

Datasheet Amniopan S2

Improved complete medium for the cultivation and cytogenetic analysis of human fetal cells from amniotic fluid and chorion villi biopsy samples

Product	Description	Catalogue-No.	Size
Amniopan S2	Complete medium for the cultivation and cytogenetic analysis of human fetal cells from amniotic fluid and chorion villi biopsy samples	P04-70101	100 ml

Product Description

Amniopan S2 is a complete ready-to-use medium intended for *in vitro* diagnostic use with a short term culture of human fetal cells from amniotic fluid or chorion villi biopsy (CVS) material for a standardized application in cytogenetic studies. This product has been quality tested by a leading clinical cytogenetic reference laboratory for this application.

Amniopan S2 is intended for *in vitro* use and has been designed for establishing cultures of human fetal cells from amniotic fluid or chorion villi biopsies (CVS), which then can be used in karyotyping, fluorescence in-situ hybridisation (FISH) or other cytogenetic procedures.

The media formulation of Amniopan S2 was further optimized on human fetal cells from amniotic fluid and CVS, with special emphasis on fast attachment of cells to the cell culture substrate and efficient cell growth to facilitate rapid diagnostic findings.

Storage conditions

Storage: -20° C in the dark
 Stability: 2 years
 Size: 100 ml, other sizes on request

Composition

Amniopan S2 is supplied frozen as a complete medium, ready to use in a 100 ml format. It is based on alpha-MEM and contains antibiotics, L-glutamine, Fetal Bovine Serum (FBS), hormones and an increased amount of growth factors. This product is manufactured under strictly supervised quality system in conformance with the ISO 9001/EN and ISO 13495 (medical products and *in vitro* diagnostics) requirements.

Suitability

Amniopan S2 is a complete medium (ready-to-use) for the cultivation of human fetal cells from amniotic fluid and chorion villi biopsy samples. It is suitable for a rapid expansion of amniotic cells in order to investigate chromosomal disorders. The state of the art diagnostic techniques for chromosomal aberrations are based on the interaction of cytomorphology including cytochemistry with immunophenotyping, chromosome banding analysis, FISH and molecular genetics. The number and quality of metaphases in Amniopan S2 are significantly higher and independent of individual batches as compared to other media.

Instructions for Use

Amniopan S2 is a complete medium, supplied in sterile, frozen condition. Additional filtration is not recommended. Detailed information concerning handling of Amniopan S2 and cell cultivation techniques are

available in a separate *Instructions for Use* brochure. Thawed Amniopan S2 can be used up to 1 week when stored at 2-8° C. Repeated warming and cooling and exposure to light has to be avoided.

Performance Testing

Amniopan S2 is tested for pH, osmolarity, bacterial, mycoplasma and fungal contamination. In addition to these standard specifications, each lot is tested for cell growth by an independent cytogenetics laboratory and the product performance is compared to a reference standard. A *Certificate of Analysis* is available upon request.

Precautions

Do not use product when the packaging appears compromised or visible precipitate is observed or the product is received thawed or partially thawed. Avoid prolonged exposure to light. As Amniopan S2 contains FBS, flocculent debris may develop upon thawing and storage.

Limitations

Each batch of Amniopan S2 is thoroughly tested for biological performance to ensure cell growth and *in vitro* diagnostic use.

However, for *in vitro* diagnostic applications each laboratory should establish and regularly perform internal quality testing procedures when selecting new cell culture media or utilising new batches of media prior to releasing these to the clinical routine.

In particular, the contribution of PAN Biotech to these procedures is limited merely to providing a culture medium which has been tested and found suitable for the intended use. PAN Biotech therefore does not guarantee a successful implementation for specific settings especially in diagnostic procedures.

In addition, PAN Biotech can not be held responsible for damage due to absence of cell growth or diagnostic failure based solely on the use of PAN Biotech medium.

Only for *in vitro* diagnostic use by means of culture and growth of human fetal cells from amniotic fluid or chorion villi biopsy sample material. Not intended for human or animal therapeutic use.

USE BIOLOGICAL MATERIAL WITH RESPECTIVE SAFETY PRECAUTIONS

Technical Support

In any case of questions or uncertainties please contact the customer service of PAN Biotech GmbH or the authorized local representative. Additional information is available on our website: www.pan-biotech.com

For technical support, questions or remarks please contact your local PAN-Biotech partner or the technical department of PAN-Biotech via email (info@pan-biotech.com).

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