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Product-Data-Sheet for extracellular vesicles from ASC/TERT300

Version: February 2022

Evercyte Ord. No.:	EV-001-0300
Designation:	EVs from ASC/TERT300
Description:	EVs are produced by telomerized adipose-derived mesenchymal stem cells grown in a hollow fiber bioreactor and are enriched from cell culture supernatants using tangential flow filtration (TFF) under sterile conditions.
Biosafety Level:	1
Shipped:	Frozen on dry ice
Particle numbers:	5 x 10 ⁹ in 50 μl buffer (Cat# EV-001-0300-A2)
Storage medium:	20 mM HEPES
EV cell factory:	ASC/TERT300 (Evercyte, Cat# CHT-001-0300), BSL1 The cells have been tested negative for HIV, HepA, HepB, HepC and Parvo-B-19, do not show bacterial (incl. mycoplasma contaminations) and fungal contaminations and are authentic as demonstrated by STR profiling. Moreover, the cells express typical marker proteins of mesenchymal stem cells are can be differentiated towards adipocytes, chondrocytes and osteoblasts.
EV production system:	EVs are produced in a hollow fiber bioreactor system (FiberCell Systems) in MesenCult [™] -ACF Plus medium (STEMCELL TECHNOLOGIES, Cat# 05448).
EV enrichment:	EVs are enriched from cell culture supernatant using tangential flow filtration with a modified Polyethersulfone (mPES) membrane with a MWCO of 300 kDa.
Characteristics:	The particles have an average size of 100-200 nm (Nanoparticle Tracking Analysis, NTA) and the presence of typical markers of EVs such as CD9, CD81 and CD63 (multiplex flow cytometry). Additionally, the EVs show anti-Inflammatory and anti-fibrotic activity as demonstrated using in vitro bioassays. 1 x 10^9 particles correspond to 3700 µg protein (BCA assay).
Thawing and storage:	Upon arrival immediately transfer the product to -80°C. Store the product at -80°C for up to 6 months. Thaw the EVs on ice, centrifuge before opening the tube to ensure that the solution is collected at the bottom of the tube and mix carefully by pipetting up and down. In order to avoid multiple freeze / thaw cycles aliquot the solution and store aliquots at -80°C until use. After thawing, store the EVs at 4°C for a maximum of 1 day.

Quality control testing:

Cell culture supernatant enriched particles are negative for Mycoplasma contaminations as tested using MycoAlertTM Mycoplasma Detection Kit from Lonza and for bacterial and fungal contaminations as tested according to Ph- Eur. 2.6.1. / USP <71>.

The Endotoxin level is below 0.01 EU/ml as tested using LAL test according to Ph. ph. 2.6.14. / USP <85>.

Please Note:

The classification of biosafety level is based on Austrian Legislation (Gentechnikbuch; Systemverordnung) and on recommendations of the Central Committee on Biological Safety (ZKBS). While Evercyte undertakes all reasonable measures to test for absence of a selected panel of known human pathogenic viruses, there is currently no test procedure available that guarantees for complete absence of infectious pathogens. The use of state-of-the art infectious virus assays or viral antigen assays may leave open the possible existence of a latent viral genome, even if a negative test result is obtained. Therefore, we recommend that all human cell lines should be handled with caution such as an organism of ACDP Hazard Group 2. People who work with our cells must follow national regulations and safety precautions. The laboratories must be equipped with a security level according to the classification of the cells / products. Evercyte assumes no liability whatsoever in connection with the receipt, handling or the consequences of improper use of our products.

Notices and disclaimers: Evercyte products are intended for laboratory research purposes only. They are not intended for use in humans.

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