55	1.7	1.7	127.1	30.3				
1:03:55	1.7	1.7	127.3	30.5				
1:08:55	1.7	1.7	127.6	29.5				
1:13:55	1.7	1.7	127.8	29.8				
1:15:04	1.7	1.7	127.9	29.8				

Elapsed Time	01:06:09
Maximum Pressure	1.7 PSIA
Minimum Pressure	1.7 PSIA
Maximum Avg. Temp.	127.9 °F
Minimum Avg. Temp.	123.2 °F
Minimum RH	29.5 %
Maximum RH	34.6 %

Nitrogen Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
1:15:05	1.7	1.7	127.9					
1:20:04	2.4	2.4	127.8					
1:25:04	3.2	3.2	127.9					
1:30:04	3.9	3.9	127.8					
1:35:04	4.7	4.7	127.8					
1:35:15	4.7	4.7	127.8					

Elapsed Time	00:20:11
Final Pressure	4.7 PSIA
Maximum Avg. Temp.	127.9 °F
Minimum Avg. Temp.	127.8 °F

EO Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
1:35:16	4 7	4 7	127 8		0	587 5		
1:40:15	5.7	5.7	127.7		116	580 9		
1:45:15	6.8	6.7	127.7		231	574.3		
1:50:15	7.7	7.6	127.7		333	567.5		
1:55:15	8.5	8.6	127.7		427	560.1		
1:55:50	8.8	8.6	127.7		454	559.5		

Elapsed Time	00:20:35
Final Pressure	8.8 PSIA
Maximum Avg. Temp.	127.8 °F
Minimum Avg. Temp.	127.7 °F
Final EtO Conc.	454 mg/l
Total EtO Weight	28.0 lbs

Tank ID	EtO Injection Start Time	EtO Injection Stop Time	Initial Weight (lbs)	Final Weight (lbs)	Used Weight (lbs)
5245	1:35:16	1:55:50	587.5	559.5	28.0
				Total Weight	28.0

Nitrogen Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
1:55:51	8.8	8.8	127.7					
2:00:50	9.8	9.8	127.7					
2:05:50	10.9	10.9	127.7					
2:10:50	12.0	12.0	127.8					
2:15:50	13.1	13.1	127.8					
2:20:50	14.2	14.2	127.9					
2:21:05	14.2	14.2	127.9					

Elapsed Time	00:25:15
Final Pressure	14.2 PSIA
Maximum Avg. Temp.	127.9 °F
Minimum Avg. Temp.	127.7 °F

