
Exosome/EV Isolation Kit

Instruction for Use (IFU)

[Product Name]

Generic name: Exosome/EV Isolation Kit

[Specifications]

Specification 1:	Chromatographic column - Standard	1 × 9
	Elution buffer (4×)	1 × 100 mL
	Equilibration buffer (3×)	2 × 120 mL
Specification 2:	Chromatographic column - Standard	1 × 9
	Elution buffer (10×)	2 × 100 mL
	Equilibration buffer (25×)	1 × 80 mL
Specification 3:	Chromatographic column - Standard	1 × 9
	Elution buffer (8×)	2 × 120 mL
	Equilibration buffer (20×)	1 × 100 mL

[Intended Use]

Exosome/EV Isolation Kit is intended for use to separate and isolate extracellular vesicles from samples such as serum, plasma, and conditioned medium.

Exosomes/EV, as carriers of intercellular communication, play a role in a variety of pathological and physiological processes, including tumor development, inflammatory reactions, tissue repair, etc. This product helps obtain extracellular vesicles that can be used to study these pathological and physiological processes from clinical samples using an efficient separation technology.

[Intended User]

The kit is intended to be used by the laboratory professional.

[Test Principle]

This product is designed to isolate and purify extracellular vesicles through agarose gel with a specific pore size using the size exclusion chromatography (SEC) principle.

[Storage Conditions and Shelf Life]

The kit can be stored at 2°C ~ 30°C for 12 months.

Please see the outer package for the production date, shelf life and expiry date.

[Applicable Instrument]

Exosome/EV Automated Isolation Platform: ExoFaster-500.

[Sample Requirements]

Serum and plasma samples can be stored at 2°C ~ 8°C for 3 days and at ≤-70°C for 1 month. Repeated freezing and thawing should be avoided. In case of any obvious precipitation, the samples should be centrifuged to take the supernatant. Samples containing high-concentration lipids or proteins should be avoided.

[Test Method]

Separation process of extracellular vesicles by chromatographic column:

1. The kit should be equilibrated to room temperature in advance (placed for at least 30 min).
2. Before the experiment, it is necessary to dilute the elution buffer and equilibration buffer with purified water according to the marked concentration ratio to obtain the applied elution buffer and equilibration buffer.

3. The applied elution buffer and equilibration buffer should be put into the designated positions in the instrument and tubes should be connected.
4. The centrifuge tube with the cap unlocked should be put in the designated position in the collection plate of the instrument.
5. The column tray number should be selected, and the "Isolate" button should be clicked to initiate the isolation process.
6. The top cap, top cover and rotary bottom cover of the chromatographic column should be removed in turn, and then the chromatographic column should be put in the designated position in the column tray of the instrument.
7. When a sample addition prompt appears on the main interface of the instrument, add a sample volume between 200 μL and 1.5 mL. For serum or plasma samples, the maximum volume is 1 mL. If the sample volume is less than 200 μL , add Elution Buffer to reach a total volume of 200 μL .
8. The instrument will automatically isolate and collect the extracellular vesicles in a centrifuge tube.
9. When a column removal prompt appears on the main interface of the instrument, remove the chromatographic column and sequentially close the rotary bottom cover, top cover, and top cap.

Cleaning process of chromatographic column (for Specification 2 and Specification 3):

1. Prepare 1000 mL 40mM sodium hydroxide solution and 1000 mL 20% ethanol solution as washing buffer and blocking buffer respectively.
2. Place the washing buffer and blocking buffer in the designated positions of the instrument and connect the tubes.
3. The column tray number should be selected, and the "Wash" button should be clicked to start the cleaning process.
4. The top cap, top cover and rotary bottom cover of the chromatographic column should be removed in turn, and then the chromatographic column should be put in the designated position in the column tray of the instrument.
5. The instrument will automatically perform subsequent cleaning steps. The column will be saved for future use. After the instrument completes the cleaning process, remove the chromatographic column and sequentially close the rotary bottom cover, top cover, and top cap. Save for future use.

[Product Performance Indicators]

1. Appearance: The structure of the chromatographic column should remain intact without any damage. The elution buffer and equilibration buffer should be clear and transparent without precipitation, suspended matters, or floccules.
2. Volume: The filling height in the chromatographic column should be 5.5 ± 0.3 cm. The volumes of elution buffer and equilibration buffer should be no less than the labeled volumes.
3. pH: The pH value should be 7.2 ± 0.2 for the elution buffer and 6.5 ± 0.2 for the equilibration buffer.
4. Flow rate: The flow rate should be within the range of 0.6 mL/min to 1 mL/min.

[Precautions]

1. For Specification 1, each chromatographic column can be used only once. For Specification 2 and Specification 3, each chromatographic column can be cleaned 4 times and used 5 times. The column must be placed vertically and should not be inverted or laid horizontally. Please check the appearance of the chromatographic column before use. It is not

recommended to continue to use a chromatographic column with any obvious crack in the filler layer, if any.

2. Due to the high concentration of the equilibration buffer and elution buffer, crystallization is highly prone to occur during storage. Before use, please check for any crystallization. If present, allow the buffer to stand at 37°C for 30 minutes, gently shaking during this time to ensure complete dissolution. The buffer may only be used after cooling to room temperature.

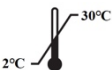
3. Do not freeze the chromatographic column.

4. The kit is intended for research use only. Please use the kit within the shelf life.

5. Please avoid strenuous vibration or pressure during use.

6. Used chromatographic columns may be potential sources of infection and must be handled in accordance with local laws and regulations.

[Symbol Definition]

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Batch Code		Use-by date		Date of manufacture
	Consult instructions for use		Manufacturer		Temperature limit (2-30°C)
	Catalogue Number		This way up		

[Basic Information]

Name of registrant/production enterprise: Shanghai Upper Bio-tech Co., Ltd

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