

RSV CLINICAL CHALLENGE STOCK: RSV MEMPHIS 37

RSV is the most important cause of pneumonia and bronchiolitis in infants and small children. Immunity to RSV does not prevent re-infection and current RSV control measures are inadequate with no RSV vaccine currently available. There is a critical need for the development of new vaccines and anti-viral therapeutics which can be enabled through the use of Meridian's RSV Memphis 37.

Product Description and Specifications:

Summary	cGMP manufactured Live Respiratory Syncytial Virus Challenge Stock (RSV Memphis 37): RSV Memphis 37 consists of an RSV high titer stock produced in characterized Vero cells infected with an RSV virus strain isolated from an original pediatric clinical sample.
Infectivity / Intended Use	RSV Memphis 37 has been used in two separate phase I clinical studies where it successfully generated a human infectivity model. When further propagated, RSV Memphis 37 can infect Mice and African Green Monkeys.
Clinical Utility	Vaccines: RSV Memphis 37 enables precisely controlled clinical studies to demonstrate protection (vs. implied protection via neutralizing Ab response). Patient sample size may be reduced, and protection demonstrated in vaccinated vs. placebo groups. Anti-viral Therapeutics: RSV Memphis 37 enables precisely controlled clinical studies to show therapeutic efficacy in eliminating or mitigating the effects of the disease in patients who have developed a controlled RSV infection as compared to control



Product Specifications:

Passage History*	RSV isolate was plaque purified and passaged 5 times in vero cells.
Infectivity	Titer > 1 x 10 ⁵ pfu/ml, by plaque assay in vero cells. Infectious in humans.
Volume / Storage	1mL per vial in 1.8mL cryovials. Store below -60°C.
Viral Bank Testing & Contaminants	Bank tested for identity, sterility, mycoplasma, viral contaminants, retroviruses, and source. No bacteria, fungus, or mycoplasma detected. No viral contaminants detected by cell culture and PCR analysis. Endotoxin < 10EU/ml.
Cell Bank Testing	Sterility, mycoplasma, adventitious agents by cell culture, <i>in vivo</i> adventitious agents, karyology, isoenzymes, bovine viruses, <i>in vitro</i> assay for porcine viral contaminants, and transmission electron microscopy.
Availability	RSV Memphis 37 is available for use in R&D studies or in minimum lot sizes for use in human clinical studies. Meridian is capable of generating higher titer, non-cGMP, R&D stocks for preclinical studies. For pricing, quantities, and additional information; contact Meridian Life Science, Inc.



Sales Terms and Conditions: Requires Material Transfer and Quality Agreements. Includes full document package: Cell Line Expansion, Accession Bank, Batch Record, COA's for Viral Bank and Cell Line. Includes rights for one human clinical trial. Additional rights available.

* Compared to NIH challenge virus: Passaged 27 times in 5 different cell lines. F.E.-H. Lee et al. / Antiviral Research 63 (2004) 191-196.

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