EO Dwell

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
2:21:06	14.2	14.2	127.9		454	559.5		
2:26:05	14.2	14.2	127.9		452	559.5		
2:31:05	14.2	14.2	128.0		453	559.5		
2:36:05	14.2	14.2	128.0		453	559.5		
2:41:05	14.2	14.2	128.1		453	559.5		
2:46:05	14.2	14.2	128.2		454	559.5		
2:51:05	14.2	14.2	128.2		454	559.5		
2:56:05	14.2	14.2	128.2		454	559.5		
3:01:05	14.2	14.2	128.3		454	559.5		
3:06:05	14.2	14.2	128.3		454	559.5		
3:11:05	14.2	14.2	128.4		454	559.5		
3:16:05	14.2	14.2	128.5		454	559.5		
3:21:05	14.2	14.2	128.5		454	559.5		
3:26:05	14.2	14.2	128.5		454	559.5		
3:31:05	14.2	14.2	128.6		454	559.5		
3:36:05	14.2	14.2	128.7		454	559.5		
3:41:05	14.2	14.2	128.7		454	559.5		
3:46:05	14.2	14.2	128.7		453	559.5		
3:51:05	14.2	14.2	128.7		453	559.5		
3:56:05	14.2	14.2	128.7		454	559.5		
4:01:05	14.2	14.2	128.8		453	559.5		
4:06:05	14.2	14.2	128.8		453	559.5		
4:11:05	14.2	14.2	128.9		453	559.5		
4:16:05	14.2	14.2	128.8		453	559.5		
4:21:05	14.2	14.2	128.9		453	559.5		
4:26:05	14.2	14.2	129.0		453	559.5		
4:31:05	14.2	14.2	129.0		452	559.5		
4:36:05	14.2	14.2	129.1		452	559.5		
4:41:05	14.2	14.2	129.0		452	559.5		
4:46:05	14.2	14.2	129.1		452	559.5		
4:51:05	14.2	14.2	129.1		452	559.5		
4:56:05	14.2	14.2	129.0		451	559.5		
5:01:05	14.2	14.2	128.9		451	559.5		
5:06:05	14.2	14.2	128.9		450	559.5		
5:11:05	14.2	14.2	129.0		450	559.5		
5:16:01	14.2	14.2	129.1		450	559.5		
5:21:01	14.2	14.2	129.1		450	559.5		
5:26:01	14.2	14.2	129.0		453	559.5		
5:31:01	14.2	14.2	129.0		453	559.5		
5:36:01	14.2	14.2	129.0		453	559.5		
5:41:01	14.2	14.2	129.1		453	559.5		
5:46:01	14.2	14.2	129.1		452	559.5		
5:51:01	14.2	14.2	129.0		452	559.5		
5:56:01	14.2	14.2	128.9		452	559.5		
6:01:01	14.2	14.2	129.0		451	559.5		
6:06:01	14.2	14.2	129.0		451	559.5		
6:11:01	14.2	14.2	129.1		451	559.5		
6:16:01	14.2	14.2	129.1		451	559.5		
6:21:01	14.2	14.2	129.1		451	559.5		
6:22:30	14.2	14.2	129.1		451	559.5		

Elapsed Time	04:01:29
Maximum Pressure	14.2 PSIA
Minimum Pressure	14.2 PSIA
Maximum Avg. Temp.	129.1 °F
Minimum Avg. Temp.	127.9 °F
Minimum EtO Conc.	450 mg/l
Maximum EtO Conc.	454 mg/l

Tank ID	EtO Injection Start Time	EtO Injection Stop Time	Initial Weight (lbs)	Final Weight (lbs)	Used Weight (lbs)
5245	4:56:56	6:22:30	559.5	559.5	0.0
				Total Weight	0.0

Evacuation

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
6:22:31	14.2	14.2	129.1					
6:27:30	12.1	12.0	128.9					
6:32:30	9.9	9.9	128.6					
6:37:30	7.7	7.7	128.3					
6:42:30	5.6	5.5	127.9					
6:47:30	3.4	3.4	127.7					
6:52:30	1.6	1.2	127.3					
6:54:27	1.2	1.2	127.2					

Elapsed Time	00:31:57
Final Pressure	1.2 PSIA
Maximum Avg. Temp.	129.1 °F
Minimum Avg. Temp.	127.2 °F

Nitrogen Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
6:54:28	1.2	1.2	127.2					
6:59:27	3.3	3.4	127.0					
7:04:27	5.5	5.5	126.9					
7:09:27	7.7	7.7	126.8					
7:14:27	9.9	9.9	126.9					
7:19:27	12.0	12.0	126.7					
7:24:27	14.2	14.2	126.9					
7:24:39	14.2	14.2	126.9					

Elapsed Time	00:30:12
Final Pressure	14.2 PSIA
Maximum Avg. Temp.	127.2 °F
Minimum Avg. Temp.	126.7 °F

■Evacuation

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
7:24:40	14.2	14.2	126.9					
7:29:39	12.1	12.1	126.8					
7:34:39	9.9	9.9	126.8					
7:39:39	7.7	7.7	126.8					
7:44:39	5.6	5.6	126.6					
7:49:39	3.4	3.4	126.5					
7:54:39	1.5	1.2	126.4					
7:56:09	1.2	1.2	126.3					

