



QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Life Technologies Corporation 5225 Verona Road Madison Wisconsin 53711 USA

Holds Certificate No:

FM 552131

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture and screening services of biochemical and cellular assays for industrial, pharmaceutical and biotech companies.

For and on behalf of BSI:

Original Registration Date: 2009-12-08 Latest Revision Date: 2018-11-27



tomas Carlos Pitanga, Chief Operating Office

ncer Assurance – Americas

Effective Date: 2018-12-08 Expiry Date: 2021-12-07

Page: 1 of 2

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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Certificate No: FM 552131

Location

Life Technologies Corporation 5225 Verona Road Madison Wisconsin 53711 USA

Life Technologies Corporation 3 fountain Drive, Inchinnan Business Park Paisley Renfrewshire PA4 9RF United Kingdom **Registered Activities**

The manufacture and screening services of biochemical and cellular assays for industrial, pharmaceutical and biotech companies.

Providing screening services for biochemical and cellular assays, utilizing Madison site products, to further support customer needs.

Original Registration Date: 2009-12-08 Latest Revision Date: 2018-11-27 Effective Date: 2018-12-08 Expiry Date: 2021-12-07

Page: 2 of 2

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QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Life Technologies Ltd. **3** Fountain Drive Inchinnan Business Park Paislev PA4 9RF United Kingdom

Holds Certificate Number:

MD 507152

and operates a Quality Management System which complies with the requirements of ISO 13485;2016 & EN ISO 13485:2016 for the following scope:

> The design, manufacture and distribution of In-Vitro Diagnostics and products for cell culture, molecular biology and microbiology.

I M SIA

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2006-10-02 Latest Revision Date: 2018-09-27

Effective Date: 2018-10-02 Expiry Date: 2021-10-01

Page: 1 of 1



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QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Life Technologies Corporation Also Trading As: Invitrogen 3175 Staley Road Grand Island New York 14072 USA

Holds Certificate Number:

MD 647016

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of liquid and powder tissue culture media, sera, reagents and distribution of biochemicals. The above activities are for cell culture research, industrial bioprocessing and related markets.

JM Sr

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-02-01 Latest Revision Date: 2018-11-02 Effective Date: 2018-11-06 Expiry Date: 2021-11-05

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Certificate No: MD 647016

Location

Life Technologies Corporation Also Trading As: Invitrogen 3175 Staley Road Grand Island New York 14072 USA

Life Technologies Corporation Also Trading As: Invitrogen 1775 Baseline Road Grand Island New York 14072 USA **Registered Activities**

The design, development, manufacture and distribution of liquid and powder tissue culture media, sera, reagents and distribution of biochemicals. The above activities are for cell culture research, industrial bioprocessing and related markets.

Product Laboratory Testing - Mycoplasma and Sales.



Effective Date: 2018-11-06 Expiry Date: 2021-11-05

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QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Life Technologies Ltd. **3** Fountain Drive Inchinnan Business Park Paislev PA4 9RF United Kingdom

Holds Certificate Number:

MD 507152

and operates a Quality Management System which complies with the requirements of ISO 13485;2016 & EN ISO 13485:2016 for the following scope:

> The design, manufacture and distribution of In-Vitro Diagnostics and products for cell culture, molecular biology and microbiology.

I M SIA

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2006-10-02 Latest Revision Date: 2018-09-27

Effective Date: 2018-10-02 Expiry Date: 2021-10-01

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RPMI 1640 Medium

For various human clinical samples

Pub. No. MAN0018935 Rev. 1.0

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Intended Use

For in vitro diagnostic use

The isolation of human viruses from clinical samples using cell culture remains necessary because it is the only technique capable of providing a viable isolate that can be used for antiviral susceptibility testing. An additional advantage is that in contrast to most antigen and nucleic acid detection methods, viral culture allows detection of multiple viruses, not all of which may have been suspected at the time diagnostic culture was requested.

RPMI 1640 cell culture media products are for professional use. They are used in medical laboratories by personnel who have received specialized education and training with regard to procedures utilizing In Vitro Diagnostic products. IVD products of this type are not intended as sole determinant in a diagnostic situation. Test results are interpreted by a healthcare professional as part of the clinical management of a patient.

Principle and explanation of procedure

RPMI is a commonly used cell culture media for diagnostic virology (1, 2). RPMI 1640 Medium was originally developed to culture human leukemic cells in suspension and as a monolayer. Roswell Park Memorial Institute (RPMI) 1640 Medium has since been found suitable for a variety of mammalian cells, including HeLa, Jurkat, MCF-7, PC12, PBMC, astrocytes, and carcinomas.

RPMI 1640 Medium is unique from other media because it contains the reducing agent glutathione and high concentrations of vitamins. RPMI 1640 Medium contains biotin, vitamin B12, and PABA, which are not found in Eagle's Minimal Essential Medium or Dulbecco's Modified Eagle Medium. In addition, the vitamins inositol and choline are present in very high concentrations. RPMI 1640 Medium contains no proteins, lipids, or growth factors. Therefore, RPMI 1640 Medium requires supplementation, commonly with 10% Fetal Bovine Serum (FBS). RPMI 1640 Medium uses a sodium bicarbonate buffer system (2.0 g/L), and therefore requires a 5–10% CO₂ environment to maintain physiological pH.

