

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Thermo Fisher Scientific  
Life Technologies GmbH  
Frankfurter Str. 129B  
Darmstadt  
64293  
Germany

Holds Certificate No:

**FM 558504/(11770)**

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

The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets

For and on behalf of BSI:



Denelise L'Ecluse, Managing Director Assurance - Continental Europe

Original Registration Date: 2010-05-18

Latest Revision Date: 2024-07-29

Effective Date: 2022-05-12

Expiry Date: 2025-05-11

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...making excellence a habit.™

Certificate No: **FM 558504/(11770)**

Location	Registered Activities
Thermo Fisher Scientific Life Technologies GmbH Frankfurter Str. 129B Darmstadt 64293 Germany	The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets
Thermo Fisher Scientific Life Technologies Magyarország Kft. Váci út 41-43 Budapest 1134 Hungary	The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets
Thermo Fisher Scientific Life Technologies Czech Republic s.r.o. Krenova 438/1 Praha 6 16200 Czech Republic	The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets
Thermo Fisher Scientific Life Technologies Polska Sp. z o.o. Bonifraterska 17 Warsaw 00-203 Poland	The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets
Thermo Fisher Scientific Life Technologies s.r.o Laurinska 18 Bratislava 81101 Slovakia	The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets
Thermo Fisher Scientific Life Technologies Austria Zweigniederlassung Dresdner Straße 89 Wien A-1200 Austria	The sale, service and support of instrumental systems, applications and consumables used for Life Science, research and applied markets

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +49 (0)69 22 228 9200.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: **FM 558504/(11770)**

Location

Life Technologies Europe B.V.  
Zweigniederlassung Reinach  
c/o Thermo Fisher Scientific (Schweiz)  
AG  
Neuhofstrasse 11  
4153 Reinach BL  
Switzerland

Registered Activities

The sale, service and support of instrumental systems,  
applications and consumables used for Life Science, research  
and applied markets



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KaryoMAX™ Giemsa Stain

**Lot Number:** 2938486  
**Item Number:** 10092  
**Expiration Date:** 2026-05  
**Storage Temp:** 15 to 30C  
**Storage Instructions:** Protect from light  
**Originated From:** L210731

For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals.

TEST	TEST ID	SPECIFICATION	RESULT	UNITS
<b>Chrom 10 Banding Resolution Act Std. Dev</b>	PERBLD0007	Check and Record	4.002	
<b>Chrom 10 Banding Resolution Actual</b>	PERBLD0006	Check and Record	37.700	
<b>Chrom 10 Banding Resolution Cont Std Dev</b>	PERBLD0009	Check and Record	4.907	
<b>Chrom 10 Banding Resolution Control</b>	PERBLD0008	Check and Record	37.800	
<b>Peripheral Blood Performance Testing</b>	PERBLD0001	Acceptable	Acceptable	

- Testing is performed on the raw material.

Read SDS.

Storage and handling precautions: Limit product exposure to air. Cap tightly.

Recommended Dilution Instructions: Peripheral Blood Chromosomes: 3 mL Giemsa Stain, 48.5 mL Gurr Buffer (pH 6.8)

NOTICE: Effective 22MAY2023 the product description has been updated to KaryoMAX(TM) Giemsa Stain per ECR1101109. If you have questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or Techsupport@thermofisher.com globally.

NOTICE: Effective 13MAY2022 the Intended Use Statement has been updated to For Research Use or Further Manufacturing. Not for use or direct administration into humans or animals per ECR1087081. If you have questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or Techsupport@thermofisher.com globally.

Hotchkiss

Quality Systems Department

Date: 20-Nov-2024

### References

- PERBLD0007: The chromosome 10 banding resolution represents the standard deviation for the mean value for the actual lot. This is a parameter assessed by the Peripheral Blood Performance Test, see reference.
- PERBLD0006: The chromosome 10 banding resolution represents the mean value for the actual lot. This is a parameter assessed by the Peripheral Blood Performance Test, see reference.
- PERBLD0009: The chromosome 10 banding resolution represents the standard deviation for the mean value for the control lot. This is a parameter assessed by the Peripheral Blood Performance Test, see reference.
- PERBLD0008: The chromosome 10 banding resolution represents the mean value for the control lot. This is a parameter assessed by the Peripheral Blood Performance Test, see reference.

