ClearLine	Technical data sheet	Ref : 509096
		Version date : 04/07/2022

Lymphosep, Lymphocyte Separation Media

Code IUD-ID :

Code article	Conditionnement	Code IUD-ID
L0560-100	100 ml	03770026925003
L0560-500	500 ml	03770026925010

Storage conditions: Room temperature, protected from light

Shelf life: 24 months

Composition: Displayed on website and also available on request

Colour: translucent, slightly yellowish

pH: 7.0 ± 0.5

Osmolality: 300 ± 20 mOsm/kg

Endotoxin: < 10 EU/ml

Sterility tests:
- bacteria in aerobic and anaerobic conditions
- fungi and yeast

Cell Growth test: Not applicable

Other test:
Density: 1.077 ± 0.001

Recommended use:
- Respect storage conditions of the product
- Do not use the product after its expiry date
- Store product in an area protected from light
- Manipulate the product in aseptic conditions (e.g. : under laminar air flow)
- Wear clothes adapted to the manipulation of the product to avoid contamination (e.g. : gloves, mask, hygiene cap, overall…)
- Lymphosep can be used until 7 days after opening. Bottle must be closed after each use.

The product is intended to be used for in vitro diagnostic and scientific purposes. Do not use it in therapy, human or veterinary applications.

DOMINIQUE DUTSCHER SAS

Manufacturer contacts :
Biowest – Rue de la Caille – 49340 Nuaillé – France
Tel : +33(0)2 41 46 42 42
Website : https://www.biowest.net/

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Applications:
Lymphosep is designed for the simple, rapid isolation of lymphocytes from whole blood that has been diluted and treated with anti-coagulant or defibrinating agent.
For best results, use blood drawn less than 2 hours before. Do not use blood more than 24 hours from when it was drawn.

Uses:
1) Thoroughly mix the Lymphosep by inverting the bottle gently.
2) Aseptically transfer 3 ml of Lymphosep to a 15 ml centrifuge tube.
3) Mix 2 ml of defibrinated or heparined blood with 2 ml of physiological saline (PBS w/o Ca w/o Mg) or balanced salt solution (L0615).
4) Carefully layer the diluted blood over 3 ml of Lymphosep (room temperature) in the 15 ml centrifuge tube, creating a sharp blood-Lymphosep interphase. DO NOT MIX! The quality of the separation is dependent upon a sharp interphase between the lymphocytes and the solution.
5) Centrifuge the tube at 400G at room temperature for 15 to 30 minutes. Centrifugation should sediment erythrocytes and polynuclear leukocytes and band mononuclear lymphocytes above the Lymphosep.
6) Aspirate the top layer of clear plasma to within 2-3 mm above the lymphocyte layer.
7) Aspirate the lymphocyte layer plus about half of the Lymphosep layer below it and transfer it to a centrifuge tube. Add an equal volume of buffered balanced salt solution to the lymphocyte layer in the centrifuge tube and centrifuge for 10 minutes at room temperature (18°C to 25°C) at a speed sufficient to sediment the cells without damage i.e., 160-260 g. Washing the cells removes Lymphosep and reduces the percentage of platelets.
8) Wash the cells again with buffered balanced salt solution (L0615) and resuspend in the appropriate medium for your applications.

Signs of Deterioration:
Medium should be clear and free of particulate and flocculent material. Do not use if medium is cloudy or contains precipitate.
Other evidence of deterioration may include colour change or degradation of physical or performance characteristics.

Product elimination after use:
Empty bottles of Lymphosep must be rinsed before being eliminated with plastic waste.
If bottles still contain Lymphosep, they must be incinerated in an approved facility.

Procedure for management of damaged product:
In case of damage on product integrity (leaking bottle, contamination…), the product must not be use and must be destroyed by incineration in an approved facility according applicable laws where user is located.

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Remarks:
- CAUTION : the product is not for human or animal therapeutic use. Uses other than the intended use may be a violation of local law.
- Each laboratory must carry out their own testing procedures on new media according to national legislation prior to releasing them to the lab for routine in vitro applications.
- Each clinician/scientist must make an independent judgment on whether this medium is suitable for use in in vitro diagnostic applications conducted in their laboratory.
- Biowest does not guarantee the successful outcome of any diagnostic testing based solely on the use of Biowest brand medium.
- Every serious incident linked to the Lymphosep device must immediately be notified to Biowest, its distributor (if any) and competent authority of member state where user is located.

CE marked:
Lymphosep is a CE marked qualitative medical device for IVD which fulfils the requirements of Regulation 2017/746.

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