



# CHANG Media

TIME AND COST-EFFICIENT CELL CULTURE MEDIA SOLUTIONS FOR CYTOGENETIC APPLICATIONS

# Rely On CHANG Media

## for Successful Analysis

Cytogenetic laboratories rely on high-quality media to produce clear, analyzable metaphases from each precious sample—making the media used an indispensable tool for successful analysis. This is the reason many leading laboratories rely on CHANG media for all their cytogenetic applications.

Dr. Chang's original formulation has been the gold-standard for cytogenetic applications for decades—and today we continue to build on her foundation. Renowned for our unwavering commitment to excellence, all FUJIFILM Irvine Scientific products are developed and produced according to the highest medical standards and manufactured in state-of-the-art cGMP compliant facilities. Each cell- or tissue-specific medium is optimized to produce superior growth and morphology in peripheral blood, bone marrow, amniotic fluid, chorionic villi (CVS) and product of conception (POC) samples.

With an unrivalled Quality System focused on risk mitigation and quality assurance, you can rely on CHANG media for quality, consistency, and exceptional performance.



### Performance

- Each formula is optimized to deliver consistent, analyzable results
- Fast growth and high mitotic index
- Superior morphology
- Every lot performance tested on cytogenetic samples at an independent, non-affiliated laboratory

### Convenience & Consistency

- Save time and avoid mixing with complete, ready-to-use media
- Manufactured in large batch sizes for consistent performance lot-to-lot
- Long shelf life to reduce the burden of quality control testing
- Lot holds of one year available for your convenience

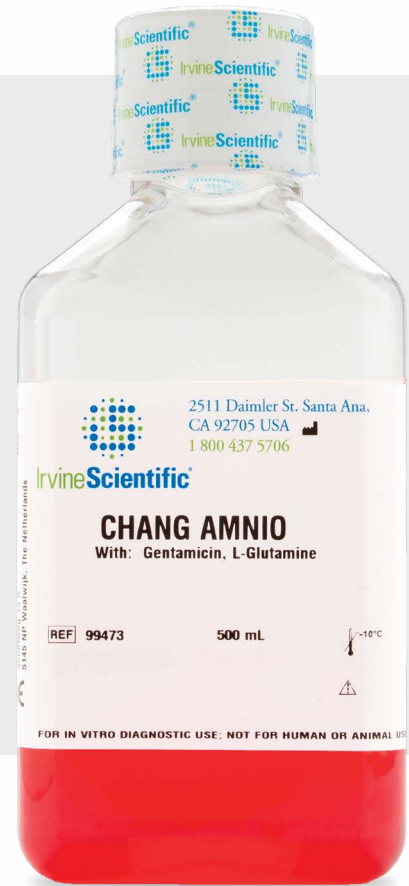
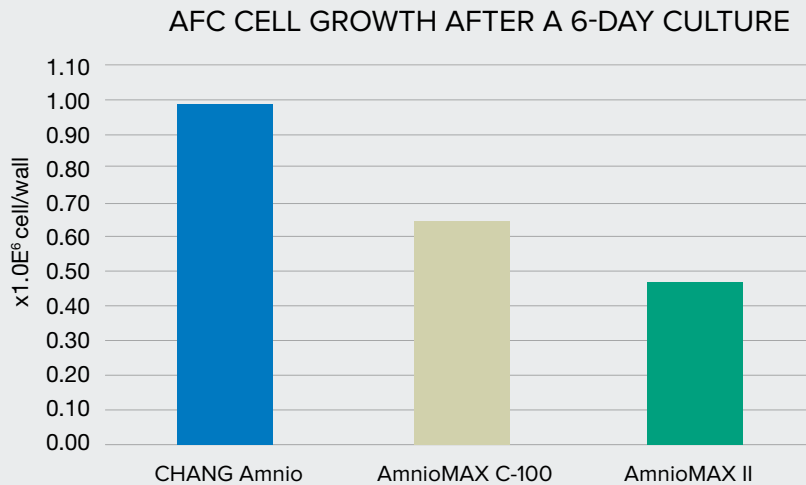
### Quality