- 
- PERBLD0001: The Karyomax range of media and reagents are evaluated for performance using a test system comparable to the protocols routinely used in cytogenetic laboratories. Test samples of the reagent or media are run in parallel against a previously qualified control lot in a system pertinent to the normal usage in a cytogenetic laboratory. The resulting preparations are analyzed for statistical difference in mitotic index and colony quantity and quality or banding resolution where relevant.

# GIBCO® media and culture supplements for cytogenetic analysis

- Optimized and prequalified for cytogenetics
- Provide high mitotic index
- Deliver excellent chromosomal morphology
- Produce clear, reproducible results that are easy to analyze and interpret

Every day, you make critical decisions based on what you see through a microscope. When your cytogenetics analysis is supported by GIBCO® media and culture supplements, you can be confident in the conclusions you reach.

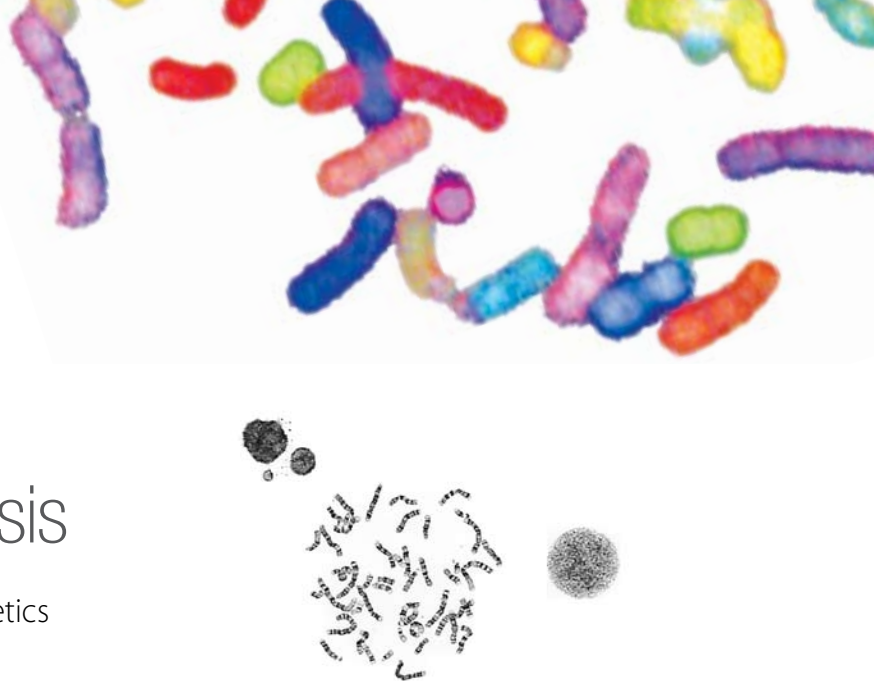
You'll get clear, reproducible results that are simple to analyze and interpret when you use the most trusted cell culture media and reagents for cytogenetics: MarrowMAX™, AminoMAX™, and PB-MAX™ products.

## Superior performance

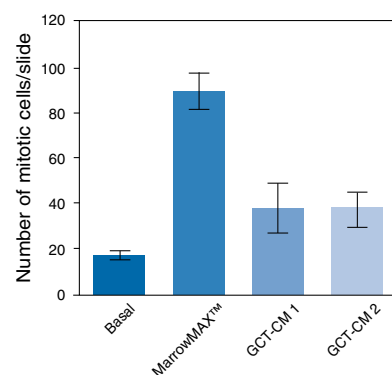
- High mitotic index and superior chromosomal morphology (Figure 1)
- Outperforms commercially available giant cell tumor conditioned medium (GCT-CM) (Figure 2)
- Consistent lot-to-lot performance (Figure 3)

