

# LymphoSure

## Intended Use

LymphoSure is a preparation of stabilized human peripheral blood which is used as a reference control in flow cytometry. It is intended for *in vitro* diagnostic use only.

## Precautions

All human source material used in the manufacture of this product has been screened non-reactive for antibodies to Syphilis, Hepatitis B and HIV1/HIV2. The product should nevertheless be handled using standard safety precautions and should be disposed of in line with appropriate biological waste management procedures.

## Storage and Stability

LymphoSure is guaranteed to be stable until the expiry date indicated, provided the correct storage procedures have been followed. The product should be stored at the recommended temperature range of between 2°C and 8°C. DO NOT FREEZE.

## Guarantee

In the unlikely event that the product degenerates before its expiry date (poor scatter properties or poor staining of the cells), it will be replaced by Synexa Life Sciences free of charge within 5 working days. Please contact Synexa on +27-21-9339580 and quote the Lot Number shown on this insert.

## Instructions for Use

- Remove the vial from the packaging and note the corresponding reference ranges.
- Ensure homogenous mixing by inverting the tube gently several times (DO NOT VORTEX).
- Use the recommended volume of monoclonal antibody mixture and add 50  $\mu$ L of LymphoSure to the tube.
- Incubate at room temperature for 15 minutes.
- Add the recommended volume of RBC lysis buffer and analyze within 20 minutes of preparation.
- Analyze by flow cytometry in the same manner as a patient sample.
- FDA guidelines (Bioanalytical Method Validation, May 2001) advise the use of two levels of control (low and normal) with every batch of patient samples analyzed.