

Intended use

CytogenAmnio Medium is used to cultivate human amniotic and chorionic villi cells. It is intended for human genetic *in vitro* diagnostics.

Composition

Basal medium, pre-tested FBS, hormones and growth factors, phenol red, buffering by means of NaHCO₃; contains gentamycin and L-glutamine.

Shelf life and storage

Unopened CytogenAmnio medium can be stored for 18 months from the date of manufacture if stored at ≤-18°C. After opening, store the bottle at +2°C to +8°C and use for a maximum of 7 days. Avoid repeated thawing and freezing.

Thawing

Thaw CytogenAmnio Medium at +2°C to +8°C overnight. Thawing in a water bath at 37°C is not recommended. Mix Amniogrow Plus Medium well before use. The normal pH is 7.2, as indicated by the phenol red indicator. In the event of a pH deviation (yellow or pink), the pH value is equilibrated by incubation of the bottle, slightly opened (approx. ¼ rotation of the lid) in a 5% CO₂ incubator until the medium has reached the normal colour red. CytogenAmnio Medium does not contain any components whose quality is impaired by pH fluctuations of +/- 2. Warmed medium at 37°C and the correct pH value ensures an optimal start for the culture.

Standard protocol

The methods described below are proven instructions for the use of CytogenAmnio in the cultivation of amniotic and chorionic villi cells. CytogenAmnio Medium is filled under aseptic conditions. Maintaining the sterility of the product is necessary for its use in *in vitro* diagnostics, and this must be strictly adhered to by the user. Of course, this high-quality medium can be integrated into your own workflow. It is up to the user to decide whether the protocols, etc., are transferred completely or only partially into their own protocols.

Bottle method

- Concentrate cells through centrifugation at a low speed
- Remove 90–95% of the supernatant and resuspend the cells in the remaining amniotic fluid
- Dilute the cell suspension with pre-heated CytogenAmnio medium to at least 2 ml to obtain 2 ml per culture bottle
- Incubate at +37°C, 5% CO₂, in the incubator
- On the 5th day, check the growth and replace the medium with fresh CytogenAmnio
- Replace used medium regularly until harvesting
- For optimal results, change the medium the day before harvesting

In situ method

- Concentrate cells through centrifugation at a low speed
- Remove 90–95% of the supernatant and resuspend the cells in the remaining amniotic fluid
- Dilute the cell suspension with pre-heated CytogenAmnio to at least 2 ml to obtain 0.5 ml suspension per cover slip (4 in total)
- Incubate at +37°C, 5% CO₂, in the incubator
- On the second day, add 2 ml of CytogenAmnio
- After 4–5 days, check the growth of the cells

- Immediately afterwards, carefully aspirate the entire medium and replace with 2 ml pre-heated fresh CytogenAmnio medium
- Recommendation: change the medium every 2 days
- For optimal results, change the medium the day before harvesting

Important notes

- Occasionally, calcium oxalate crystals can form, but, to date, they have not shown any negative effects on cell growth.
- Thawing in a water bath at 37°C. should be avoided, as precipitates can form.












Warnings and precautions

- Maintaining the sterility of the product is necessary for its use, and this must be strictly adhered to by the user.
- Not suitable for therapeutic use with humans or animals.
- May only be used by trained, specialist personnel.
- Do not use bottles whose packaging has been damaged.
- Do not use CytogenAmnio Medium beyond its expiry date, which is stated on the label.
- The patient samples constitute biological material, and, therefore, safety precautions must be taken in accordance with local regulations for working with potentially infectious material.
- Cytogen GmbH does not guarantee the success of diagnostic testing solely through the use of Cytogen products.
- Report serious incidents that have occurred in connection with this product to the manufacturer and the competent authorities.


CE marking

With CytogenAmnio, Cytogen offers a CE-marked medium that meets the regulatory requirements for *in vitro* diagnostic medical devices set by the European Commission.

Explanation of symbols

	Observe instructions for use		Manufacturer
	<i>In vitro</i> diagnostic medical device		Date of manufacture
	Article number		Sterilised using aseptic methods
	Production lot number, batch		Do not use if the packaging is damaged
	Use by		Keep away from sunlight
	Temperature limit		

Manufacturer

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