
 <p>8</p>	Document ID:	TDS-AMG-001-100ML	Version:	001
	Date of Issue:	10-JAN-2023	Approved by:	Dr. Iman Kamranfar
	Review Date:	10-JAN-2025	Signature:	
	Title:	TECHNICAL DATASHEET		

AMNIOGROW I

Complete Karyotyping Medium for Amnion and Chorionic Villi Cells

Filtration, Treatment	Sterile Filtered; Contains preselected serum, L-Glutamine and gentamicin.
Product Code	AMG-001-100ML
Shelf Life	24 months from DOM
Storage Temperature	Store between -5°C to -20°C protected from light. Once opened, store at +2°C to +8°C and use within 2 weeks
Shipping Temperature	Frozen (Dry ice)
Thawing	+37°C in water bath and swirl gently to homogenize
CO2 concentration, optimum	5 %

QC Specifications

Physical and Chemical Analysis	Method	Specifications	Units
Appearance	Visual	Clear amber to red frozen liquid	n/a
pH at RT	Electronic pH Meter	6.8 - 7.6	n/a
Osmolality	Osmometer	Test and report	mOsm/kg
Endotoxin	LAL Kinetic	≤ 10.0	EU/ml
Sterility			
Aerobic Bacteria	Internally Validated	Not detected	n/a
Anaerobic Bacteria	Internally Validated	Not detected	n/a
Fungi (Yeast & Mold)	Internally Validated	Not detected	n/a

GENERAL INFORMATION/FORMULATION

This medium is ready to use product. It has been specifically developed for the cultivation of human primary amnion and chorionic villi cells, which are intended for the preparation of karyograms, fluorescence *in situ* hybridization and other cytogenetic methods. The medium is supplied frozen.

The medium is formulated based on the basal medium MEM Alpha Modification and already supplemented with preselected foetal bovine serum, L-Glutamine and 50 µg/ml gentamicin.

INSTRUCTION FOR USE



The medium may be used in both open and closed culture systems.

Important information:

This medium is ready to use and no further supplements are needed. It is recommended to use cells from 2.5 ml of amniotic fluid per one coverslip. The following protocol and the volumes indicated are only general guidelines for use. This high-quality medium can be used within established procedures. It is up to the user to adopt the optimized protocol described below either partially or completely.

In situ Culture of Amniotic Fluid Cells:

1. Concentrate the cells by centrifugation of the amniotic fluid: Centrifuge 20 ml of amniotic fluid at 750 rpm for 10 minutes.
2. Carefully decant the amniotic fluid from the cell pellet into a sterile test tube.
3. Resuspend the cell pellet with 2 ml of amniotic fluid.
4. Add 2 ml of the medium and swirl gently.
5. Culture 0.5 ml of the cell suspension on each coverslip in a tissue culture dish.

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6. Incubate cultures at +37°C in a 5 % CO₂ atmosphere.
7. Add 2 ml of the medium to each culture on day 2.
8. Check cultures for growth after 4 to 5 days. Feed cultures once growth has been observed. To feed cultures, carefully aspirate all of the exhausted culture medium and replace with 2 ml of fresh medium.
Recommendation: feed cultures every 2 days.
9. When the cultures have colonies of sufficient size, proceed with harvesting.
10. For best results, feed cultures with the medium the day before the harvest.

Flask Method Culture of Amniotic Fluid Cells:

1. Use the same procedure as for the *in-situ* culture, with the following adaptations:
2. Resuspend the cell pellet with 4 ml of amniotic fluid. Add 16 ml of the medium and swirl gently.
3. Culture 5 ml per T25 flask. Place the cap loosely on the flask and incubate undisturbed at +37°C in a 5 % CO₂ atmosphere.
4. Check all flasks for growth after 5 days.
5. For best results, feed cultures with this medium the day before the harvest.

Recommendations for Closed Systems:

This medium may be used in closed culture systems as long as the physiological pH of 6.9 to 7.4 is maintained. Closed systems depend on adequate buffering capacity of media.

- Method 1: Supplement this medium with 2 % (v/v) sterile 1.0 M HEPES solution. The HEPES solution must be set to pH 7.0 at +20°C. HEPES supplemented medium can subsequently be used on cells in closed culturing flasks.
- Method 2: Pre-equilibrate the flask containing this medium and cells at +37°C in a 5 % CO₂ atmosphere for 1 hour prior to closing the flask.
- Method 3: Flush each culture flask containing this medium and cells with 5 % CO₂ – 95% air through 0.2 µm sterile filter for 20 seconds. Tighten the caps and incubate the flasks at +37°C.

PRECAUTIONS AND DISCLAIMER

The medium is not intended for therapeutic use.

Each laboratory is obliged to perform representative tests according to the valid legal regulations and in its own environment to ensure that it is suitable for this purpose before the medium can be used in routine diagnostics.

Do not use if a visible precipitate is observed in the medium.

Use this medium does not guarantee the successful outcome of any prenatal diagnostic testing.

Do not use this medium beyond the expiration date indicated on the product label.

Serana Europe - Leading Manufacturer and Supplier of Cell Culture Products

Serana Europe GmbH is a leading manufacturer and supplier of cell culture products. Our product range includes animal & human sera, sterile liquid & powdered classical media, reagents, supplements, and buffer solutions for cell culture applications. Serana's products are used in all areas where cell culture is performed. This includes the biopharmaceutical industry for the production of vaccines, therapeutic proteins and diagnostics. In addition, we are a major supplier to Academic R&D institutes (universities, hospitals & clinics), private research organizations and various biotech companies.