Contents and storage

All quality control testing results are reported on lot-specific Certificate of Analysis available on our website: thermofisher.com.

Product	Cat. No.	Storage	Shelf life ^[1]
RPMI 1640 (1X)	11835030 ^[2]	2°C to 8°C	
[+] L-Glutamine	11835055 ^[2]		12 months
[-] Phenol Red	11835063 ^[3]	Protect from light	
	11875085 ^[4]		
	11875093 ^[4]		
	11875101 ^[2]		
RPMI Medium (1X) 1640	11875119 ^[4]	2°C to 8°C	12 months
[+] L-Glutamine	11875127 ^[2]	Protect from light	12 months
	11875135 ^[4]		
	11875168 ^[2]		
	11875176 ^[2]		





Product	Cat. No.	Storage	Shelf life ^[1]
RPMI Medium (1X) 1640 [-] L-Glutamine	21870076 ^[4] 21870084 ^[4] 21870092 ^[4] 21870100 ^[4]	2°C to 8°C Protect from light	24 months
RPMI 1640 W/GLUT (1X) (CE)	21875034 ^[3] 21875042 ^[3] 21875059 ^[3]	2°C to 8°C Protect from light	12 months
RPMI 1640 (1X) [+] L-Glutamine [+] HEPES	22400071 ^[2] 22400089 ^[4] 22400097 ^[2] 22400105 ^[4] 22400121 ^[2] 22400197 ^[2]	2°C to 8°C Protect from light	12 months
RPMI 1640 W/O L-GLUTAMINE (CE)	31870017 ^[3] 31870025 ^[3]	2°C to 8°C Protect from light	12 months
RPMI 1640 W/O PHENOL RED	32404014 ^[3]	2°C to 8°C Protect from light	12 months
RPMI 1640 W/25MMHEPES W/OL-GLUT	42401018 ^[3] 42402016 ^[3]	2°C to 8°C Protect from light	12 months
RPMI MEDIUM 1640 W/HEPES (CE)	52400017 ^[3] 52400025 ^[3]	2°C to 8°C Protect from light	12 months
RPMI 1640 W/GLUTAMAX-I (1X)	61870010 ^[3] 61870036 ^[2] 61870127 ^[2] 61870143 ^[2] 61870150 ^[2]	2°C to 8°C Protect from light	12 months
RPMI 1640 W/HEPES W/GLUTAMAX-I	72400013 ^[3] 72400021 ^[3]	2°C to 8°C Protect from light	12 months
RPMI (1X) + GlutaMAX -I	72400047 ^[2] 72400120 ^[2] 72400146 ^[2] 72400153 ^[2]	2°C to 8°C Protect from light	12 months

I Shelf life is determined from Date of Manufacture. Do not use beyond the labelled expiration date.
Manufacturer: Life Technologies Corporation | 3175 Staley Road | Grand Island, NY 14072
Manufacturer: Life Technologies™ Ltd. | 3 Fountain Drive, Inchinnan Business Park | Paisley PA49RF, Scotland, United Kingdom |Tel: +44 (0)141 81416305
Dual manufactured.

Precautions

Do not use the product if packaging, including bottles and vials, have been compromised and/or show evidence of microbial contamination, cloudy appearance, discoloration, drying, cracking, or other signs of deterioration.



CAUTION! Human samples are potentially biohazardous. Follow standard precautions for handling, storage and disposal.



WARNING! Do not use for injection or infusion! Please report any serious incidents in relation to the device to the manufacturer and the Competent Authority of the EU Member State in which the user and/or patient is established.

- Once opened, use RPMI 1640 Medium within 14 days for maximal growth performance.
- Avoid repeated warming/cooling and prolonged exposure to light.
- Do not use beyond labeled expiration date.
- All solutions that come into contact with clinical samples must be sterile. Always use proper aseptic techniques and work inside a laminar flow hood. Consult our **Gibco Cell Culture Basics** for aseptic handling.

Test protocol

There is no single type of cell culture that can support the growth of all medically relevant viruses. As such, virology laboratories must maintain several different cell culture types. The choice of cell line used for a specific specimen is determined by the information communicated from the ordering physician to the laboratory and by knowledge of the specimens usually isolated from a given specimen type.

Ready to-use commercial cell culture media undergoes strict quality control to ensure sterility, but may become contaminated while handling. Follow the below guidelines for sterile handling to avoid contamination.

- Always wipe your hand and work area with 70% ethanol.
- Wipe the outside of the containers, flasks, plates, and dishes with 70% ethanol before placing them in the cell culture hood.
- Avoid pouring media and reagents directly from bottles or flasks.
- Use sterile pipette tips and pipettes to work with liquids, and use each pipette tip only once to avoid cross-contamination. Do not unwrap sterile pipettes until they are ready to be used. Keep pipettes and tips within the clean work area.
- Do not talk while performing sterile procedures and perform your cell culture as rapidly as possible to minimize contamination.

