Cytiva
925 West 1800 South
Logan, Utah 84321
USA

Change Control Notification

Logan, Utah, USA, 19 June 2020 TW392538H

Regarding: GE Healthcare Life Sciences (Biopharma business) is now Cytiva. Certificates of Analysis and Label updates.

Dear Customer,

As part of our change control program, we write to notify you that Danaher Corporation's purchase of the GE Healthcare Life Sciences Biopharma business units consisting of BioProcess, Cell & Gene Therapy and Genomics & Cellular Research is now complete. As of 01 Apr 2020, we began doing business as Cytiva.

Cytiva is now part of the Danaher Corporation, which is a public company.

Affected products

A global change control notification, TW392538, was distributed through the Regulatory Support CCN website to cover all impacted GE Healthcare Life Science Biopharma business units and products. This notification specifically covers all HyClone products.

What is not changing

This is a change of the company brand name only. There is no change to the products, nor the legal entity. Please be assured that we will continue to deliver our products and services to you as usual. The following main items WILL NOT CHANGE at this time as a result of the transition steps:

- Our quality management system
- Processes for change control including change control notifications
- Manufacturing processes
- Manufacturing locations
- Equipment used in the manufacturing of our products
- Products, product specifications and drawings as such will not change even though brand name and/or logo will get updated
- Product names
- Product part/code numbers
- Lot numbering system
- Quality release claims
- Terms of legal agreements will remain in effect according to their respective terms
- Your account teams and contact

Product documentation provided under the company name GE Healthcare Life Sciences including manuals and instructions, specifications, statements, Regulatory Support Files, Validation Guides, Certificates of Suitability (CEPs), and vendor questionnaires REMAIN VALID until they are updated/revised.

What is changing

Company Brand changes

- The company brand name Cytiva will gradually be included in labelling and/or other product documentation such as certificates, user documentation etc. This means that the GE brand will be removed or replaced on our products and product documentation over time. The changes in label and product documentation imply no difference in product quality or performance. Product quality release claims remain unchanged.
- All Certificates of Suitability and other documents required for import and export of applicable products such as animal-derived sera will be updated to reflect the Cytiva brand name. The timeline for release of the updated certificates is outside of our control and is subject to the processing time of the European Directorate for the Quality of Medicines (EDQM).

Re-branding

- Labels and certificates will be updated with the Cytiva name including logo over time. Examples of updated certificates and labels are provided below. In addition, updated certificates and label examples will be published at www.cytiva.com/4customers.
- Technical drawings will be updated with new brand name at the time they are being revised for other reasons.
- Packaging material where the GE brand and logo is displayed will be updated over time to either include the Cytiva brand and logo or remove the GE company name and logo.

Mixed branding

- Please note that finished products in our warehouses are rotated on a regular basis using first in, first out inventory management and will not be re-labeled. During the transition phase, documents for products or services will be changed gradually in the coming year. For products with a longer shelf life (>2 years) the transition phase can last for several years.
- Mixed branding on products (shipments with differently branded products within the same shipment and/or a product carrying both brands) will occur during the transition phase. For products with a longer shelf life (>2 years) the transition phase can last for multiple years.

Please prepare to receive certain goods with brand name and legal entity details for both Cytiva and GE Healthcare Life Sciences for a period of time. Please ensure that your warehouse and Quality Control release personnel are informed and take necessary actions.

Web and email addresses

Our web address has changed to www.cytiva.com and our email addresses are firstname.lastname@cytiva.com. For a limited period of time, our old email addresses will be forwarded to our new address. Please update your contacts accordingly.

More Information

For updated information related to our transition into Cytiva, such as answers to frequently asked questions, legal entity updates and other relevant information, please visit www.cytiva.com/4customers.

Attachment

- Label and certificate examples

To receive future notifications about our products, please register and subscribe for change control notifications at our website: www.cytiva.com/rsf. We recommend the use of business-related e-mail addresses instead of personal e-mail addresses, ensuring better information sustainability (example: supplier.notifications@company.com).

