

September 2020

Dear Customer,

We write to notify you of changes to labels, Certificate of Analysis and analytical specifications for the below mentioned affected products.

Affected products

The products in scope of this customer letter include among others research consumable products including Amersham™ Western blotting consumables, Whatman™ filtration products, Sera-Mag™ magnetic beads, HyClone™ sera and media products, Biacore™ consumables, and chromatography consumables from ranges including Sepharose™, Capto™, Superdex™, Sephadex™, Superose™, MabSelect™, HiTrap™, HiScreen™, HisTrap™, HiLoad™, HiPrep™, HiScale™, Tricorn™, Source™, Resource™, StrepTrap™, and SpinTrap™.

What is not changing

This is a change of the company brand name only. There is no change to the products. 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, and vendor questionnaires REMAIN VALID until they are updated/revised.

Change description

Labels and Certificate of Analysis are updated with the Cytiva name including logo and legal entity name. Examples of updated certificates and labels are included with this customer letter. Below are examples of changes that may be introduced (these will not be applied to all products):

- Change of company brand name and logo (applies to all)
- To align the presentation of code numbers on labels and Certificate of Analysis, code numbers on labels are now written without dashes in the same way as on Certificate of Analysis.
- Numbering of test/characteristics on Certificate of Analysis is removed (when not already implemented in earlier updates)
- Minor editorial changes (e.g. ml changed to mL)
- Migration of product booklets, manuals, and instructions for use to the Cytiva.com website for some products in the Amersham Western blotting consumables family
- Analytical specifications for affected products will be updated to next edition with corresponding changes.

Reason for the change

Following the Danaher Corporation's purchase of the GE Healthcare Life Sciences Biopharma business units consisting of BioProcess, Cell & Gene Therapy and Genomics & Cellular Research, our company name is now changed to Cytiva. For more information, including changes to local legal entities, please see change control notification "GE Healthcare Life Sciences (Biopharma business) is now Cytiva" dated 1 April 2020, available on cytiva.com/4customers.

Impact of change

Labels and certificates will be updated with the Cytiva name including logo over time. Please note that finished products in our warehouses are rotated on a regular basis using first expired, 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.

Implementation of change

Our manufacturing operations have begun implementing the changes detailed in this letter.

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 cytiva.com/4customers.

Attachment

Label and certificate examples

While your organization is assessing the potential impact of these changes, please do not hesitate to contact your regional Customer Service team or find your local contact information at cytiva.com/support/contact-us

Sincerely,




A handwritten signature in black ink, appearing to be 'E. Abate', written over a horizontal line.





Emmanuel Abate
VP Genomics & Cellular Research
Cytiva

Attachment

Example of HyClone label with new and previous company branding

Example of HyClone Certificate of Analysis with new and previous company branding

			
 SH30022.05	DMEM/HIGH GLUCOSE	Cat No.:	SH30022.05
	+ 4.00 mM L-Glutamine,	Lot No.:	AF12345678
	+ 4500 mg/L Glucose,	Bag No.:	001
	- Sodium Pyruvate	Volume:	200 Liters
		Exp. Date:	31/MAY/2021
		Store At:	2 to 8° C
0.1 um Sterile Filtered			
Cytiva Life Sciences HyClone Laboratories 925 West 1800 South Logan, Utah 84321 1-435-792-8000		FOR FURTHER MANUFACTURING OR RESEARCH USE. NOT FOR DIAGNOSTIC OR THERAPEUTIC USE.	
www.cytiva.com			
SH40014.01			

		DMEM/HIGH GLUCOSE	
 SH30022.LS	+ 4.00 mM L-Glutamine,	0.1 um Sterile Filtered	
	+ 4500 mg/L Glucose,	Cat No.:	SH30022.LS
	- Sodium Pyruvate	Case Qty.:	6 X 1000mL
		Lot No.:	AF29527015
		EXP Date:	31/MAY/2021
	STORE AT:	2 to 8° C	
GE Healthcare Life Sciences HyClone Laboratories 925 West 1800 South Logan, Utah 84321 1-435-792-8000		FOR FURTHER MANUFACTURING OR RESEARCH USE. NOT FOR DIAGNOSTIC OR THERAPEUTIC USE.	
www.gelifesciences.com/hyclone		 0660 6	
SH40014.01			

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.

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.





