

**CAUTION**

**Handle in accordance with established bio-safety practices.**

**Designated Purpose**

Amnioquick serves the cultivation and growth of human amniotic cells and chorionic villi and is to be used exclusively for *in vitro* diagnostic purposes on samples taken from humans.

**Composition**

Basal Media, pretested FBS, hormones and growth factors. Buffered with HCO<sup>3</sup>. Contains Gentamycin (50 µg/ml) and L-Glutamine.

**Shelf Life and Storage**

Amnioquick is stable for 2 years after production when stored at ≤-18 °C. Due to quality and sterility Amnioquick should be used within a maximum of 2 days after opening and storing at +2 °C to +8 °C.

**Thawing**

Amnioquick medium can be thawed at +2 °C to +8 °C overnight or in a +37 °C water bath. Mix medium thoroughly by swirling prior to use. In case of pH variation (pink or yellow) open cap slightly (about ¼ turn) and incubate bottle in a 5% CO<sub>2</sub> incubator until normal coloration (phenol red). Amnioquick does not contain components sensitive to pH changes of +/- 2. Warm medium at the proper pH is best for the initialization of cultures.

**Protocol**

The protocol below provides guidance for amnion and chorionic villi cell culture using Amnioquick. The medium is bottled under aseptic conditions. The maintenance of sterility is absolutely necessary for the use in *in vitro* diagnostics and must be strictly adhered to by the user. This high quality medium can naturally be used within established procedures. It is up to the user to adopt either parts or all of the optimized protocol described below.

***In situ* Method**

- Concentrate the cells by centrifugation of the amniotic fluid at low speed.
- Remove 90 – 95% of the supernatant and resuspend the cell pellet in the remaining volume of the patient's own amniotic fluid.
- Dilute the concentrated cell suspension with Amnioquick medium to a volume of 2 ml to allow a final plating volume of 0.5 ml per coverslip (total of 4 coverslips).
- Incubate cultures at +37 °C in a 5% CO<sub>2</sub> atmosphere.
- Add 2 ml of Amnioquick medium to each culture on day 2.
- 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 Amnioquick medium. Recommendation: feed cultures every 2 days.
- Check cultures for growth after 5 days, and harvest when sufficient colonies are observed.
- For best results, feed cultures with Amnioquick medium the day before the harvest.

**Flask Method**

- Concentrate the cells by centrifugation of the amniotic fluid at low speed.
- Remove 90 – 95% of the supernatant and resuspend the cell pellet in the remaining volume of the patient's own amniotic fluid.
- Dilute the concentrated cell suspension to a minimum of 2 ml with prewarmed Amnioquick medium to allow a final plating volume of 2 ml per flask.
- Incubate cultures at +37 °C in a 5% CO<sub>2</sub> atmosphere.
- On day 5 check for growth. Remove medium and replace with fresh Amnioquick medium and harvest if sufficient cell growth is observed.
- Completely exchange exhausted medium every other day until harvest.
- For best results, feed cultures with Amnioquick medium the day before the harvest.

**Important Remarks**

- For *in vitro* diagnostic use only (IVD)
- CAUTION: Not for human or animal therapeutic use. Uses other than the intended use may be a violation of local law.
- Each laboratory must carry out their own testing procedures on new media according to national legislation prior to releasing them to the lab for routine *in vitro* applications.
- Each clinician/scientist must make an independent judgment on whether this medium is suitable for use in *in vitro* diagnostic applications conducted in their laboratory.
- CytoGen GmbH does not guarantee the successful outcome of any diagnostic testing based solely on the use of CytoGen brand medium.

**CE marked**

With Amnioquick, CytoGen offers a CE marked medium for IVD which fulfils the requirements of the directive 98/79/EC defined by the European Commission.

**MANUFACTURER**

CytoGen – Produkte für Medizin + Forschung GmbH  
Langgasse 73  
D-35576 Wetzlar  
Germany

Tel. +49 6441 679 55 88  
Fax +49 6441 679 55 89  
E-Mail: [cytogen@eurobiz.de](mailto:cytogen@eurobiz.de)  
Web: [www.cytogen.info](http://www.cytogen.info)

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