Quality control

Standard evaluations for cell culture media are pH, osmolality, endotoxins and sterility testing for liquid products. All quality control testing results are reported on lot specific Certificate of Analysis available on our website: **thermofisher.com**.

Related products

Product	Source
Gentamicin 50 mg/mL	15750078
Gibco Amphoteracin B	15290018
Penicillin Streptomycin 10,000 U/mL	15140122
PBS, pH 7.4	10010031
Phytohemagglutinin, M form (PHA-M)	10576015
FBS	16000044

References

- Winn, W. C., & Koneman, E. W. (2006). Koneman's color atlas and textbook of diagnostic microbiology (6th ed.). Philadelphia: Lippincott Williams & Wilkins.
- 2. WHO Guidelines on the Establishment of Virology Laboratories in Developing Countries, 2008.
- Griffith, B P. "Principles of laboratory isolation and identification of the human immunodeficiency virus (HIV)" Yale journal of biology and medicine vol. 60,6 (1987): 575-87.
- 4. Krowicka, Halina et al. "Use of tissue culture cell lines to evaluate HIV antiviral resistance" AIDS research and human retroviruses vol. 24,7 (2008): 957-67.

Labeling symbols

The symbols present on the product label are explained in the following table.



Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and

Conditions of Sale at **www.thermofisher.com/us/en/home/global/ terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.



Manufacturer: Life Technologies Corporation | 3175 Staley Road | Grand Island, NY 14072

EC REP

European Regulatory Affairs Life Technologies Europe B.V. Kwartsweg 2, 2665 NN Bleiswijk The Netherlands Tel: +31 (0) 10 714 5000

Manufacturer: Life Technologies[™] Ltd. | 3 Fountain Drive, Inchinnan Business Park | Paisley PA49RF, Scotland, United Kingdom | Tel: +44 (0)141 81416305



Manufacturer: Dual manufactured products

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Revision history: Pub. No. MAN0018935

Revision	Date	Description
1.0	12 November 2019	New document

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(MEM) Minimal Essential Medium

For various human clinical samples

Pub. No. MAN0018900 Rev. 1.0

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Intended use

For in vitro diagnostic use

The isolation of human viruses from clinical samples using cell culture remains necessary because it is the only technique capable of providing a viable isolate that can be used for antiviral susceptibility testing. An additional advantage is that in contrast to most antigen and nucleic acid detection methods, viral culture allows detection of multiple viruses, not all of which may have been suspected at the time diagnostic culture was requested.

MEM cell culture media products are for professional use. They are used in medical laboratories by personnel who have received specialized education and training with regard to procedures utilizing In Vitro Diagnostic products. IVDs of these types are not intended as sole determinant in a diagnostic situation. Test results are interpreted by a healthcare professional as part of the clinical management of a patient.

Principle and explanation of procedure

MEM (Minimal Essential Medium) is one of the most commonly used of all cell culture media for diagnostic virology (1, 2). MEM can be used with a variety of suspension and adherent mammalian cells, including HeLa, BHK-21, 293, HEP-2, HT-1080, MCF-7, fibroblasts.

MEM was developed by Harry Eagle, based on his earlier formulation of Basal Medium Eagle (BME). MEM is available with Earle's salts for use in a CO_2 incubator, or with Hanks' salts for use without CO_2 . This product is made with Earle's salts. MEM contains no proteins, lipids, or growth factors. Therefore, MEM requires supplementation, commonly with 10% Fetal Bovine Serum (FBS). MEM uses a sodium bicarbonate buffer system (2.2 g/L), and therefore requires a 5-10% CO_2 environment to maintain physiological pH.

Contents and storage

All quality control testing results are reported on lot-specific Certificate of Analysis available on our website: thermofisher.com.

Product	Cat. No.	Storage	Shelf life ^[1]
MEM (1X) [+] Earle's Salts [+] Non-Essential Amino Acids [-] L-Glutamine	10370021 ^[2] 10370047 ^[3] 10370070 ^[3] 10370088 ^[2]	2°C to 8°C Protect from light	24 months
MEM (1X) [+] Earle's Salts [-] L-Glutamine	11090073 ^[2] 11090081 ^[2] 11090099 ^[2] 11090100 ^[2]	2°C to 8°C Protect from light	24 months
MEM (1X) [+] Earle's Salts [+] L-Glutamine	11095072 ^[2] 11095080 ^[2] 11095098 ^[2] 11095114 ^[2]	2°C to 8°C Protect from light	12 months