- Manufactured in compliance with cGMP guidelines
- Regulatory compliance, including FDA 510k and CE marked
- ISO 13485:2016 Quality System
- Stringent raw material controls
- Quality control tested for pH, osmolality, sterility, and endotoxin with Certificate of Analysis (CoA)

### Support

- Renowned for our unmatched individualized customer service
- Expert technical support from experienced cytogeneticists

# Outperforms Other Media



## CHANG Solutions for Amniotic Fluid, CVS & POC Culture

### CHANG Amnio

CHANG Amnio is a complete, ready-to-use medium containing a specialized mixture of proteins developed for the optimal culture of human amniotic fluid cells, Chorionic Villus Sampling (CVS), and tissues, for use in karyotyping and other cytogenetic testing.

- CHANG Amnio supports both flask and *in situ* methodologies
- Faster growth and higher mitotic index
- Better morphology
- High colonies per dish *in situ*
- Each lot performance tested on early passage amniocytes

### CHANG Medium C

- Ideal for labs with limited freezer space
- Basal medium plus supplement in convenient lyophilized or frozen form
- For use in open and closed systems

### CHANG D without Gentamicin

- The ideal choice for labs that prefer a medium free of antibiotics
- For use in both flask and *in situ* methodologies



CHANG Amnio has been used by our department for many years for the development of cultured human amniotic fluid cells, chorionic villus samples, and other tissues. It provides us with high growth rates, and beautiful metaphases that are easy to analyze.

Meaghan Chung, ACL Laboratories

# CHANG Solutions for Bone Marrow Culture

## CHANG Marrow

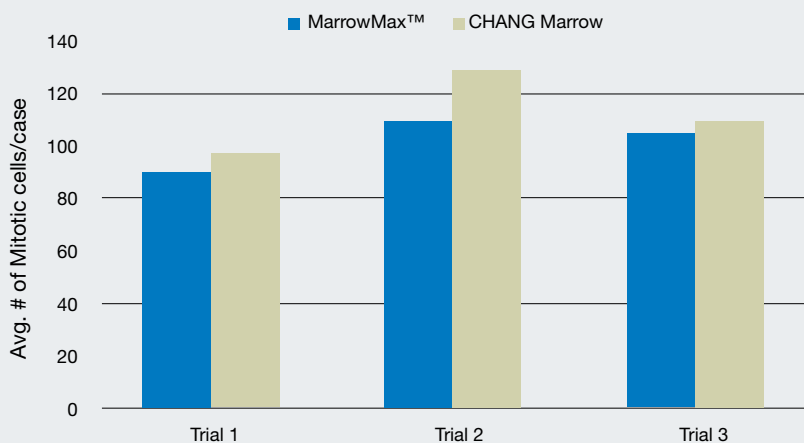
CHANG Marrow is a complete, ready-to-use medium designed for the culture of human bone marrow cells. Based on IMDM with a unique blend of growth factors, including GCT, it is optimized to deliver superior growth and morphology, and for better detection of abnormal cells—essential for diagnosis and prognosis of hematopoietic disorders and tumors.

- Rapid growth and high mitotic index
- Supports growth of rarer, hard-to-culture cells for better detection of malignancies
- Excellent morphology of chromosomes
- Fewer culture failures
- Each lot performance tested by an independent certified cytogenetics laboratory

We chose CHANG Marrow because it's comparable to, or even better quality than other media.

*Dr. Philip D. Cotter, Principal and Co-founder, ResearchDx, a leading Contract Diagnostics Organization for biopharmaceutical and diagnostic industries*

## Outperforms Other Media



**Clinical evaluation: Average Mitotic cells per culture:**

For each trial, 20 specimens from 20 different patients were set in culture in CHANG Marrow and MarrowMax. After two days of culture, the number of mitotic cells was tallied for culture. The average number of mitotic cells per culture is represented in the chart above for each medium.



## CHANG Medium BMC

CHANG Medium BMC is an alternative medium for bone marrow culture for cells or applications where RPMI basal medium is preferred.

