



CYTOMARK

Blood Controls

Cellular Controls for Flow Cytometry

CD4 Blood Controls

Instructions for Use

RUO



Product Description

Cytomark CD4 Blood Controls are stabilised preparations of human leukocytes for use as complete process controls when enumerating CD4+ T cells in human blood samples.

Two CD4 Blood Controls are available: a CD4 Normal Blood Control that contains CD4+ T cells in the normal range (410-1590 cells/ μ l) and a CD4 Low Blood Control that contains CD4+ T cells in a low range (200-300 cells/ μ l). Quality control analysis is performed on a BD FACSCalibur with Cytognos reagents in combination with Perfect Count Microspheres using the lyse, no wash method. A detailed QC statement with lot-specific ranges for lymphocyte counts is provided in the Certificate of Analysis with this product.

Principle and Intended Use of CD4 Blood Controls

Cytomark Blood Controls are manufactured using our patented CytoFix technology which stabilises leukocytic antigens for up to 3 months.

Cytomark Blood Controls are commonly used for flow cytometric analysis:

- To verify the use of reagents such as conjugated monoclonal antibodies and red blood cell lysis solutions.
- To validate the performance of the instrument.
- To validate operator technique.

CD4 Blood Controls are controls designed to contain normal (CD4 Normal Blood Control) and low (CD4 Low Blood Control) levels of CD4+ T cells in whole blood, that include lymphocytes, monocytes and granulocytes.

Procedure

1. Remove the CD4 Blood Control from 2-8°C storage and incubate at room temperature (18-25°C) for 15 minutes before use.
2. Mix gently by inversion for 30 seconds to ensure the cells are suspended. Do not vortex.
3. Analyse, e.g. on a flow cytometer.
N.B. Ensure that the manufacturer's instructions are followed when using the flow cytometer and related reagents.
4. After use, return to 2-8°C storage to ensure maximum open vial stability.
N.B. If leukocyte sub set values are not within the expected range, as shown on the Certificate of Analysis for the batch:
 - **Review the operating procedures of the instrument.**
 - **Assay an un-opened vial of the CD4 Blood Control.**
 - **Assess the antibody conjugates used in the panel. Cross linking of proteins may occur when using CD4 Blood Controls. We therefore recommend that all antibody conjugates are validated prior to routine use. Samples of CD4 Blood Controls are available on request.**

Ordering Information

| Product Code | Product | Quantity |
|--------------|--------------------------------------|-----------|
| CF04-N | CD4 Normal Blood Control | 1.5ml |
| CF04-L | CD4 Low Blood Control | 1.5ml |
| CF04-Duo | CD4 Low and Normal Blood Control Set | 2 x 1.5ml |
| CF04-N-S | CD4 Normal Blood Control | 0.5ml |
| CF04-L-S | CD4 Low Blood Control | 0.5ml |
| CF04-Duo-S | CD4 Low and Normal Blood Control Set | 2 x 0.5ml |

Storage Conditions and Stability

CD4 Blood Controls are stable for 3 months from the date of manufacture when stored at 2-8°C. Open vial stability is one month. **Vials must not be frozen.** A certificate of analysis can be provided with every CD4 Blood Controls product.

Warning Statements

1. CD4 Blood Controls are for research use only.
2. This product is for use as indicated and should not be used as a calibrator. Alteration by dilution or addition of any materials to the product invalidates the use of the product.
3. Do not use CD4 Blood Controls beyond the expiration date on the box and vials.
4. Incubation times or temperatures other than those specified may give erroneous results.
5. Clumping of the cell suspension indicates instability or deterioration, in which case the CD4 Blood Controls should not be used.
6. Use good laboratory practice (GLP) when handling this product.
7. 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. However, this product should be handled as if capable of transferring infection and disposed of with the proper precautions. Disposal by incineration is recommended.
8. Avoid contact of CD4 Blood Controls with the skin and mucous membranes. Any contact should be washed off with cold water immediately.

Cytomark is a division of Caltag Medsystems Ltd, a company registered in the UK, company number 4162330.






Caltag Medsystems Ltd
Whiteleaf Business Centre
11 Little Balmer
Buckingham
MK18 1TF
UK

Tel: +44 (0) 1280 827460
Fax: +44 (0) 1280 827466

Email: cytomark@caltagmedsystems.co.uk



www.cytomark.co.uk

| Language | RUO | REF | LOT |  |  |  |  |  |
|----------|--------------------------------|-----------------|------------------|---|---|---|---|---|
| US | Research use only | Code No. | Lot | Exp. Date | Store | Biological risks | Consult instructions for use | Manufacturer |
| GB | Research use only | Cat. No. | Lot | Exp. Date | Storage | Biological risks | Consult instructions for use | Manufacturer |
| D | Forschung verwenden Sie nur | Kat. Nr. | Ch-B | Verw. bis | Lagerung | Biogefährdung | Beachten Sie die Gebrauchsanleitung | Hersteller |
| F | Recherche uniquement | Reference | N° de Lot | Date de peremption | Stockage | Risques biologiques | Suivre les instructions d'utilisation | Fabricant |
| ES | La investigación solo utilizan | No. De. Cat. | Nº Lot | Caducidad | Almacenaje | Riesgos biológicos | Consultar las instrucciones de uso | Fabricante |
| PT | Uso da pesquisa somente | Referencia | Nº De Lot | Validade | Armazenar | Riscos biológicos | Consulte instruções de utilização | Fabricante |
| I | Utilizzare solo la ricerca | Codice | Lotto N° | Scadenza | Conservare | Rischi biologici | Vedere le istruzioni per l'uso | Fabbricante |
| GR | Έρευνα χρησιμοποιούν μόνο | Κωδικός Αριθμός | Αριθμός Πρωτίδος | Ημερομηνία Αιτίας | Αποθήκευση | Βιολογικοί κίνδυνοι | Συμβουλευτείτε τις οδηγίες χρήσης | Κατασκευαστής |
| PL | Badania używać tylko | Nr Katalogowy | Lot | Termin Waznosci | Przechowywanie | Zagrożenie biologiczne | Odwolaj się do instrukcji obsługi | Producent |
| CZ | Výzkum používejte pouze | Kód | Šarže | Expirace | Skladování | Biologická rizika | Nahledněte do návodu k použití | Výrobce |