Product	Cat. No.	Storage	Shelf life ^[1]
	11120001 ^[3]		
	11120037 ^[3]		
MEM Vite and Calenting (100V)	11120052 ^[2]	-5°C to -20°C	10
MEM Vitamin Solution (100X)	11120061 ^[3]	Protect from light	12 months
	11120062 ^[3]		
	11120097 ^[2]		
	11130036 ^[3]		
MEM AMINO ACIDS 50X	11130051 ^[2]	2°C to 8°C	12 months
[-] L-Glutamine	11130077 ^[3]	Protect from light	12 months
	11130097 ^[2]		
	11140035 ^[3]		
	11140050 ^[2]	2°C to 8°C	18 months
	11140068 ^[3]	Protect from light	To months
	11140076 ^[2]		
MEM (10X)			
[+] Earle's Salts	11430030 ^[2]	2°C to 8°C	24 months
[-] L-Glutamine	11430098 ^[2]	Protect from light	
[-] Sodium Bicarbonate			
MEM (1X)	11575032 ^[2]	2°C to 8°C	
[+] Hank's Salts	11575098 ^[2]	Protect from light	12 months
[+] L-Glutamine			
MEM (1X)			
[+] Earle's Salts	12360038 ^[2]	2°C to 8°C	24 months
[+] 25 mM HEPES	12360098 ^[2]	Protect from light	24 11011113
[-] L-Glutamine			
	12561049 ^[2]		
ΜΕΜ ΔΙ ΡΗΔ	12561056 ^[2]	2°C to 8°C	12 months
	12561072 ^[2]	Protect from light	
	12561099 ^[2]		
	12571048 ^[2]		
MEM AL PHA	12571063 ^[2]	2°C to 8°C	12 months
	12571071 ^[2]	Protect from light	
	12571089 ^[2]		
MEM (1X)	21090022 ^[3]	2°C to 8°C	
[+] Earle's Salts	21090055 ^[3]	Protect from light	12 months
[-] L-Glutamine			
Medium 199 (2X)	21157029 ^[3]	2°C to 8°C	12 months
	21157030 ^[3]	Protect from light	
Medium 199 [10X]	21180021 ^[3]	2°C to 8°C	12 months
	21180022 ^[3]	Protect from light	
MEM (10X)	21430020 ^[3]	2°C to 8°C	
[+] Earle's Salts	21430079 ^[3]	Protect from light	12 months
[-] L-Glutamine			

Product	Cat. No.	Storage	Shelf life ^[1]
MEM (1X)	21575022[3]	290 to 990	
[+] Hank's Salts	21575022	2 C 10 0 C	12 months
[+] L-Glutamine	21373077**	Frotect from tight	
Modified Eagle Medium (2X)	21935028 ^[3]	2°C to 8°C	10
[+] L-Glutamine	21935029 ^[3]	Protect from light	12 months
Medium 199 (1X)			
[+] Hank's Salts	22350029 ^[3]	2°C to 8°C	10
[+] L-Glutamine	22350078 ^[3]	Protect from light	12 months
[+] 25 mM HEPES			
	22561021 ^[3]	2°C to 8°C	
MEM ALPHA W/O NUCLEOSIDES	22561054 ^[3]	Protect from light	12 months
	22571020 ^[3]	2°C to 8°C	
MEM ALPHA W/NUCLEOSIDES	22571038 ^[3]	Protect from light	12 months
MEM [1X]			
[+] Farle's Salts	31095029 ^[3]	2°C to 8°C	12 months
[-] L-Glutamine	31095052 ^[3]	Protect from light	
Medium 199 (1X)			
[+] Farle's Salts	31150022 ^[3]	2°C to 8°C	12 months
[+] L-Glutamine	31150030 ^[3]	Protect from light	
Modium 199 (1Y)			
[+] Farle's Salts	31153026 ^[3]	2°C to 8°C	
	31153027 ^[3]	Protect from light	12 months
$[+] 1.25 \alpha/L \text{ NaHCO}_3$	01100027	i rotect nom tight	
MEM (1X)			
[+] Farle's Salts	32360026 ^[3]	2°C to 8°C	
[+] 25 mM HEPES	32360034 ^[3]	Protect from light	12 months
[-] L-Glutamine			
MEM AL PHA (1X) GlutaMAX-I			
	32561029 ^[3]	2°C to 8°C	12 months
[-] Deoxyribonucleosides	32561094 ^[3]	Protect from light	
	32561037[2]	2°C to 8°C	
MEM ALPHA	32561102 ^[2]	Protect from light	12 months
	22571029[3]		
MEM ALPHA (1X), GlutaMAX-I	32571034 ^[2]	2°C to 8°C	
[+] Ribonucleosides	32571093[3]	Protect from light	10 months
[+] Deoxyribonucleosides	32571101 ^[2]	i roteet nom tight	
	<u>(1000020[3]</u>		
MEM (1X) GlutaMAX-I	41070020 ⁶³	2°C to 8°C	
[+] Farle's Salts	41090093 ^[3]	Protect from light	12 months
	41090101 ^[2]		
Medium 199 (1X) GlutaMAX-I	/1150020 ^[3]	2°C to 8°C	
[+] Farle's Salts	4115002011	Protect from light	12 months
		i i otecci i oni ugite	

Product	Cat. No.	Storage	Shelf life ^[1]
MEM (1X), GlutaMAX-I [+] Earle's Salts [+] 25 mM HEPES	42360024 ^[3] 42360081 ^[3]	2°C to 8°C Protect from light	12 months
МЕМ	42360032 ^[2] 42360099 ^[2]	2°C to 8°C Protect from light	12 months
MEM (1X) [+] Earle's Salts [-] L-Glutamine	51200038 ^[2] 51200046 ^[3] 51200087 ^[3] 51200098 ^[2]	2°C to 8°C Protect from light	24 months

[1] Shelf life is determined from Date of Manufacture. Do not use beyond labeled expiration date.