Elapsed Time	00:31:30
Final Pressure	1.2 PSIA
Maximum Avg. Temp.	126.9 °F
Minimum Avg. Temp.	126.3 °F

■Nitrogen Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
7:56:10	1.2	1.2	126.3					
8:01:09	3.3	3.4	126.3					
8:06:09	5.5	5.5	126.3					
8:11:09	7.7	7.7	126.2					
8:16:09	9.9	9.9	126.3					
8:21:09	12.0	12.0	126.3					
8:26:09	14.2	14.2	126.3					
8:26:20	14.2	14.2	126.3					

Elapsed Time	00:30:11
Final Pressure	14.2 PSIA
Maximum Avg. Temp.	126.3 °F
Minimum Avg. Temp.	126.2 °F

■Evacuation

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
8:26:21	14.2	14.2	126.3					
8:31:20	12.1	12.1	126.4					
8:36:20	9.9	9.9	126.4					
8:41:20	7.7	7.7	126.2					
8:46:20	5.6	5.6	126.3					
8:51:20	3.4	3.4	126.2					
8:56:20	1.5	1.2	126.0					
8:57:40	1.2	1.2	126.0					

Elapsed Time	00:31:20
Final Pressure	1.2 PSIA
Maximum Avg. Temp.	126.4 °F
Minimum Avg. Temp.	126.0 °F

Nitrogen Inject

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
8:57:41	1.2	1.2	126.0					
9:02:40	3.3	3.3	126.0					
9:07:40	5.5	5.5	125.9					
9:12:40	7.7	7.7	126.0					
9:17:40	9.8	9.9	126.0					
9:22:40	12.0	12.0	126.0					
9:27:40	14.2	14.2	126.1					
9:27:50	14.2	14.2	126.1					

Elapsed Time	00:30:10
Final Pressure	14.2 PSIA
Maximum Avg. Temp.	126.1 °F
Minimum Avg. Temp.	125.9 °F

Evacuation

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
9:27:51	14.2	14.2	126.1					
9:32:50	12.1	12.1	126.1					
9:37:50	9.9	9.9	126.0					
9:42:50	7.7	7.7	126.0					
9:47:50	5.6	5.6	126.0					
9:52:50	3.4	3.4	125.9					
9:57:50	1.5	1.2	125.9					
9:59:06	1.2	1.2	125.8					

Elapsed Time	00:31:16
Final Pressure	1.2 PSIA
Maximum Avg. Temp.	126.1 °F
Minimum Avg. Temp.	125.8 °F

Air Inbleed

Time	Pressure (PSIA)	Setpoint (PSIA)	Avg. Temp (°F)	RH (%)	EtO Conc (mg/l)	EtO Weight (lbs)	Product Temperature (°F)	Steam Valve (%)
9:59:07	1.2	1.2	125.8					
10:04:06	3.5	3.3	125.7					
10:09:06	5.3	5.5	125.6					
10:14:06	7.7	7.7	125.5					
10:19:06	9.8	9.9	125.5					
10:24:06	12.0	12.0	125.5					
10:28:49	14.2	14.1	125.6					

Elapsed Time	00:29:43
Final Pressure	14.2 PSIA
Maximum Avg. Temp.	125.8 °F
Minimum Avg. Temp.	125.5 °F

Detailed Run Record

STERIS Isomedix Services
3459 South Clinton Ave.
South Plainfield, NJ 07080
Tel: 908-757-3727
Tel: 908-757-2926

Steris Load #:	30709	**Customer Name:**	RAPID MICRO BIOSYSTEM
Chamber #:	5	**Cust. Load Number:**	EL00016
Spec. ID:	3	**Cust. Spec.:**	Cycle 3 - Test/Study Cycle
Spec. Rev:	5	**Date Processed:**	10/24/2020

17 of 17 steps processed.
0 non-conformities occured.