While your organization is assessing the potential impact of these changes, please do not hesitate to respond to the email delivering this communication or contact our Technical Support team at hyclone.techsupport@cytiva.com.

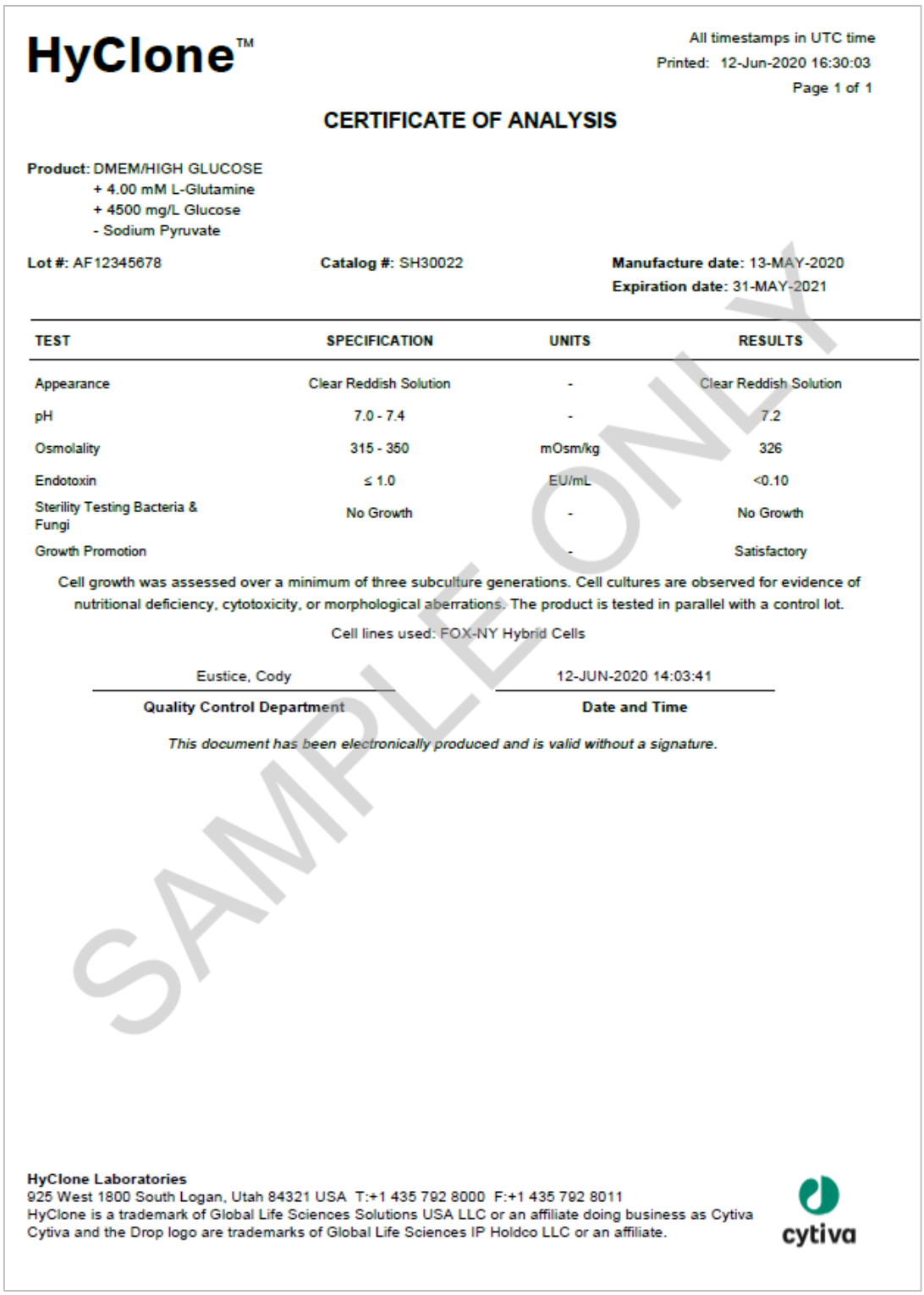
Yours sincerely,

Blake Hadfield

Customer Support Team Lead

Attachment

Certificate of Analysis (COA) layout for Logan (LIMS generated)