- Complete, ready-to-use medium for bone marrow culture
- Based on RPMI 1640 supplemented with 10% Giant Cell Tumor-conditioned Medium and gentamicin
- Each lot performance tested on clinical bone marrow cultures by an independent clinical cytogenetics laboratory

## IS Giant Cell Tumor-conditioned Medium

A unique conditioned medium derived from a human tumor cell line, IS Giant Cell Tumor-conditioned Medium provides a winning combination of GM-CSF, G-CSF, IL-1, and IL-6 to ensure dependable performance in a wide range of applications. This liquid medium easily grows hematopoietic cells, improves bone marrow cytogenetic analysis, isolates and recovers HIV, and produces and grows human hybridomas.

# CHANG Solutions for Peripheral Blood Culture

## CHANG Medium MF

CHANG Medium MF is designed to support both stimulated and unstimulated culture of peripheral blood and bone marrow cultures. Its mitogen-free formula provides the flexibility to use the optimal mitogen for the clinical indication.

- Rapid growth and high mitotic index
- Use any mitogen, or in an unstimulated protocol
- Complete, ready-to-use, RPMI based medium with 20% FBS and gentamicin
- Each lot performance tested on clinical peripheral blood and bone marrow cultures by an independent clinical cytogenetics laboratory



## Save Time & Money with Complete Media

Reclaim your time and take control of your results with CHANG complete media. Making media in-house is not as cost-effective as it appears when accounting for the hidden costs and risks.

### CHANG complete media lets you:

- Minimize contamination-prone handling of components
- Avoid inconsistencies or errors when aliquoting
- Avoid lengthy thaw times, and labor spent mixing
- Reduce QC testing
- Benefit from the consistency provided by cGMP manufacturing at large scale
- Minimize concerns about quality and consistency thanks to our rigorous Quality Assurance testing practices

Discover how switching from mixing media in-house to CHANG complete media can help increase efficiency and save labor and material costs, while freeing up your skilled staff to focus on other important tasks.





# Quality Service You Can Rely On

It is vital for cytogenetic laboratories to maintain an uninterrupted supply chain of high-quality cell culture media for both quality control purposes, and to ensure the ability to promptly test high-risk or urgent cases. Issues can quickly derail vital tests and adversely impact turnaround times and patient services.

We understand the critical importance of having a team of experts on hand to help you address any issue, from supply to optimizing protocols.

We help you **estimate your media usage** to set aside lots to meet your annual needs

Lot holds up to a year to **guarantee lot inventory**, reducing the need for additional quality control testing

**Standing orders** available

Experts in cytogenetic cell culture are **available to help** with technical issues

**Documentation and traceability** information provided for all manufactured lots

## Quality Control

**Certificates of Analysis (CofA)** are provided with each shipment, with test results reported on a lot-specific basis for:

- **Functional and Performance** testing for growth, mitotic index and morphology.
- **Sterility**—testing performed in accordance with the Code of Federal Regulations (CFR) Title 21, Part 610.12 or current USP <71>. CHANG media are sterilized using aseptic processing techniques (filtration). Serum used in the production of CHANG Amnio has been tested for viral contamination per CFR Title 9 Part 113.53. It has also been screened for mycoplasma contamination.
- **Endotoxin**—measured using the LAL gel clot or kinetic chromogenic methodology.
- **pH**—measured at a 1X concentration in accordance with finished product specifications.
- **Osmolality**—testing performed either by the freezing point or vapor pressure methodology on precalibrated instrumentation using specific Standard Operating Procedures to ensure accuracy and consistency.

- US FDA (510k)
- CE marked
- ISO 13485:2016 Certified Quality System

# Ordering Information

## Prenatal Tissue Culture Media

Item	Catalog #	Size	Additional Info	Shelf Life*	Storage
CHANG Amnio	99473	100 mL 500 mL	Complete, ready-to-use. Contains gentamicin.	2 years	Below -10°C
CHANG Medium <i>In Situ</i>	T104	100 mL	Does not contain antibiotics.	2 years	Below -10°C
CHANG Medium D	T105	100 mL 500 mL	Does not contain antibiotics.	2 years	Below -10°C
CHANG Medium D w/antibiotics	99404	100 mL	Contains gentamicin.	2 years	Below -10°C
<b>CHANG Medium C—consists of 2 part system: a basal medium (B) and supplement in frozen or lyophilized format (C)</b>					
CHANG Medium B Basal	C100	90 mL	Must not be frozen.	2 years	2–8°C
CHANG C Frozen supplement	C106	14 mL	Does not contain antibiotics.	2 years	Below -10°C
CHANG Medium C, lyophilized	T101-019	100 mL	Does not contain antibiotics.		2–8°C

