

Product Data Sheet for Extracellular Vesicles (EV) from BM- MSC/TERT292

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Phoenestra Order No.: PHOE0001

Description:	Extracellular Vesicles (EV) isolated from telomerized Bone Marrow Mesenchymal Stromal Cells (BM-MSC/TERT292)
Biosafety Level (BSL):	1
Shipment conditions:	Frozen on dry ice
Storage conditions:	-80°C (<-60°C)
Thawing conditions:	Thaw on ice or in refrigerator (2-8°C); avoid repeated freeze/thaws Avoid prolonged hold times at room temperature and light exposure
Storage buffer:	20 mM HEPES, pH7.2, 100 mM NaCl
Cell line:	BM-MSC/TERT292 (Human telomerized Mesenchymal Stromal Cells)
Tissues Source:	Human Bone Marrow
Cell cultivation and EV production:	EVscale™ proprietary Agitated Packed Bed process in Perfusion mode (adherent). Culture supernatants are harvested at certain timepoint and tested for extracellular particle (EP) numbers. Supernatants are further processed by ultra-/diafiltration (UFDF) which is used as a synonym for Tangential Flow Filtration (TFF). Further processing details are available upon request.
Quality Control (Cells)	Cell vials are taken from a released R&D cell bank and cultivated in 2D before inoculation of the EVscale™ bioreactor system. MSC/TERT cells are checked for cell number and viability as well as typical MSC surface markers (CD73, CD90, CD105) and a negative marker (CD34). At the end of the cultivation run, cells are again checked for viability and marker expression.
Quality Control (EV)	See respective CoA
Expiry Date	See respective proposal
Extended characterization data (EV)	Bioassay data, small RNA sequencing and marker protein panels are available upon request
Bioburden	0.2 µm filtered
Virus Testing	Cells have been tested negative for HAV and Parvo B19 with Roche DPX-PCR (cobas® TaqScreen DPX-Test), for HBV, HCV, HIV nucleic acids with Roche-Multiplex-PCR (cobas® TaqScreen MPX Test, v2.0). The negative testing results justify a classification of the production cell line and the product(s) isolated from culture supernatants (without dedicated virus inactivation or removal) as BSL 1. Nevertheless, these EV preparations are derived from cultivations of human cells which always hold the potential of contamination with viruses or other potentially pathogenic species. These samples should therefore be handled with the usual precautions regarding safety or waste inactivation/disposal when working in / with cell culture products (BSL 2 or any national/local equivalent).

Please note

People who work with our products must follow national regulations and safety precautions. The laboratories must be equipped with a security level according to the classification of the products. Phoenestra assumes no liability whatsoever in connection with the receipt, handling or the consequences of improper use of our products. Notices and disclaimers: these Phoenestra products are intended for laboratory research purposes only. **They are not intended for use in humans.**

Handling Recommendations

Storage

- 1.) The samples are shipped on dry ice. Upon arrival, transfer the aliquots to a -80°C freezer.
- 2.) Maintain a freezer organization level that enables localization of the samples within seconds. Preferably store small aliquots in respective boxes.
- 3.) Avoid temperature fluctuations during storage.

Thawing

- 1.) Thaw samples gently at 2-8°C in a rack in the refrigerator. Avoid too big temperature shocks, while thawing.

Handling

- 1.) Work aseptically to avoid contamination.
- 2.) Use the sample immediately after thawing, at least on the same day. Prolonged hold times may compromise its quality.
- 3.) Perform dilutions with cold buffer (2-8°C).
- 4.) Alternatively, sample preparation and dilutions can also be done at room temperature (RT), hold times at RT should be minimized.
- 5.) Use low-binding, DNase-, RNase- and pyrogen-free tubes for dilutions.
- 6.) In case of extended waiting times (>30 minutes), store the sample in the refrigerator (2-8°C) and protected from light until further use.
- 7.) Avoid freeze-thaw cycles.