HyClone™

All timestamps in UTC time
Printed: 12-Jun-2020 16:30:03
Page 1 of 1

CERTIFICATE OF ANALYSIS

Product: DMEM/HIGH GLUCOSE
+ 4.00 mM L-Glutamine
+ 4500 mg/L Glucose
- Sodium Pyruvate

Lot #: AF12345678 **Catalog #:** SH30022 **Manufacture date:** 13-MAY-2020
Expiration date: 31-MAY-2021

TEST	SPECIFICATION	UNITS	RESULTS
Appearance	Clear Reddish Solution	-	Clear Reddish Solution
pH	7.0 - 7.4	-	7.2
Osmolality	315 - 350	mOsm/kg	326
Endotoxin	≤ 1.0	EU/mL	<0.10
Sterility Testing Bacteria & Fungi	No Growth	-	No Growth
Growth Promotion		-	Satisfactory

Cell growth was assessed over a minimum of three subculture generations. Cell cultures are observed for evidence of nutritional deficiency, cytotoxicity, or morphological aberrations. The product is tested in parallel with a control lot.

Cell lines used: FOX-NY Hybrid Cells

Eustice, Cody — 12-JUN-2020 14:03:41

Quality Control Department — **Date and Time**

This document has been electronically produced and is valid without a signature.

SAMPLE ONLY

HyClone Laboratories
925 West 1800 South Logan, Utah 84321 USA T:+1 435 792 8000 F:+1 435 792 8011
HyClone is a trademark of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva
Cytiva and the Drop logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate.

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COA layout for Pasching (LIMS generated)

HyClone™

All timestamps in UTC time
Printed: 16-Jun-2020 11:22:09
Page 1 of 1

CERTIFICATE OF ANALYSIS

Product: ActiCHO™ P
with Poloxamer-188
without Insulin
without L-Glutamine

Lot #: Cytiva CoA Template **Catalog #:** SH31025 **Manufacture date:** 24-MAR-2020
Expiration date: 24-MAR-2022

TEST	SPECIFICATION	UNITS	RESULTS
Appearance	Free Flowing, Light Brown to Light Orange Powder	-	Free Flowing, Light Brown to Light Orange Powder
Solubility	Soluble	-	Soluble
Moisture	≤ 5.00	%	1.66
pH without $NaHCO_3$	3.1 - 3.9	-	3.6
Osmolality without $NaHCO_3$	247 - 303	mOsm/kg	277
Osmolality with (1.8 g/L) $NaHCO_3$	285-330	mOsm/kg	285
Bioburden	≤ 100	CFU/g	5
Endotoxin	≤ 1	EU/mL	0.12
Particle Size Distribution	≥ 50% passage through sieving net (63 µm)	%	65
HPLC - Amino acid profile	Complies (80-120% recovery)	-	Complies
Growth Promotion	Satisfactory	-	Satisfactory

Cell growth was assessed over a minimum of three subculture generations. Cell cultures are observed for evidence of nutritional deficiency, cytotoxicity, or morphological aberrations. The product is tested in parallel with a control lot.

Cell lines used: CHO-K1 Cells

Gusenbauer, Stefanie	24-MAR-2020 10:00:51
Quality Control Department	**Date and Time**

This document has been electronically produced and is valid without a signature.

