

AmnioMAX(TM) - II Complete
+ Gentamicin Sulfate
+ L-Glutamine

Lot Number: 2277179
Item Number: 11269
Expiration Date: 2023-10
Storage Temp: -5 to -20C
Storage Instructions: Store in the dark

For In Vitro Diagnostic Use

TEST	TEST ID	SPECIFICATION	RESULT	UNITS
Colony Number Actual	CYTOGE0006	≥ 8.000	8.000	
Cytogenetic Performance Assay	CYTOGE0004	Acceptable	Acceptable	
HCV Antibody Screening	VIRUS0115	Non Reactive	Non Reactive	
Hepatitis B Surface Antigen Screening	VIRUS0113	Non Reactive	Non Reactive	
HIV 1 & 2 Antibody Screening	VIRUS0114	Non Reactive	Non Reactive	
Mitotic Colonies	CYTOGE0009	≥ 25.0	52.0	%
Osmolality	OSMO0002	280 - 335	310	mOsm/kg
pH	PH0003	7.2 - 7.6	7.3	
Sterility Testing	STERI0006	Negative	Negative	

Read SDS.

GIBCO BRL 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 1,000 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 cell culture products.

Notice: Effective 01/09/2014, the specification for this product has changed per CO#: 35341. Test specifications Colony Number Control and Mitotic Colonies Control have been removed and test specification Mitotic Colonies Actual has been replaced with Mitotic Colonies. If you have questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or Techsupport@lifetech.com globally.



Quality Systems Department

Date: 25-May-2022

References

- CYTOGE0006: Colony number actual: This number represents the mean value for colony number for the actual lot. This is a parameter assessed by Cytogenetic Performance Assay.
- CYTOGE0004: Testing is performed by a leading clinical cytogenetic reference laboratory. Each lot is tested utilizing a six (6) day in situ growth assay using pooled primary amniotic fluid cells. Each test is analyzed using 2 parameters: 1.) Mitotic Colonies and 2.) Colony Number. Detailed information is available as noted below.
- VIRUS0115: FDA Licensed / Approved blood screening tests.
- VIRUS0113: FDA Licensed / Approved blood screening tests.
- VIRUS0114: FDA Licensed / Approved blood screening tests.

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- CYTOGE0009: Mitotic colonies actual: This number represents the number of mitotic colonies expressed as a percentage of total Colony Number. This parameter is assessed by Cytogenetic Performance Assay.
 - OSMO0002: Thermo Fisher Scientific Specifications.
 - PH0003: Thermo Fisher Scientific Specifications.
 - STERI0006: Current edition of USP.