[2] Manufacturer: Life Technologies Corporation | 3175 Staley Road | Grand Island, NY 14072

[3] Manufacturer: Life Technologies[™] Ltd. | 3 Fountain Drive, Inchinnan Business Park | Paisley PA49RF, Scotland, United Kingdom |Tel: +44 (0)141 81416305

Precautions

Do not use the product if packaging, including bottles and vials, have been compromised and/or show evidence of microbial contamination, cloudy appearance, discoloration, drying, cracking, or other signs of deterioration.



CAUTION! Human samples are potentially biohazardous. Follow standard precautions for handling, storage and disposal.

WARNING! Do not use for injection or infusion! Please report any serious incidents in relation to the device to the manufacturer and the Competent Authority of the EU Member State in which the user and/or patient is established.

- Once opened, use MEM within 14 days for maximal growth performance.
- Avoid repeated warming/cooling and prolonged exposure to light.
- . Do not use beyond labeled expiration date.
- All solutions that come into contact with clinical samples must be sterile. Always use proper aseptic techniques and work inside a laminar flow hood. Consult our **Gibco Cell Culture Basics** for aseptic handling.

Test protocol

There is no single type of cell culture that can support the growth of all medically relevant viruses. As such, virology laboratories must maintain several different cell culture types. The choice of cell line used for a specific specimen is determined by the information communicated from the ordering physician to the laboratory and by knowledge of the specimens usually isolated from a given specimen type.

Ready to-use commercial cell culture media undergoes strict quality control to ensure sterility, but may become contaminated while handling. Follow the below guidelines for sterile handling to avoid contamination.

- Always wipe your hand and work area with 70% ethanol.
- Wipe the outside of the containers, flasks, plates, and dishes with 70% ethanol before placing them in the cell culture hood.

- Avoid pouring media and reagents directly from bottles or flasks.
- Use sterile pipette tips and pipettes to work with liquids, and use each pipette tip only once to avoid cross-contamination. Do not unwrap sterile pipettes until they are ready to be used. Keep pipettes and tips within the clean work area.
- Do not talk while performing sterile procedures and perform your cell culture as rapidly as possible to minimize contamination.

Quality control

Standard evaluations for cell culture media are pH, osmolality, endotoxins and sterility testing for liquid products. All quality control testing results are reported on lot specific Certificate of Analysis available on our website: **thermofisher.com**.

Related products

Unless otherwise indicated, all materials are available through **thermofisher.com**.

Item	Source
MEM Amino Acids Solution (50X)	11130051
MEM Non-Essential Amino Acids Solution 11140050	
MEM Vitamin Solution (100X)	11120052
L-Glutamine (200 mM)	A2916801
Antibiotic-Antimycotic (100X)	15240096
PBS, pH 7.4 100100	

References

- Winn, W. C., & Koneman, E. W. (2006). Koneman's color atlas and textbook of diagnostic microbiology (6th ed.). Philadelphia: Lippincott Williams & Wilkins
- 2. WHO Guidelines on the Establishment of Virology Laboratories in Developing Countries, 2008.

3. Eisfeld AJ, Neumann G, Kawaoka Y. Influenza A virus isolation, culture and identification. Nat Protoc. 2014;9(11):2663-81.

Labeling symbols

The symbols present on the product label are explained in the following table.

	MANUFACTURER	\sum	USE BY
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	li	CONSULT INSTRUCTIONS FOR USE
REF	CATALOG NUMBER		CAUTION, CONSULT ACCOMPANYING DOCUMENTS
LOT	BATCH CODE		UPPER AND LOWER LIMITS OF TEMPERATURE
STERILE A	Sterilized using aseptic processing technique	*	PROTECT FROM LIGHT
CE	European Mark of Conformity	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at www.thermofisher.com/us/en/home/global/ terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.