Global Life Sciences Solutions Austria GmbH & Co KG
Krempistraße 5 4061 Pasching T:+43 7229 64865 F:+43 7229 64866

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COA layout for Singapore (manually generated)

HyClone™

CERTIFICATE OF ANALYSIS

Product: MEM/EBSS
+ Earle's Balanced Salts
+ 2.0 mM L-Glutamine
− Sodium Bicarbonate
(+ 2.2 g/L)

Lot #: MXXXXXXXXX **Catalog #:** SH30008 **Expiration Date:** MMM/YYYY

Test	Specification	Units	Results
Appearance	Off-White Powder		*
Solubility	Clear Solution at 1X concentration		*
Moisture	≤ 2.00	%	*
(From in-process test)			
pH without $NaHCO_3$	5.4 – 6.4		*
pH with 2.2 g/L $NaHCO_3$	7.0 – 8.0		*
Osmolality without $NaHCO_3$	225 – 260	mOsm/kg	*
Osmolality with 2.2 g/L $NaHCO_3$	265 - 310	mOsm/kg	*
Endotoxin	≤ 1.0	EU/mL	*
Growth Promotion	Satisfactory		*

Cell growth was assessed over a minimum of three subculture generations. Cell cultures are observed for evidence of nutritional deficiency, cytotoxicity, or morphological aberrations. The product is tested in parallel with a control lot.

Cell Line used: VERO Cells

Quality Control Department **Date**

Global Life Sciences Solutions Singapore Pte Ltd
26 Tuas South Street 1 Singapore 638034
1-436-792-8000

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COA layout for Tauranga (manually generated)

HyClone™

Product: **Foetal Bovine Serum**
Collected and Processed in New Zealand
Catalog #: **SH30406**
Lot #: **XXXXXXXXXX**
Filtration: **Triple 0.1 µm Sterile Filtered**
Manufacture Date: **XX-XXX-XX**
Expiration Date: **XX-XXX-XX**
Total Batch Volume: **xxxx.x L**

CERTIFICATE OF ANALYSIS

Test (Method)	Specification	Units	Results
Endotoxin (Kinetic Turbidimetric USP<85>/Ph. Eur 2.6.14)	≤ 20	EU/mL	0
Haemoglobin USP <857> Monograph (Spectrophotometric)	≤ 25	mg/100mL	0.0
Sterility Testing - Bacteria and Fungi (Current USP <71>, Ph. Eu 2.6.1)	No Growth		0
Virus Testing (9 CFR 113.53)			
Fluorescent Antibody			
Bluetongue	Not Detected		0
Bovine Adenovirus	Not Detected		0
Bovine Parvovirus	Not Detected		0
Bovine Respiratory Syncytial Virus	Not Detected		0
Bovine Viral Diarrhoea Virus	Not Detected		0
Rabies	Not Detected		0
Reovirus	Not Detected		0
Cytopathogenic Agents – e.g. IBR	Not Detected		0
Haemadsorbing Agents – e.g. PI3	Not Detected		0
Mycoplasma (USP<63>/Ph. Eur 2.6.7/PTC 1993)	Not Detected		0
Total Protein (Ph. Eur. 2.5.33)	3.0 - 4.5	g/dL	0.0
pH (USP <791> Ph. Eur. 2.2.3)	7.00 - 8.00		0.00
Osmolality (USP <785>/Ph.Eur.2.2.35)	280 – 360	mOsm/Kg	0
Cell Culture Growth			
FOX-NY Hybrid Cells MRC-5 Cells	Satisfactory		0
Double Immunodiffusion (Ouchterlony)	Positive for Bovine		0
Beta Serum Neutralization Titer - EMEA/CVMP/743/00 (4.3.3.3) and EMA/CHMP/BWP/457920/2012 (7.3.4)			
BVDV Genotype 1	FIO		0
BVDV Genotype 2	FIO		0
Gamma Glutamyl Transferase (WID0464-6.12) (enzymatic rate method)	FIO	U/L	0

This product was manufactured from Foetal Bovine Blood collected in New Zealand Ministry for Primary Industries (MPI) inspected abattoirs in New Zealand from clinically healthy bovine animals which were born, continuously reared, and slaughtered in New Zealand and passed ante-mortem and post-mortem inspections.