## Convenience

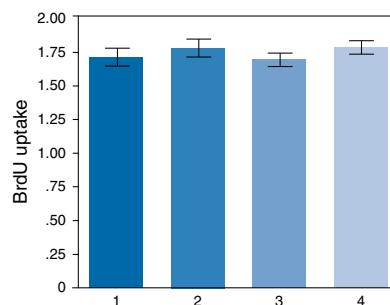
- Complete, ready-to-use medium
- Fully supplemented with serum, gentamicin, and L-glutamine
- Store either frozen or refrigerated



**Figure 1—Chromosome spread from bone marrow cells.** Cells were cultured in MarrowMAX™ Medium for 24 hours, and G-banding analysis was performed.



**Figure 2—Performance of MarrowMAX™ Medium.** Cells were cultured in: basal medium without conditioned medium; MarrowMAX™ Medium; Supplier 1 Medium (GCT-CM 1); and Supplier 2 medium (GCT-CM 2) (both Supplier 1 and Supplier 2 media contain GCT-conditioned medium). Mitotic cells were assayed 24 hours after plating.



**Figure 3—Consistency of MarrowMAX™ Medium.** Normal bone marrow mononuclear cells were seeded at  $1 \times 10^5$  cell/ml in 4 different lots of MarrowMAX™ Medium. BrdU uptake was measured by absorbance at 405 nm. Results are mean  $\pm$  SEM for  $n = 10$ .



## Cytogenetic and Diagnostic Testing

### Peace of mind with each product

- Manufactured in compliance with the FDA's Quality System regulation (cGMP) and the current requirements of ISO 9001
- Application-tested by an independent, certified cytogenetics laboratory to deliver clear, reproducible results in standard clinical cytogenetic protocols
- Extended shelf life of 18 months when stored unopened at -20°C and 60 days stored at 4°C

### We know what matters

At Invitrogen, we understand the high level of service and support required in cytogenetics laboratories, so we strive to help you in every way possible. Have questions? Need data? Contact Invitrogen's cytogenetics specialists at 1 800 955 6288 or visit [www.invitrogen.com/cytogenetics](http://www.invitrogen.com/cytogenetics).

### Ordering Information

Product	Size	Cat. no.
MarrowMAX™ Bone Marrow Medium * (contains gentamicin)	100 ml	12260-014
AmmioMAX™-II Complete Medium (contains gentamicin)	100 ml	11269-016
AmnioMAX™-C100 Complete Medium (system) The system contains both the basal medium (90 ml) and the supplement (15 ml) (supplement contains gentamicin)	1 set	12558-011
AmnioMAX™-C100 Basal Medium, liquid	90 ml	17001-082
	450 ml	17001-074
AmnioMAX™-C100 Supplement, liquid (contains gentamicin)	15 ml	12556-015
	75 ml	12556-023
PB-MAX™ Karyotyping Medium (contains gentamicin)	100 ml	12557-013
	500 ml	12557-021
KaryoMAX™ Colcemid® Solution, liquid (10 mg/ml), in HBSS	10 ml	15210-040
KaryoMAX™ Colcemid® Solution, liquid (10 mg/ml), in PBS	10 ml	15212-012
KaryoMAX™ Giemsa Stain Stock Solution	100 ml	10092-013
Fungizone® Antimycotic, liquid	20 ml	15290-018
Phytohemagglutinin (M Form) (PHA), lyophilized †	10 ml	10576-015

\* This product is subject to Limited Use Label License No. 31. These products are for in vitro use and are not intended for human or animal therapeutic use. Uses other than the labeled intended use may be a violation of federal law. † The noted products are for laboratory use only and not for diagnostic use. The safety and efficacy of these products in diagnosis or other clinical uses has not been established. Colcemid® is a registered trademark of CIBA-GEIGY Corporation.

Visit us at [www.invitrogen.com/cytogenetics](http://www.invitrogen.com/cytogenetics) to learn about related reagents for cytogenetic cell culture.