European Regulatory Affairs

The Netherlands Tel: +31 (0) 10 714 5000

Life Technologies Europe B.V. Kwartsweg 2, 2665 NN Bleiswijk

EC REP



Manufacturer: Life Technologies Corporation |

3175 Staley Road | Grand Island, NY 14072

Manufacturer:

Life Technologies[™] Ltd. | 3 Fountain Drive, Inchinnan Business Park | Paisley PA49RF, Scotland, United Kingdom | Tel: +44 (0)141 81416305

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Revision	history	Puh	Νo	MAN0018900
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Revision	Date	Description
1.0	12 November 2019	New document

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invitrogen cell culture



Medium 106

Cat. no. M-106-500

500 ml

Product Description

Medium 106 is a sterile, liquid tissue culture medium intended for use as one component in a complete culture environment for the growth of normal human dermal fibroblasts. Medium 106 is a basal culture medium containing essential and non-essential amino acids, vitamins, other organic compounds, trace minerals, and inorganic salts. Medium 106 does not contain antibiotics, antimycotics, hormones, growth factors, or proteins. This medium is HEPES and bicarbonate buffered and is designed for use in an incubator with an atmosphere of $5\% \text{ CO}_2/95\%$ air. To support the plating and long term proliferation of human dermal fibroblasts, Medium 106 must be supplemented with Low Serum Growth Supplement Kit (LSGS Kit, cat. no. S-003-K).

Intended Use

Medium 106 is intended for use in the routine culture of normal human dermal fibroblasts. When supplemented with LSGS or LSGS Kit, Medium 106 will support the plating and proliferation of fibroblasts at densities between 1×10^2 cells/cm² and 1×10^5 cells/cm². Additional applications for use may include primary isolation of fibroblasts from dermal tissue. *This product is for research use only. Not for use in animals, humans, or diagnostic procedures.*

Caution: If handled improperly, some components of this product may present a health hazard. Take appropriate precautions when handling this product, including the wearing of protective clothing and eyewear. Dispose of properly.

Storage and Stability

Medium 106 is stored at 4° C in our facility and is shipped at ambient temperature. Upon receipt, Medium 106 should be stored at 4° C and should <u>not</u> be frozen. **Protect from light.** Several components of this tissue culture medium are light-labile, and we recommend that the medium not be exposed to light for lengthy periods of time. If the medium is warmed prior to use, do not exceed 37° C. When stored in the dark at 4° C, the product is stable until the expiration date on the label.

Follow the instructions on page 2 to prepare the medium for use.

For research use only.

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Cascade Biologics[™]

invitrogen cell culture

Preparation of Supplemented Medium 106 with LSGS

Note: For information on LSGS (cat. no. S-003-10), refer to the LSGS product sheet.

- 1. Thaw one bottle of LSGS. Take one bottle of medium from cold storage. Make sure that the caps of the vessels are tight.
- 2. Gently swirl the bottle of supplement. Avoid splashing the supplement into the cap of the bottle or causing the supplement to foam.
- 3. Wipe the outside of the containers with a disinfecting solution such as 70% ethanol or isopropanol.
- 4. Using sterile technique in a laminar flow culture hood, transfer the entire contents of the bottle of supplement to the bottle of medium.
- 5. Tightly cap the bottle of supplemented medium and swirl the contents to ensure a homogeneous solution. Avoid causing the medium to foam.

Storage and Stability of Supplemented Medium 106

Once Medium 106 has been supplemented with LSGS, the supplemented medium should be stored in the dark at 4° C and should <u>not</u> be frozen. When stored in the dark at 4° C, the supplemented medium is stable for 1 month.

GIBCO[®] invitrogen cell culture

Preparation of Supplemented Medium 106 with LSGS Kit

Note: For information on LSGS Kit (cat. no. S-003-K), refer to the LSGS Kit product sheet.

- 1. Thaw the frozen components of the LSGS Kit. Take one bottle of medium from cold storage. Make sure that the caps of the vessels are tight.
- 2. Gently swirl each component of the LSGS Kit. Avoid splashing the components into the caps of the bottles or causing any of the components to foam.
- 3. Wipe the outside of the containers with a disinfecting solution such as 70% ethanol or isopropanol.
- 4. Using sterile technique in a laminar flow culture hood, transfer the desired amount of each component of the LSGS Kit to the bottle of medium in the following order: fetal bovine serum; recombinant human basic fibroblast growth factor/heparin; hydrocortisone, recombinant human epidermal growth factor. Note: addition of less than the entire amount of any component may affect the performance of the supplemented medium.
- 5. If antibiotics/antimycotics are desired, add the antibiotic/antimycotic solution included in LSGS Kit using the same technique as above.
- 6. Tightly cap the bottle of supplemented medium and swirl the contents to ensure a homogeneous solution. Avoid causing the medium to foam.

Storage and Stability of Supplemented Medium 106

Once Medium 106 has been supplemented with LSGS Kit, the supplemented medium should be stored in the dark at 4° C and should <u>not</u> be frozen. When stored in the dark at 4° C, the supplemented medium is stable for 1 month.

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Buffered Saline Solutions

For various human clinical samples

Pub. No. MAN0018562 Rev. 1.0

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Intended Use

For in vitro diagnostic use

Buffered saline solutions are isotonic saline solutions used to maintain pH and osmotic balance as well as provide cells with water and essential inorganic ions. Buffered saline solutions are used in a variety of laboratory applications, such as washing cells, transporting cells, diluent of human biological samples, or for reagent preparation. Thermo Fisher Scientific offers a wide range of buffered saline solutions including those with and without; calcium chloride, magnesium chloride, magnesium sulfate, and phenol red.

