Serum free cell culture medium for use in the preparation and isolation of purified lymphocytes directly from whole blood

PACKAGE INSERT

For In Vitro Diagnostic Use

500 mL bottles (product code: A18398DJ / AV.200/500)
50 mL bottles (product code: A18398SA / AV.200/50)
Instructional Information

Intended Use

AIM-V® serum free cell culture medium is intended for use in the preparation of peripheral blood mononuclear cells (PBMCs) from whole blood and for use as a culture medium for in vitro testing using the ELISPOT method.

Principle of Use

PBMCs, separated from whole blood samples, are washed with AIM-V medium and the cell pellet is re-suspended in the medium. The cells are counted using a haemocytometer or automated cell counter before being diluted to the required concentration in AIM-V. The AIM-V medium is provided as a 500 mL or 50 mL bottle.

Warnings and Precautions

1. For In vitro diagnostic use only.
2. For professional use only; operators must be trained in this procedure.
3. Blood samples should be considered as potentially hazardous. Care should be taken when handling material of human origin.
4. Handling of whole blood samples and assay components, during use, storage and disposal should be in accordance with procedures defined in appropriate national biohazard safety guidelines or regulations.
5. Any deviation from recommended procedures for pipetting, washing techniques, centrifugation times and/or temperatures may alter the purity of PBMC isolations and influence subsequent test results.
6. Do not use beyond expiration date.
7. Use aseptic techniques when using this product.
8. Do not store AIM-V in direct light.
9. Do not use if the AIM-V bottle is damaged or if the medium has a yellow colouration or particulate matter in the solution.

Materials Provided

1 x bottle of AIM-V cell culture medium (either 500 mL or 50 mL).

Storage and Stability

Store at 2-8 °C unopened until the expiration date shown on the bottle. Use within 31 days of opening the bottle, or before the expiration date on the bottle, whichever is earlier.

Equipment and Materials Required but not Provided

1. 15 mL centrifuge tubes.
2. A centrifuge for the fractionation of PBMCs capable of at least 1000 RCF (g) and able to maintain the samples at ambient room temperature (18-25 °C).
3. Biosafety Level 2 (BL 2) cabinet (recommended).
4. Pipettes and sterile pipette tips.
Procedure

Note: The following steps should be performed using the principles of Good Laboratory Practice:

1. Ensure that the AIM-V is warmed to 37 °C prior to use.
2. Isolate PBMC fraction from whole blood using polysucrose-based density gradient centrifugation or an alternative PBMC isolation method.
3. Aspirate the cloudy PBMC layer after cell separation, and make up to ~10 mL with AIM-V in a 15 mL centrifuge tube. Invert the centrifuge tube to mix.
4. Centrifuge at 600 x g for 7 minutes. Discard the supernatant.
5. Resuspend the cell pellet with AIM-V make up to ~10 mL with AIM-V and centrifuge at 350 x g for a further 7 minutes.
6. Discard the supernatant and resuspend the cell pellet in 0.7 mL AIM-V for cell counting.
7. Prepare an appropriate dilution of PBMCs in AIM-V, as required by the ELISPOT assay. For example, the T-SPOT.TB test protocol requires 250,000 cells per well with 4 wells for each test.

Quality Control

AIM-V serum free cell culture medium was evaluated for use with the ELISPOT method during the design and development of the T-SPOT.TB test. Experimental reports demonstrate that the use of the medium has no detrimental effect on the viability or functionality of T cells when used in the test. Refer to the T-SPOT.TB test ‘Instructions for Use’ for further information.
Glossary of symbols

- Use by/Expiration date (Year-Month-Day)
- Lot number
- Catalogue number
- Attention, see instructions for use
- Manufacturer
- Sufficient for “n” tests
- In vitro diagnostic device
- Temperature limitation/Store between
- Consult instructions for use
- Processed using aseptic techniques
- Keep away from sunlight
- EU Authorised Representative

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