EliteCell Biomedical Corp
Contact us: info@ecbiomed.com

# Certificate of Analysis



**Product:** EliteGro™-Lite
Cell Culture Supplement. For In-vitro Use. Not for Human or Animal Consumption.

**Country of Origin:**
**Storage Temperature:** -15 ℃ to -30 ℃

**Lot No.: NLRYMMXXX**
**Production Date:** YYYY-MM-DD
**Expiration Date:** YYYY-MM-DD

Manufactured by Biomedical EliteCell Corp.

## Lot Acceptance Criteria:

| Item | Specification | Result |
|---|---|---|
| Endotoxin USP <85> | < 5 EU/ml | < X EU/ml |
| Sterility USP <71> | No Growth | No Growth |
| Mycoplasma USP <63> | No Detected | No Detected |
| Total Protein USP <1057> | 2.0-4.0 g/dL | X.X g/dL |
| pH USP <791> | 6.5-8.5 | X.X |
| Osmolality USP <785> | 250-320 mOsm/Kg | XXX mOsm/Kg |
| Appearance[1] | Yellow to Buff liquid | Yellow to Buff liquid |
| Cell Growth Verification | Expansion of human Mesenchymal Stem Cells for ≥ 3 Passages | |

## Raw Material[2,3]:

| Item | Specification | Result |
|---|---|---|
| HIV-1 RNA | non-reactive | non-reactive |
| HCV RNA | non-reactive | non-reactive |
| HBV DNA | non-reactive | non-reactive |
| WNV-RNA | non-reactive | non-reactive |
| HBsAg | non-reactive | non-reactive |
| Anti-HIV I/II | negative | negative |
| Anti-HCV | negative | negative |
| Anti-HBc | negative | negative |
| Anti-HTLV-I/II | negative | negative |
| Serological Test for Syphilis | negative | negative |
| Trypanosoma cruzi | negative | negative |

1. Particulates will be observed after thawing. Particulate formation is normal will not affect performance. Filtration is not recommended.
2. All testing is performed on raw material donors by approved diagnostic tests for transfusable materials.
3. No additional virus inactivation/removal treatments are conducted in EliteGro™-Lite manufacture, users are suggested to assess the risk to their final product if intended for human use.

Signature of responsible person: _____ Date: _____
Director, Quality Assurance