Buffered saline solutions are for professional use. They are used in medical laboratories by personnel who have received specialized education and training with regard to procedures utilizing In Vitro Diagnostic products. IVD products of this type are not intended as sole determinant in a diagnostic situation. Test results are interpreted by a healthcare professional as part of the clinical management of a patient.

Principle and explanation of procedure

Isotonic solutions are generally utilized to maintain cells for a short period time in a viable condition while the cells are manipulated outside of their regular growth environment. A physiological pH (6.8 to 7.4) value can be important to maintain viability when investigating human biological samples in an in vitro diagnostic application. Isotonic solutions can also be used for rinsing and washing steps in various diagnostic procedures (1-4).

Contents and storage

All quality control testing results are reported on lot-specific Certificate of Analysis available on our website: thermofisher.com.

Product	Cat. No.	Storage	Shelf life ^[1]
Phosphate Buffered Saline (PBS) 7.4 (1X)	10010001 ^[2] 10010002 ^[2]	15°C to 30°C	12 months
Phosphate Buffered Saline (PBS) 7.4 (1X)	10010023 ^[3] 10010031 ^[2] 10010049 ^[3] 10010072 ^[2]	15°C to 30°C	24 months
Phosphate Buffered Saline (PBS) 7.4 (1X)	10010015 ^[4]	15°C to 30°C	36 months
Phosphate Buffered Saline (PBS) 7.2 (1X)	20012019 ^[4]	15°C to 30°C	36months
Phosphate Buffered Saline (PBS) 7.2 (1X)	20012027 ^[2] 20012043 ^[2] 20012050 ^[2] 20012099 ^[2]	15°C to 30°C	24 months
Phosphate Buffered Saline (PBS) 7.4 (10X)	70011036 ^[4] 70011044 ^[2] 70011069 ^[2]	15°C to 30°C	24 months
Phosphate Buffered Saline (PBS) 7.2 (10X)	70013016 ^[4]	15°C to 30°C	36 months



For In Vitro Diagnostic Use.



Product	Cat. No.	Storage	Shelf life ^[1]
Phosphate Buffered Saline (PBS) 7.2 (10X)	70013032 ^[2]	1500 + 0000	0.4
	70013073 ^[2]	15°C to 30°C	24 months
	14040083 ^[4]		
	14040091 ^[4]		
	14040141 ^[2]		
Dulbecco's Phosphate Buffered Saline (DPBS) (1X)	14040133 ^[2]		
[+] Calcium Chloride	14040117 ^[3]	2°C to 8°C	36 months
[+] Magnesium Chloride	14040097 ^[2]		
	14040182 ^[2]		
	14040216 ^[3]		
	14190086 ^[4]		
	14190094 ^[4]		
Dulbecco's Phosphate Buffered Saline (DPBS) (1X)	14190144 ^[3]		
[-] Calcium Chloride	14190136 ^[3]	15°C to 30°C	36 months
[-] Magnesium Chloride	14190230 ^[4]		
	14190250 ^[3]		
	14190235 ^[3]		
Dulbecco's Phosphate Buffered Saline (DPBS) (1X)	14190342 ^[3]		
[-] Calcium Chloride	14190359 ^[2]	15°C to 30°C	12 months
[-] Magnesium Chloride	14190367 ^[3]		
Dulbecco's Phosphate Buffered Saline (DPBS) (1X)			
[-] Calcium Chloride	14190240 ^[4]	15°C to 30°C	24 months
[-] Magnesium Chloride			2
	1/200059[4]		
Dulbecco's Phosphate Buffered Saline (DPBS) (10X)	14200007		
[-] Calcium Chloride	14200075 ^[2]	15°C to 30°C	36 months
[-] Magnesium Chloride	14200166 ^[2]		
Dulbacco's Phosphate Buffered Saline (DPBS) (10)	16080068[4]		
[+] Calcium Chloride	14000040	2°C to 8°C	24 months
[+] Magnesium Chloride	14000000	201000	24 11011115
	14000070		
Hanks' Balanced Salt Solution (HBSS) (1X)	14025050[2]		
[+] Calcium Chloride	14025072[2]	15°C to 20°C	24 months
[+] Magnesium Chloride	14025078-2	15 0 10 50 0	30 11011(115
[-] Phenol Red	14025134		
Hender' Delensed Collection (UDCC) (4V)	24020020[/]		
Hanks Balanced Salt Solution (HBSS) (1X)	24020083[4]		
[+] Calcium Chloride	24020091[4]	15°C to 30°C	36 months
	24020117123		
	24020178		
Hanks Balanced Salt Solution (HBSS) [1X]	14170120 ^[2]		
[-] Calcium Chloride	14170112 ^[2]	1500 . 0000	
L-J Magnesium Chloride	14170097 ^[2]	15°C to 30°C	36 months
L-J Magnesium Sultate	14170161 ^[2]		
L+J Phenol Red			

