Product Description

The in vitro cultivation of amniotic fluid cells and chorionic villi is an essential part of every diagnostic cytogenetics laboratory, since the preparation of metaphase chromosome spreads is dependent upon obtaining cells in division. Amniocentesis and chorionic villi sampling are the major invasive diagnostic procedures used for the detection of fetal chromosomal abnormalities. BIO-AMF™-1 Medium is specifically optimized for the primary culture of human amniotic fluid cells and chorionic villi samples used in prenatal diagnostic testing. The supplement is supplied frozen and contains serum.

Precaution and Disclaimer

- Do not use if a visible precipitate is observed in the medium.
- Use of Biological Industries BIO-AMF™-1 Medium does not guarantee the successful outcome of any prenatal diagnostic testing.
- Do not use BIO-AMF™-1 Medium beyond the expiration date indicated on the product label.

The product is prepared by an aseptic, strict, validated process in order to minimize as possible the risk for contamination and to ensure the safety and quality of the product. The membrane filtration and aseptic process is validated by media fill to ensure a safety level of 1 to 5000 bottles. Due to the residual risks of sample contamination, and the severity in such case, we recommend to establish parallel test systems as part of the procedure.

Storage and Stability

- Do not use BIO-AMF™-1 Medium beyond the expiration date indicated on the product label.
- The complete medium is stable for 14 days when stored at 2-8°C.
- Do not freeze the complete medium. Protect both the basal medium and the complete medium from light.

Instructions for Use

For the preparation of 500ml complete medium, use 01-190-1A with 01-192-1E. For the preparation of 100ml complete medium, use 01-190-1B with 01-192-1D. Thaw the BIO-AMF™-1 Supplement by swirling in a 37°C water bath, and aseptically transfer the contents to the bottle of BIO-AMF™-1 Basal Medium. Mix the complete medium by swirling the bottle, and add 2mM L-Glutamine (L-Glutamine Solution 200mM, Cat. No. 03-020-1). Antibiotics may be added if desired (Gentamicin, Cat. No. 03-035-1).
**Quality Control**

BIO-AMF™-1 Basal Medium and Supplement are tested for sterility, pH and osmolality. In addition, each batch is tested for cell growth using primary human amniotic fluid cells in a leading clinical cytogenetics laboratory. For full specifications please check the lot specific Certificate of Analysis (CoA).

**Quality Assurance**

- For in vitro diagnostic use. The medium is not intended for therapeutic use.
- Listed in Europe under CE IVD class I, thus comply with European In-Vitro Diagnostic Devices Directive (98/79/EC) requirements.
- Manufactured under ISO 13485 QMS and in compliance with applicable cGMP guidelines.
- Manufactured under controlled environments and processes in accordance with:
  - ISO 13408 – Aseptic Processing of Health Care Products;
  - ISO 14644 – Airborne Particulate Cleanliness Classes in Clean Rooms and Clean Zones;

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**Product Label Symbols**

- **REF** Indicates the manufacturer’s catalogue number so that the product can be identified.
- **LOT** Indicates the manufacturer’s batch code so that the batch or lot can be identified. Note: Synonyms for batch code are lot number and batch number.
- **E C** Indicates the date after which the product is not to be used.
- **Sterile** Indicates the temperature limits to which the product can be safely exposed.
- **I V D** Indicates a product that has been manufactured using accepted aseptic techniques.
- **I V D** Indicates that the product meets the requirements of the applicable EC directives.
- **I N F O** Indicates the need for the user to consult the instructions for use.