GIBCO™
Invitrogen Corporation

AMNIOMAX™ Product Information

AMNIOMAX C-100 and AMNIOMAX-II Complete

CAUTION: **Human origin materials are non-reactive (donor level) for anti-HIV 1 & 2, anti-HCV, and HB_sAg. Handle in accordance with established bio-safety practices.**

SUMMARY OF AMNIOMAX™ PRODUCT FEATURES

Product Features	*AMNIOMAX™ C-100* *Basal*	*Supplement*	*AMNIOMAX™-II Complete*
Catalog No.	17001 *450 mL* *90 mL* 27000-Kit	12556 *75 mL* *15 mL* 12558-011-Kit	11269 *100 mL*
Primary AFC Tested	+	+	+
Complete Medium	+ (Kit)	+ (Kit)	+
Antibiotic	-	Gentamicin	Gentamicin
Improved Buffering	-	-	+
Extended Stability (50 days unopened at 4°C)	-	-	+

Intended Use

GIBCO™ **AMNIOMAX** media are intended for use in *in vitro* diagnostic procedures which require the cultivation of human amniotic fluid cells. These products have been rigorously quality control tested by a leading U.S. clinical cytogenetic reference laboratory for this application (see Performance Testing).

Background

Successful prenatal diagnosis is dependent upon a variety of invasive and non-invasive techniques to both monitor fetal gestation and to detect fetal abnormalities or dysfunctions. Amniocentesis and chorionic villus sampling (CVS) constitute the major invasive diagnostic procedures used for clinical diagnosis and are used routinely today to detect underlying fetal chromosomal abnormalities[1-2], metabolic enzyme defects[3-8], and to conduct DNA analysis[9].

It was first recognized in the 1960's that amniotic fluid cells could be successfully cultured *in vitro.* The cytogenetic and biochemical composition of these cells were shown to adequately reflect fetal status and therefore this procedure could be utilized for prenatal diagnostic purposes[10]. This method requires the rapid *ex vivo* cultivation and karyotyping of these amniotic fluid-derived cells which represent a variety of different histotypes[11-14]. These cells have traditionally been propagated in either conventional cell culture medium supplemented with bovine serum or in specialized culture medium[15-17].

Product Description

AMNIOMAX products were developed specifically for the *in vitro* prenatal diagnostic testing of human amniotic fluid specimens and designed for ease of handling. Each formulation has been optimized by thorough performance testing on primary human amniotic fluid samples with attachment and growth promoting substances to minimize diagnostic turn-around time by maximizing colony attachment and growth. Every manufactured lot of product is similarly tested against rigorous standards to ensure necessary clinical performance.

AMNIOMAX complete media products are supplied, ready-to-use and already contain antibiotics, L-glutamine and FBS offering additional convenience to the end-user.

Precautions

FOR USE IN *IN VITRO* DIAGNOSTIC PROCEDURES REQUIRING THE CULTIVATION AND GROWTH OF HUMAN AMNIOTIC FLUID CELLS.

ADDITIONAL SUPPLEMENTATION TO **AMNIOMAX** PRODUCTS IS **NOT** RECOMMENDED. ADDITION OF Fungizone® MAY BE TOXIC.

Any concerns relating to product appearance should be directed to Technical Services.

DO NOT USE PRODUCTS IF:

1) PACKAGING APPEARS COMPROMISED
2) AMNIOMAX C-100 BASAL OR AMNIOMAX-II COMPLETE MEDIUM IS NOT AN ORANGISH-RED COLOR.
3) AMNIOMAX C-100 SUPPLEMENT OR AMNIOMAX-II COMPLETE IS RECEIVED THAWED.

Storage Conditions and Shelf-Life

AMNIOMAX C-100 - Store frozen supplement at -5 to -20°C, in the dark. Store liquid basal medium at 2 to 8°C, in the dark. Do not use beyond labeled expiration date.

AMNIOMAX-II Complete - Store frozen medium at -5 to -20°C, in the dark. AMNIOMAX-II Complete has an extended shelf-life of 50 days once thawed and stored unopened at 4°C. Do not use beyond labeled expiration date.

Refer to label for individual product expiration dates.

Instructions For Use

AMNIOMAX C-100 - When ready to use, **completely thaw frozen supplement at 4ºC and gently swirl to ensure a homogeneous liquid**. Aseptically transfer entire contents of supplement to AMNIOMAX C-100 basal and gently swirl to ensure a homogeneous complete medium.

AMNIOMAX-II Complete - **When ready to use, completely thaw frozen medium at 4ºC and gently swirl to ensure a homogeneous liquid**. **Thawing at 37ºC may result in precipitate formation and should be avoided.**

AMNIOMAX media products **-** Once opened, store complete media in the dark at 2 to 8°C and use within 7 to 10 days for maximal growth performance. Repeated warming/cooling and prolonged exposure to light should be avoided.

Since AMNIOMAX media products contain FBS, flocculent debris may develop upon thawing and storage.

Performance Testing

GIBCO **AMNIOMAX** products are extensively performance tested at the time of production. In addition to standard specifications such as pH, osmolality, bacterial and fungal checks, each manufactured lot is tested to confirm consistent biological performance. Quantitative growth assays using pooled primary human amniotic fluid cells are used to test biologic performance. Each manufactured lot is screened for amniotic cell growth by a leading clinical cytogenetic reference laboratory using an *in situ* growth assay. Product performance is compared to a reference standard. Please refer to Certificate of Analysis for further information.

Limitations

Each manufactured lot of **AMNIOMAX** media is thoroughly performance tested on primary amniotic fluid isolates to ensure product performance for *in vitro* diagnostic use for this application.

EACH CLINICIAN/SCIENTIST MUST MAKE AN INDEPENDENT JUDGEMENT ON WHETHER THIS MEDIUM IS SUITABLE FOR USE IN *IN VITRO* DIAGNOSTIC APPLICATIONS CONDUCTED IN THEIR LABORATORY. INVITROGEN CORP DOES NOT GUARANTEE THE SUCCESSFUL OUTCOME OF ANY DIAGNOSTIC TESTING BASED SOLELY ON THE USE OF GIBCO BRAND MEDIUM. INVITROGEN'S CONTRIBUTION TO THESE PROCEDURES IS SIMPLY AT THE STEP OF PROVIDING A CULTURE OR HANDLING MEDIUM FOR THESE PROCEDURES.

GIBCO cell culture liquid products are prepared by an aseptic process for which each step has been validated to ensure that all products meet the industry standard sterility assurance level of 10^{-3}; i.e., product that demonstrates a contamination level of no more than 1 of 1000 units during the manufacturing process. The highest level of sterility assurance (equal to or greater than 10^{-6}) cannot be achieved without terminal sterilization which is harmful to the performance of these cell culture products.

References

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For further information on this or other GIBCO™ products, contact Technical Services at the following:

United States TECH-LINE℠ : 1 800 955 6288
Canada TECH-LINE: 1 800 757 8257

Outside the U.S. and Canada, refer to the GIBCO products catalogue for the TECH-LINE in your region.

You may also contact your Invitrogen Sales Representative or our World Wide Web site at www.invitrogen.com.

For *in vitro* diagnostic use.
CAUTION: Not for human or animal therapeutic use.
Uses other than the labeled intended use may be a violation of local law.