Global Life Sciences Solutions New Zealand
433 Old Highway Tauranga New Zealand
1-435-792-6000

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HyClone™

Product:	**Foetal Bovine Serum** **Collected and Processed in New Zealand**		
Catalog #:	**SH30406**	Manufacture Date:	**XX-XXX-XX**
Lot #:	**XXXXXXXXXX**	Expiration Date:	**XX-XXX-XX**
Filtration:	**Triple 0.1 µm Sterile Filtered**	Total Batch Volume:	**xxxx.x L**

CERTIFICATE OF ANALYSIS

The World Organisation for Animal Health (O.I.E) Scientific Commission has recognised New Zealand as a country with a negligible BSE risk.

New Zealand has been classified in accordance with Article 5(2) of regulation (EC) No 999/2001 as a country or region posing a negligible Bovine Spongiform Encephalopathy (BSE) risk.

New Zealand HyClone Foetal Bovine Serum products have been granted a Certificate of Suitability to the European Pharmacopoeia Monograph, Certificate #R1-CEP-2000-211.
https://www.cytivalifesciences.com/en/us/support/quality/certificates

The country of origin for this lot has been independently verified by Oritain™ website:
https://oritain.com/partners/ge-healthcare/

Traceability Certified by the ISIA (International Serum Industry Association) website:
https://www.serumindustry.org/

Gavin Hoggard
QA/QC Manager

Date

Global Life Sciences Solutions New Zealand
433 Old Highway Tauranga New Zealand
1-435-792-8000

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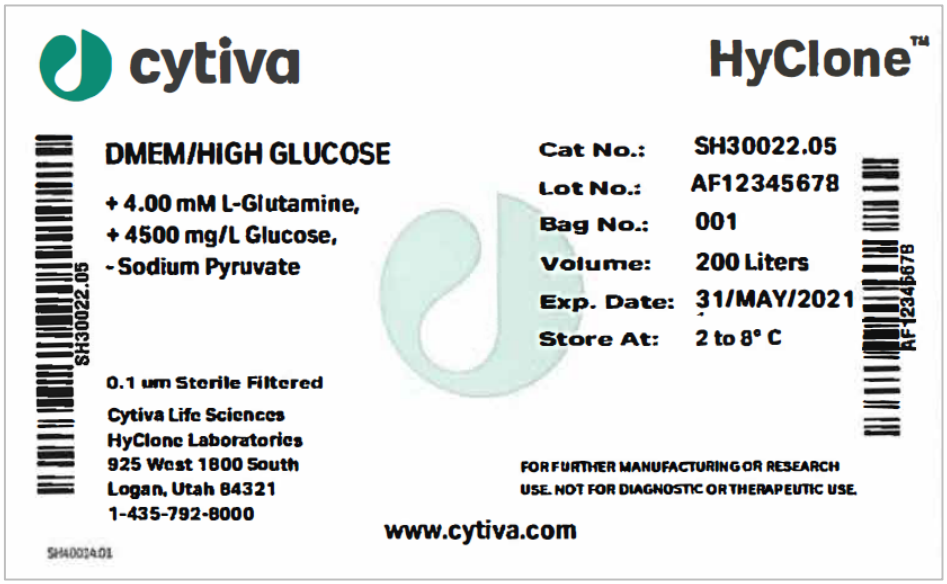
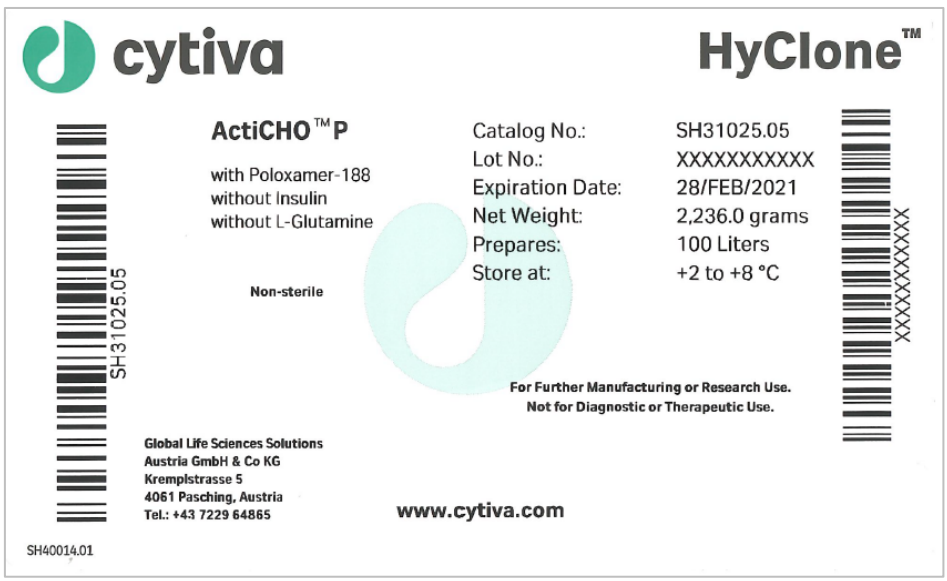
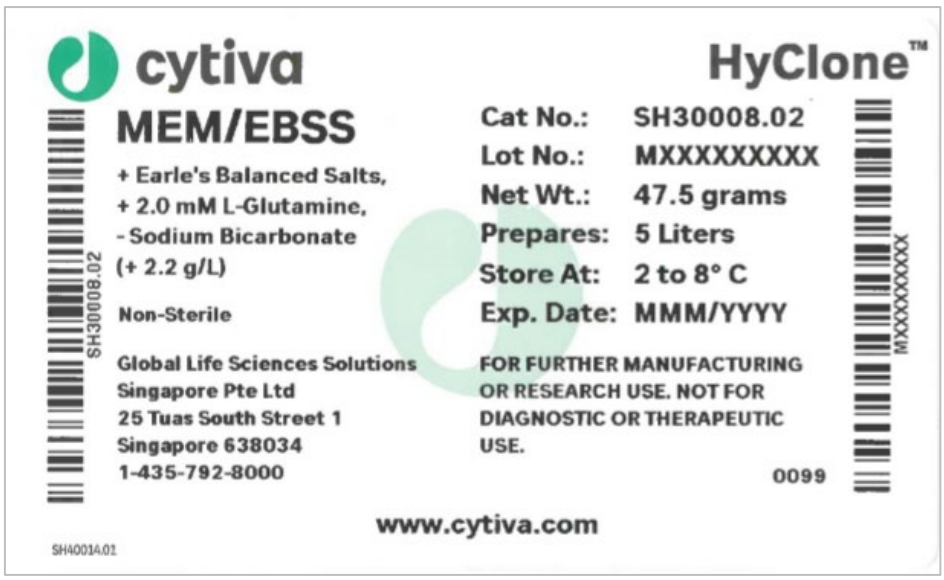
Examples of labels with new branding






