www.cellgro.com

Mediatech, Inc.

# Certificate of Analysis

**Description:** **McCoy's 5A, 1X, sterile[1] with L-glutamine & 25mM HEPES**

**Cat #: 10-051-CI**
**Lot #: 10051028**
**Expiration Date: 10/13**

**MSDS:** **Available upon request**

**Shipping:** Ambient

**Storage:** Store refrigerated at **2-8°C**.

**Stability:** This product has data supporting a shelf life of **18** 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 "Guidelines 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 "For Information Only."***

---

| TEST PARAMETERS | SPECIFICATION | RESULT |
|---|---|---|
| Cell Line[2] | | |
| LM | Pass | Pass |
| PRK | Pass | Pass |
| NG-108 | Pass | Pass |
| Toxicity[3] | | |
| L929 | Pass | Pass |
| pH[4] | 7.2 ± 0.2 @ 20-25°C | 7.3 @ 22°C |
| Osmolality[5] | 305 ± 30 mOsm/Kg $H_2O$ | 310 mOsm/Kg $H_2O$ |
| Endotoxin[6] | ≤ 0.25 EU/mL | 0.0088 EU/mL |
| Mycoplasma[7] | Tested Negative | Negative |
| Sterility[8] | 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 of the media 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 and density. Finished medium is tested for cellular growth and the absence of cytotoxicity using guidelines outlined in the current edition of USP.
3. Testing to confirm media is not visibly toxic to cells following Q10.317.XX.009.
4. 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).
5. 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 Q06.033) using guidelines outlined in the current edition of USP).
6. 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 Parenteral Drugs, Biological Products, and medical Devices" (SOP Q10.241).
7. 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. 2 Razin and J.G. Tully, eds., Academic Press, NY (1983) pp. 159-165 (SOP Q10.230).
8. Tested by the membrane filtration techniques following SOP Q10.210.

NOTE: This product is intended for IVD, Manufacturing and Research Uses Only. Utilization of this product apart from the labeled intended use may be a violation of Federal Law.

Approved: 04 May 2012
Quality Systems

Verified By/Date: 07 MAY 2012

1.800.CELLGRO TOLL FREE
703.471.5955 LOCAL AREA
703.471.1086 FACSIMILE

9345 DISCOVERY BOULEVARD MANASSAS, VIRGINIA