Product	Cat. No.	Storage	Shelf life ^[1]
Hanks' Balanced Salt Solution (HBSS) (1X) [-] Calcium Chloride [-] Magnesium Chloride [-] Magnesium Sulfate [-] Phenol Red	14175046 ^[4] 14175053 ^[4] 14175095 ^[2] 14175079 ^[2] 14175103 ^[2] 14175145 ^[2]	15°C to 30°C	36 months
Hanks' Balanced Salt Solution (HBSS) (1X) [-] Calcium Chloride [-] Magnesium Chloride [+] Phenol Red [+] Sodium Bicarbonate Hanks' Balanced Salt Solution (HBSS) (10X)	14170070 ^[4] 14170088 ^[4]	15°C to 30°C	36 months
[-] Sodium Bicarbonate	14060040 ^[4]	15°C to 30°C	36 months
Hanks' Balanced Salt Solution (HBSS) (10X) [-] Calcium Chloride [-] Magnesium Chloride	14180046 ^[4]	15°C to 30°C	36 months
Hanks' Balanced Salt Solution (HBSS) (10X) [-] Calcium Chloride [-] Magnesium Chloride [-] Sodium Bicarbonate [-] Phenol Red	14185045 ^[4]	15°C to 30°C	24 months
Hanks' Balanced Salt Solution (HBSS) (10X) [-] Sodium Bicarbonate [-] Phenol Red	14065056 ^[2] 14065098 ^[2]	15°C to 30°C	24 months
Hanks' Balanced Salt Solution (HBSS) (10X) [-] Sodium Bicarbonate [-] Phenol Red	14065049 ^[4]	15°C to 30°C	36 months
Hanks' Balanced Salt Solution (HBSS) (10X) [-] Calcium Chloride [-] Magnesium Chloride [-] Magnesium Sulfate	14185052 ^[2] 14185098 ^[2]	15°C to 30°C	24 months
Earle's Balanced Salt Solution (EBSS) (1X) [-] Calcium Chloride [-] Magnesium Chloride [-] Phenol Red	14155048 ^[4] 14155063 ^[2] 14155098 ^[2]	15°C to 30°C	36 months
BME, Basal Medium (Eagle) (1X) [+] Earle's Salts [+] Phenol Red [-] L-glutamine [-] HEPES	41010026 ^[4]	2°C to 8°C Protect from light	12 months
HEPES Buffer Solution 1 M	15630049 ^[4] 15630056 ^[4]	2°C to 8°C	24 months

Shelf life is determined from Date of Manufacture. Do not use beyond the labelled expiration date.
Manufacturer: Life Technologies Corporation | 3175 Staley Road | Grand Island, NY 14072
Dual manufactured.
Manufacturer: Life Technologies™ Ltd. | 3 Fountain Drive, Inchinnan Business Park | Paisley PA49RF, Scotland, United Kingdom |Tel: +44 (0)141 81416305

Precautions

Do not use the product if packaging, including bottles and vials, have been compromised and/or show evidence of microbial contamination, cloudy appearance, discoloration, drying, cracking, or other signs of deterioration.



CAUTION! Human samples are potentially biohazardous. Follow standard precautions for handling, storage and disposal.



WARNING! Do not use for injection or infusion! Please report any serious incidents in relation to the device to the manufacturer and the Competent Authority of the EU Member State in which the user and/or patient is established.

- Once opened, use Buffered Saline Solutions within 14 days for maximal growth performance.
- Avoid repeated warming/cooling and prolonged exposure to light.
- Do not use beyond labeled expiration date.
- All solutions that come into contact with clinical samples must be sterile. Always use proper aseptic techniques and work inside a laminar flow hood. Consult our **Gibco Cell Culture Basics** for aseptic handling.

Test protocol

Buffered saline solutions have many different uses in diagnostic protocols such as cell washing, diluents or as transport media. Refer to the appropriate procedures. Several procedures and applications are provided in the references.

Cellular suspensions prepared in a buffered saline solution should not be stored longer than several hours as cellular viability may decrease. Therefore, the suitability of the buffered saline solution for a specific cell type should be tested prior to use.

Quality control

Standard evaluations for cell culture media are pH, osmolality, endotoxins and sterility testing for liquid products. All quality control testing results are reported on lot specific Certificate of Analysis available on our website: **thermofisher.com**.

References

- Lennette EH, Halonen P and Murphy FA . Laboratory Diagnosis of Infectious Disease - Principles and Practices (1988).Springer, New York, p.43.
- 2. WHO Manual for the laboratory diagnosis and virological surveillance of influenza, 2011.
- Winn, W. C., & Koneman, E. W. (2006). Koneman's color atlas and textbook of diagnostic microbiology (6th ed.). Philadelphia: Lippincott Williams & Wilkins.
- 4. WHO Guidelines on the Establishment of Virology Laboratories in Developing Countries, 2008.

Labeling symbols

The symbols present on the product label are explained in the following table.



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Manufacturer: Dual manufactured products

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Revision history: Pub. No. MAN0018473

Revision	Date	Description
1.0	12 November 2019	New document

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