cytiva
HyClone™
MEM/EBSS
+ Earle's Balanced Salts,
+ 2.0 mM L-Glutamine,
- Sodium Bicarbonate
(+ 2.2 g/L)
Non-Sterile
Global Life Sciences Solutions
Singapore Pte Ltd
25 Tuas South Street 1
Singapore 638034
1-435-792-8000
Cat No.: SH30008.02
Lot No.: MXXXXXXXXX
Net Wt.: 47.5 grams
Prepares: 5 Liters
Store At: 2 to 8° C
Exp. Date: MMM/YYYY
FOR FURTHER MANUFACTURING OR RESEARCH USE. NOT FOR DIAGNOSTIC OR THERAPEUTIC USE.
0099
www.cytiva.com
SH4001A.01


cytiva
HyClone™
NEWBORN CALF SERUM
Cat. No.: SH30401.02
Lot No.: DF12345678
Bottle Volume: 1000 mL
Net Volume: 12 L
Mfg. Date: 25/MAY/2020
Exp. Date: 25/MAY/2025
Collected and Processed in New Zealand
STORE AT -10°C OR LOWER
NOT FOR HUMAN OR ANIMAL CONSUMPTION. FOR PHARMACEUTICAL USE ONLY
BBP7
Global Life Sciences Solutions New Zealand
433 Old Highway
Tauranga, New Zealand
+1-435-792-8000 www.cytiva.com
0001
12
SH40014.01