

CytoFix™

Cellular Controls for Flow Cytometry

CytoFix™ CD4+ Controls

Intended Use

CytoFix™ CD4+ controls are a stabilized preparation of whole human blood for use as a positive control when evaluating CD4+ enumeration procedures.

Summary / Principles

CD4+ enumeration by flow cytometry provides a rapid and accurate assessment of the frequency of CD4+ T-cells present in human blood. Quantitation of CD4+ has been shown to be useful in the evaluation of immunodeficiency. CytoFix™ CD4+ controls possess surface antigens that are detectable with monoclonal antibodies.

Subsets of leukocytes can be distinguished on the basis of light scatter properties as well as the presence of surface antigens. CytoFix™ CD4+ controls are designed to represent normal peripheral blood leukocytes where lymphocytes, monocytes and granulocytes are distinguishable on the basis of light scatter properties on a flow cytometer

Reagents

CytoFix™ CD4+ whole blood controls contain stabilized human lymphocytes.

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|-------|----------|------------|--------|
| CF04N | CytoFix™ | CD4 normal | 1.5 mL |
| CF04L | CytoFix™ | CD4 low | 1.5 mL |

Quality control analysis is performed on a BD FACs Calibur with BD MultiTest™ reagents and Trucount™ tubes using the no wash method. A detailed QC statement is provided with all products.

Statements of warnings

1. For In Vitro Diagnostic use only
2. All human source material used to manufacture this product was non reactive for hepatitis B, negative for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), HIV-1 RNA and HCV RNA. As no known test method can assure

complete absence of human pathogens, this product should be treated with the appropriate precautions.

3. This product should not be disposed of in general waste, but should be disposed of with infectious medical waste. Disposal by incineration is recommended.
4. This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product vial invalidates any diagnostic use of the product.
5. CytoFix™ controls should not be used as a calibrator.
6. Do not use the reagent beyond the expiration date printed on the label.
7. Use Good Laboratory Practices (GLP) when handling this reagent

Storage & Stability

CytoFix™ CD4⁺ controls are stable for a maximum of 90 days when unopened and stored at 4-10°C or to the expiration date shown on the label. Opened vials are stable for 30 days from the date of opening when stored at 4-10°C.

Indications of Product Deterioration

If leukocyte sub set values are not within the expected range as shown on the batch assay sheet, or granulocytes show a loss of forward scatter.

1. Review the operating procedures of the instrument
2. Assay an un-opened vial of CytoFix™ CD4⁺ control
3. Clumping of the cell suspension indicates instability or deterioration, in which case the reagent should not be used.

Instructions for Use

1. Remove the product from the refrigerator and warm to room temperature (18-30°C) for 15 minutes before use.
2. To Mix:
 - a. Mix by repeated inversion for 30 seconds to ensure the cells are suspended before use.
 - b. Vials stored for an extended period may require additional mixing
3. After use, return to the refrigerator to ensure maximum open vial stability
4. Analyze for flow cytometry in the same manner as for patient samples

Procedures

1. Flow Cytometer – follow the manufacturers instructions for instrument set up and calibration
2. Antibodies – Use monoclonal antibodies according to the manufacturers instructions
3. RBC lysis – Use RBC lysis reagent according to the manufacturers instructions

Ordering Information

You can order direct from Cytomark or from affiliated distributors. Please refer to our web site www.cytomark.com for contact details of your local distributor. If a distributor is not listed for your country please contact Cytomark direct.

Call +44 (0)280 827469, fax +44 (0)1280 827466 or email sales@cytomark.co.uk

Citations

An extensive list of citations are available on the Cytomark web site www.cytomark.co.uk