Our quality assurance team guarantees exceptional quality manufacturing standards which follows relevant guidelines and regulatory requirements. We are EDQM, ISO 9001, and ISO 13485 certified, and our team is dedicated to continuously improve our quality management system. Our quality control department also offers a wide variety of relevant biological, molecular and biochemical assays as a service. We have certified manufacturing facilities in Germany and Australia, which makes us an ideal global partner with validated storage and delivery logistics world-wide.



We are EDQM, ISO 9001, and ISO 13485 certified

Our quality promise

Products manufactured by Serana utilize stringent operating and quality control procedures. Detailed production and traceability records are available for every batch produced. A battery of QC tests are performed including: physical and chemical analysis, protein profiling, sterility, virology, biochemistry and cell culture performance benchmarking. Only batches that pass Serana's rigorous quality control procedures are released for sale. Detailed certificates of analysis are prepared and made available for each lot produced.

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HUMAN BLOOD PRODUCTS BY-PRODUCTS

CLASSICAL MEDIA

CELL CULTURE SUPPLEMENTS, BUFFERS AND REAGENTS

DIAGNOSTIC PRODUCTS

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AmnioGrow™

Complete Karyotyping Medium for Amnion and Chorionic Villi Cells

Advantages

- Optimized superior formulation by Serana R & D team
- Superior chromosomal morphology and higher mitotic index in short time cultivation (Fig. 1)
- Superior growth support of short-term and long-term cultivation (Fig. 2)
- Consistent lot-to-lot performance
- Comprehensive QC specifications (in product TDS)
- Manufactured at Serana ISO 13485-certified facility in Germany

Convenience

- Complete, ready-to-use medium fully supplemented with FBS, gentamicin, and L-glutamine
- Enhanced buffering capacity to be ideal for amnion and villi cell culture in both open and closed systems
- Detailed available IFU in the product TDS
- Flexible to be ordered in different volume packaging from 50ml to 1000ml per Unit.

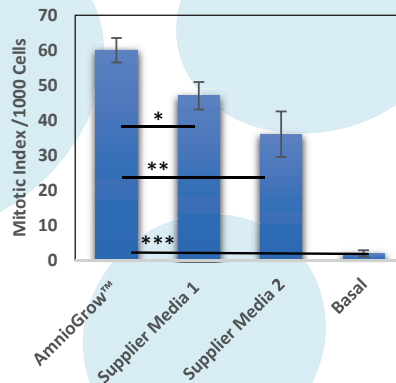
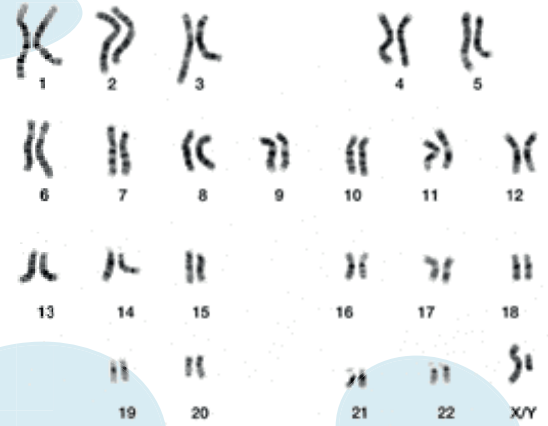


Fig. 1. Superiority of AmnioGrow™ in providing higher Mitotic Index (MI). MI ± SE (0.5 h colcemid incubation time after 6 days culturing). One-way ANOVA with subsequent Tukey HSD post hoc test ($p < 0.05$).

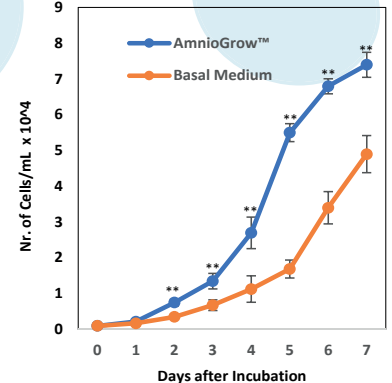


Fig. 2. Superiority of AmnioGrow™ in providing higher aminocytes growth over eight days of incubation. Secondary aminocytes were cultured in either AmnioGrow™ medium or basal medium supplemented with FBS. One-way ANOVA with subsequent Duncan post hoc test ($p < 0.01$). Error bars represent SE.

AMNIOGROW

Filtration, Treatment	Sterile Filtered; Contains preselected FBS, L-Glutamine and gentamicin.
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QC Specifications

Physical and Chemical Analysis	Method	Specifications	Units
pH at RT	EP 2.2.3	6.8 - 7.6	n/a
Osmolality	EP 2.2.35	Test and report	mOsm/kg
Endotoxin	LAL Kinetic (EP 2.6.14)	≤ 10.0	EU/ml
Sterility			
Bacterial, Fungal & Mycoplasma	Internally Validated	Not detected	n/a

For the latest technical data and pricing, please refer to the Serana-Europe website.
serana-europe.com/products/amg-001-100ml



ORDERING INFORMATION

PRODUCT	OPTIONS	VOLUME	STORAGE	SHELF LIFE	CODE
AmnioGrow™	Complete Karyotyping Medium for Amnion and Chorionic Villi Cells	100 ml	-15 to -20°C	2 Years	AMG-001-100ML

For complete current specifications and other technical information please see the technical data sheet on our website www.serana-europe.com

Should you have any specific product requirements that our stock product offering cannot fulfill;

please don't hesitate to ask if we can tailor-make a product to your specifications.