All timestamps in UTC time

Printed: 11-Jun-2020 22:07:47

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CERTIFICATE OF ANALYSIS

Product: DMEM/HIGH GLUCOSE

+ 4.00 mM L-Glutamine

+ 4500 mg/L Glucose

- Sodium Pyruvate

Lot #: AF29527015

Catalog #: SH30022

Manufacture date: 21-MAY-2020

Expiration date: 31-MAY-2021

TEST	SPECIFICATION	UNITS	RESULTS
Appearance	Clear Reddish Solution	-	Clear Reddish Solution
pH	7.0 - 7.4	-	7.3
Osmolality	315 - 350	mOsm/kg	335
Endotoxin	≤ 1.0	EU/mL	<0.10
Sterility Testing Bacteria and 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

Gerber, Straton

11-JUN-2020 22:07:18

Quality Department

Date and Time

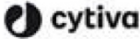
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GE Healthcare Life Sciences HyClone Laboratories


925 West 1800 South Logan, Utah 84321 USA T: +1 435 792 8000 F: +1 435 792 8011



Example of Amersham label with new and previous company branding



Amersham™



RPN2236
Lot
Pack
Expiry
Store at Room Temperature
Ship at Room Temperature
Do Not Freeze
Light sensitive material

ECL™ Prime Western Blotting Detection Reagent


Warning: for research use only. Not recommended or intended for diagnosis of disease in humans or animals. Do not use internally or externally in humans or animals. See SDS(s) and/or SS(s) for specific component

Amersham and ECL are trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva

Global Life Sciences Solutions Operations UK Ltd, Amersham Place, Little Chalfont, Buckinghamshire HP7 9NA UK +44 (0) 870 606 1921


cytiva.com

Made in Italy



RPN2236
Lot
Pack
Expiry
Store at room temperature
Ship at room temperature
Do not freeze
Light sensitive material

Amersham™
ECL™ Prime Western Blotting Detection Reagent



Warning: For research use only Not recommended or intended for diagnosis of disease in humans or animals. Do not use internally or externally in humans or animals. See SDS(s) and/or SS(s) for specific component handling instructions.

Global Life Sciences Solutions Operations UK Ltd, Amersham Place, Little Chalfont, Buckinghamshire HP7 9NA UK +44 (0) 870 606 1921

cytiva.com

Made in Italy

Example of Whatman label with new and previous company branding
Example of Certificate of Conformity layout with new and previous company branding



Whatman™



UN503NPUDPP

Whatman Mini-UniPrep™

SYRINGELESS FILTER DEVICE

Lot No.

dp PP Filter Media

Polypropylene Housing

Pore Size 0.45 µm

1000 Units

Whatman and Mini-UniPrep are trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva

Global Life Sciences Solutions Operations UK Ltd, Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA UK +44 (0) 870 606 1921

cytiva.com

Made in UK

Whatman™

SYRINGELESS FILTER DEVICE

Mini-UniPrep™

dp PP Filter Media with Polypropylene Housing

1000 Units

0.45µm Pore Size

Cat. No. UN503NPUDPP

Lot No.



(90) UN503NPUDPP (10)

U.S. Pat. Nos. 4,800,020; 4,832,850 and 4,897,193

Global Life Sciences Solutions Operations UK Ltd, Amersham Place, Little Chalfont, Buckinghamshire HP7 9NA UK +44 (0) 870 606 1921

Made in UK



Certificate of Conformity

Product Information

Product Number:

Product Name:

Lot Number:

Conformance & Quality systems statement

This is to certify that this product conforms to Cytiva specifications.

All products are manufactured via a Quality System certified to BS EN ISO9001:2015 and tested in accordance with documented quality procedures and approved as a result of meeting the required specification

Electronic signature

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Version A8

[cytiva.com](https://www.cytiva.com)

Global Life Sciences Solutions Operations UK Ltd
Amersham Place, Little Chalfont
Buckinghamshire HP7 9NA UK

Certificate of Conformity

Whatman™

Product Information

Product Number: UN503NPUDPP

Product Name: Mini-UniPrep Syringeless Filter, Depth PP, 0.45 µm, 1000pk

Lot Number/Serial Number: As W/O

Conformance & Quality systems statement

This is to certify that this product conforms to GE Healthcare Life Sciences specifications.

All products are manufactured via a Quality System certified to **BS EN ISO9001:2008** and tested in accordance with documented quality procedures and approved as a result of meeting the required specification

Electronic signature

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Version AA



imagination at work

www.gelifesciences.com

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