EliteCell Biomedical Corp
Contact us: info@ecbiomed.com

# Certificate of Analysis



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

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

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

Manufactured by Biomedical EliteCell Corp. USA
206 Archway Dr., Woodway, Texas 76712

## 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> | 4.0-7.0 g/dL | X.X g/dL |
| pH USP <791> | 6.5-8.5 | X.X |
| Osmolality USP <785> | 280-355 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 FDA licensed/investigational tests for transfusable materials.
3. No additional virus inactivation/removal treatments are conducted in EliteGro™-Adv. 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