## Bone Marrow / Peripheral Blood Tissue Culture Media

Item	Catalog #	Size	Additional Info	Shelf Life*	Storage
CHANG Marrow	91031	100 mL 500 mL	Complete, ready-to-use. Contains gentamicin.	2 years	Below -10°C
CHANG Medium MF	91005	100 mL	Complete, read-to-use. RPMI based and contains gentamicin. Mitogen free.	2 years	Below -10°C
CHANG Medium BMC	91004	100 mL 500 mL	Complete, ready-to-use. RMPI based and contains gentamicin.	2 years	Below -10°C
IS Giant Cell Tumor-conditioned Medium	91006	50 mL	Prepared from a cultured giant cell tumor line derived from a human malignant fibrous histiocytoma.	2 years	Below -10°C

## Cytogenetic Reagents and Solutions

Item	Catalog #	Size	Additional Info	Shelf Life*	Storage
Alpha MEM Earle's Salts <sup>‡</sup>	9144	500 mL	Contains 2,200 mg/L sodium bicarbonate, deoxyribonucleosides, and ribonucleosides.	2 years	2–8°C
Colcemid solution	9311	10 mL	10 µg/mL prepared in HBSS. Packaged with septum caps, and is pipette and syringe accessible.	2 years	2–8°C
Phytohemagglutinin PHA	96691	5 mL	Lyophilized powder, reconstitute with 5 mL sterile water. Approximately 45 mg/vial.	2 years	2–8°C
Potassium Chloride Solution	9281	500 mL	Formulated as 5.59 g of potassium chloride per liter of water.	2 years	15–30°C

# Ordering Information

## Classical Media, Reagents, and Buffered Salt Solutions

Item	Catalog #	Size	Additional Info	Shelf Life*	Storage
L-Glutamine (200 mM)	9317	100 mL 500 mL	Ready-to-use stock solution.	2 years	Below -10°C
Trypsin (1:250) 2.5% 10X Solution	9336	100 mL†	Without calcium, magnesium salts, and phenol red.	2 years	Below -10°C
Trypsin EDTA 1X Solution in HBSS	9341	100 mL 500 mL	Contains phenol red. Without calcium, magnesium salts, and sodium bicarbonate.	2 years	Below -10°C
Trypsin EDTA 10X Solution	9342	100 mL†	Contains 5.0 g/L trypsin (1:250) and 2.0 g/L EDTA tetrasodium salt in HBSS.	2 years	Below -10°C
RPMI 1640	9161	100 mL 500 mL 1 L	Contains L-glutamine and 2,000 mg/L sodium bicarbonate.	2 years	2–8°C
RPMI 1640 w/o L-Glutamine	9160	100 mL 500 mL 1 L	Contains 2,000 mg/L sodium bicarbonate. Without L-glutamine.	3 years	2–8°C
Gentamicin sulfate solution	9355	20 mL	50 mg/mL gentamicin in water.	2 years	15–30°C
PBS 1X-Dulbecco's Phosphate Buffered Saline Solution-Liquid‡	9240	100 mL 500 mL 1 L	Without calcium, magnesium salts, sodium bicarbonate and phenol red.	2 years	15–30°C
PBS 10X-Dulbecco's Phosphate Buffered Saline Solution-Liquid	9242	500 mL	Without calcium, magnesium salts, and phenol red.	2 years	15–30°C
HBSS 1X-Hanks' Balanced Salt Solution‡	9228	100 mL, 500 mL§	Without calcium and magnesium salts.	2 years	15–30°C
WFI water/Cell culture grade water	9309	1 L§	WFI Quality Water meets USP, PhEur, and JP grade specifications, and is 0.1 µm sterile filtered at time of fill.	2 years (bottles) 3 years (bags)	2–30°C

\*From month of manufacture

†1 L, 5 L, 10 L, 20 L, and 100 L bags available upon request

§Other sizes and packaging available on request

‡Additional formats available on our website at [www.irvinesci.com](http://www.irvinesci.com)



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