MDT 10-026CV

Mediatech, Inc.

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CERTIFICATE OF ANALYSIS

Description: **Improved MEM (Richter's Modification), 1X, with L-glutamine; without Phenol Red, Gentamycin and Proline, sterile**[1]

Cat #: 10-026-CV
Lot #: 10026005
Expiration Date: 01/02

MSDS: Available upon request

Shipping: Ambient

Storage: Store refrigerated at 2-8°C. Protect from light.

Stability: This liquid media has data supporting a shelf life of 12 months when properly stored. Avoid freezing of this media, as it may cause precipitation upon thawing.

Preparation: For addition of supplements (sera, antibiotics, growth factors), add the desired additives to the media just before use, and adjust pH. OPTIONAL: Sterile filter using a 0.2 micron filter (will reduce chances of contamination).

Mediatech is in compliance with FDA Guidelines for Class I Medical Devices, including the use of current Good Manufacturing Practices (cGMP), and with the revised FDA "Guideline for the Manufacture of *In Vitro* Diagnostic Products" (January 1994) for "Sterile" labeling. Products are prepared by an aseptic process for which each step has been validated to ensure that all Mediatech products are equal to or better than the industry's Sterility Assurance Level (SAL) of $\leq 10^{-3}$, i.e. demonstrates a manufacturing fill process of no more than 1 random contaminant per 1000 units. To ensure homogeneity, bulk products are "true-pooled" after filtration. ***Endotoxin levels are a "Release Specification", and not, as documented by others, "For Information Only".***

TEST PARAMETERS	SPECIFICATION	RESULT
Cell Line[2]		
EB-3	Pass	Pass
MRC-5	Pass	Pass
BHK-21	Pass	Pass
pH[3]	7.2 ± 0.2	7.1
Osmolality[4]	For Information Only	305 mOsm/Kg H_2O
Endotoxin[5]	≤ 0.25 EU/mL	<0.1 EU/mL
(at a 1:10 dilution)	≤ 0.025 ng/mL	<0.01 ng/mL
Mycoplasma[6]	Tested Negative	Negative
Sterility by USP XXIV[7]	Pass	Pass

1. FDA Guideline for the Manufacture of *In Vitro* Diagnostic Products (January 1994) for referencing sterile labeling practices for Class I medical devices.
2. Growth-promotion capability is analyzed by measuring the fold increase over multiple subculture generations of the appropriate cell line(s) according to predetermined standards (harvest to plant ratio) for rate of growth, density, atypical morphology, and evidence of cytotoxicity.
3. Measured with a standard pH meter. Meters are calibrated daily using standards traceable to the National Institute of Standards Technology (SOP Q10.011 using guidelines outlined in the current edition of USP).
4. Measured with a standardized osmometer, i.e. freezing point depressions. Meters are calibrated daily using standards traceable to the National Institute of Standards Technology (SOP Q06.030 using guidelines outlined in the current edition of USP).
5. Chromogenic LAL Assay using guidelines outlined by the manufacturer & FDA (December 1987), "Validation of the Limulus Amebocyte Lysate Test as an End Product Endotoxin Test for Human and Animal Parental Drugs, Biological Products, and Medical Devices" (SOP Q10.240).
6. Large volume method of Kern and Barile as per "Isolation of Mycoplasmas from Cell Culture by Agar and Broth Techniques," M.F. Barile and G.J. McGarrity in Methods in Mycoplasmology, Vol. 11.5. Razin and J.G. Tulley, eds., Academic Press, NY (1983) pp. 159-165 (SOP Q10.230).
7. Tested by the membrane filtration techniques in accordance with United States *Pharmacopeia* XXIV, Chapters [71] and [1211].

NOTE: This product is intended for *In Vitro* Diagnostic Use. Utilization of this product apart from the labeled intended use may be a violation of Federal law.

Approved: Mark Swanson 1/25/01
Quality Systems