


KaryoMAX™ Colcemid™ Solution

Catalog Numbers 15212-012, 15210-040

Pub. No. MAN0026582 Rev. B.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](https://www.thermofisher.com/support).

Intended purpose

KaryoMAX™ Colcemid™ Solution has been formulated and qualified for use in preparation of primary cell samples, including but not limited to those derived from bone marrow, amniotic fluid, and blood. The solution contains 10 µg/ml N-desacetyl-N-methylcolchicine (Colcemid™ solution) and is available in two formulations:

- KaryoMAX™ Colcemid™ Solution in phosphate-buffered saline (PBS) (Cat. No. [15212-012](#))
- KaryoMAX™ Colcemid™ Solution in Hanks' Balanced Salt Solution (HBSS) (Cat. No. [15210-040](#))

KaryoMAX™ Colcemid™ Solution products have been formulated to prevent spindle formation during mitosis, arresting cells in metaphase so that the chromosomes can be separated for cytogenetic studies and *in vitro* diagnostic (IVD) procedures.

Cytogenetic products are for professional use. They are used in medical laboratories by personnel who have received specialized education and training with regard to 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

- Cell karyotyping was developed as a method to provide information about chromosomal abnormalities through visualization of chromosomes. Chromosomes are easiest to observe during the metaphase stage of the cell cycle. To prepare for karyotyping analysis, cells are cultured for 48–72 hours, then treated with a mitotic inhibitor, such as KaryoMAX™ Colcemid™ Solution, to prevent spindle formation and stop mitosis in the metaphase stage. After treatment with KaryoMAX™ Colcemid™ Solution, cells are prepared for microscopy to allow visualization of chromosomes and evaluation for chromosomal abnormalities.
- This product is sterile filtered

Contents and storage

All quality control testing results are reported on lot-specific Certificate of Analysis available on our website: [thermofisher.com](https://www.thermofisher.com).

Product	Prepared in	Cat. No.	Storage	Shelf life ^[1]
KaryoMAX™ Colcemid™ Solution	PBS	15212-012	2°C to 8°C Protect from light.	18 months
KaryoMAX™ Colcemid™ Solution	HBSS	15210-040		

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



For In Vitro Diagnostic Use.

Related products

We recommend the following products for cytogenetic studies and IVD procedures using KaryoMAX™ Colcemid™ Solution.

Unless otherwise indicated, all materials are available through thermofisher.com. "MLS" indicates that the material is available from fisherscientific.com or another major laboratory supplier.

IMPORTANT! Each clinician must make an independent judgment on whether these products are suitable for use in IVD applications conducted in their laboratory. Life Technologies does not guarantee the successful outcome of any diagnostic testing based solely on the use of Gibco™ reagents.

Item	Source
KaryoMAX™ Giemsa Stain Solution	10092013
Gurr Buffer Tablets (pH 6.8)	10582013
Phytohemagglutinin, M form (PHA-M)	10576015
Amphotericin B, (20 mL, 50mL)	15290018, 15290026
KaryoMAX™ Potassium Chloride Solution	10575090
Trypsin (2.5%), no phenol red	15090046
Nunc™ Cell-Culture Treated Multidishes, (6-well, 75 count)	140675
Nunc™ 15mL Conical Sterile Polypropylene Centrifuge Tubes	339651
Nunc™ 50mL Conical Sterile Polypropylene Centrifuge Tubes	339653
Nunc™ Thermanox™ Coverslips, (25 mm)	174985
Nunc™ Serological Pipettes, (5 mL)	170355
MarrowMAX™ Bone Marrow Medium, (100 mL, 500 mL)	12260-014, 12260-001
PB-MAX™ Karyotyping Medium, (100 mL, 500 mL)	12557-013, 12557-021
AmnioMAX™ II Complete Medium	11269-016
AmnioMAX™ C-100 Complete Medium Kit	12558-011

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.

KaryoMAX™ Colcemid™ Solution is manufactured using aseptic processing and sterile filtration. The final product has a sterility assurance level of 10⁻³.



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



CAUTION! 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.

Procedural guidelines

- Always use proper aseptic techniques and work inside a laminar flow hood. Consult our [Gibco Cell Culture Basics](#) for aseptic handling.
- Perform all incubations in a humidified 37°C, 5% CO₂ incubator unless otherwise specified.

Guidelines for KaryoMAX™ Colcemid™ Solution

- KaryoMAX™ Colcemid™ Solution is supplied at ambient temperature. Store at 2–8°C upon arrival.
- Once opened, it is recommended to use KaryoMAX™ Colcemid™ Solution within 14 days.
- Avoid repeated warming/cooling and prolonged exposure to light.
- Do not use beyond the labeled expiration date.

Metaphase Chromosome Preparation with KaryoMAX™ Colcemid™ Solution


Procedures for use of KaryoMAX™ Colcemid™ Solution can vary depending on the application and sample of interest. Refer to the appropriate karyotyping protocol for your procedure of interest. Several protocols are provided within the reference documents below.

- [MarrowMAX Bone Marrow Medium Instructions for Use \(Pub. No. MAN0018525\)](#)
- [PB-MAX Karyotyping Medium Instructions for Use \(Pub. No. MAN0018538\)](#)
- [AmnioMAX C-100 and AmnioMAX II Complete Medium Instructions for Use \(Pub. No. MAN0018473\)](#)

Quality assurance/control



Every lot of KaryoMAX™ Colcemid™ Solution is performance tested by a certified US reference cytogenetics laboratory to ensure consistently superior performance. Peripheral blood lymphocytes from a normal adult donor are cultured for 72 hours in PB-MAX™ Karyotyping Medium before the addition of KaryoMAX™ Colcemid™ Solution to pause the cells in metaphase and allow for the measurement of mitotic index and chromosome banding resolution. In addition, each lot is tested for pH and osmolality, and must pass a sterility test prior to lot release.

Conformity symbols

Conformity mark	Description
	Indicates conformity with European Union requirements.

Labeling symbols

The symbols present on the IFU and labels that are not globally recognized as per ISO 15223 are explained in the following table.

	READ SAFETY DATA SHEET Consult Safety Data Sheet for risks associated with product.
	AUTHORISED REPRESENTATIVE IN THE UNITED KINGDOM

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.

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Revision	Date	Description
B.0	26 January 2023	Updated manufacturing address to Paisley. Removed UKCA symbol. Minor edits
A.0	29 August 2022	Initial release.

The information in this guide is subject to change without notice.

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