

FOETAL CONTROL KIT

CATALOGUE NO: FT100

DESCRIPTION: Foetal Control Kit contains tri level, assayed human whole blood solutions designed to optimise instrument settings and monitor values obtained from the flow cytometric investigation of human adult whole blood for the presence of foetal red blood cells (RBCs). This Control Kit is suitable for use with the CHEMICON range of reagents for investigation of foetomaternal haemorrhage.

PRODUCT FORMAT: Foetal Control Kit comprises of 3 separate solutions of stabilised human adult Rh D negative red blood cells supplemented with foetal Rh D positive RBCs. The three levels provided represent no foetal cells (Standard 1), low (Standard 2) and high levels (Standard 3) of Rh D positive foetal cells.

Complementary products to be used with this kit are :

- i) Quanti-D™, monoclonal antibody specific to Rh D antigen (Cat No. MAB3434H)
- ii) HbF FITC, monoclonal antibody to foetal haemoglobin FITC conjugated (Cat No. MAB3433F) and
- iii) Com-DF, the unique dual staining reagent to RhD and HbF (Cat No. MAB3435F).

PURITY AND STERILITY: Product is supplied non sterile.

WARNING: Donor units from which this material was sourced were tested and found negative for Hepatitis B surface antigen and Hepatitis C and antibodies to HIV. However, no test offers complete accuracy, and these materials should be handled as if capable of transmitting disease.

STORAGE AND STABILITY: Store at 2-8°C ensuring vials are upright. Unopened vials are stable until the expiration date. Open vials are stable for 25 thermal cycles (uses) when handled correctly. A thermal cycle constitutes performing all steps as described in the following Protocols section below. Avoid prolonged periods at temperatures >30°C. DO NOT FREEZE.

The supernatant solution should be straw colored to light pink. Discoloration of the supernatant fluid due to haemolysis may be caused by excessive heat or freezing and may indicate product deterioration. Inability to recover expected values may also be indicative of product deterioration. Incomplete mixing, instrument malfunction, or defective stains are other potential sources of unacceptable results. Do not use this product if deterioration is suspected.

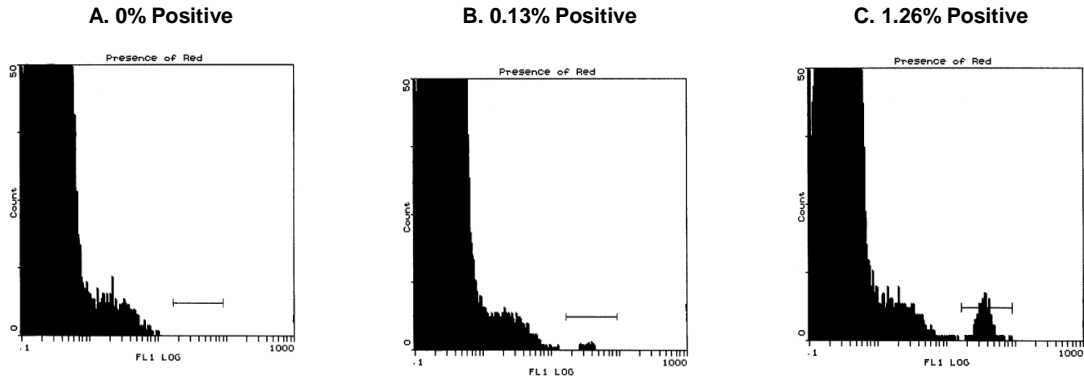
APPLICATIONS: The Kit is intended for use as control material for the flow cytometric investigation of human adult whole blood for the presence of foetal RBCs. Each laboratory should establish a mean and acceptable range for each lot of control material. The laboratory mean should fall within the listed Mean Range. Laboratories may consider results acceptable when at least 95% of test results are within the laboratory's expected range. Please refer to the Certificate of Analysis for expected ranges of each standard.

PROTOCOLS:

1. Allow vial to warm at ambient temperature for 10 minutes. DO NOT mix during this time.
2. To mix the contents of each vial, roll each vial between the palms of each hand 20 times. Gently invert 10 times, caring not to shake. Continue to mix in this manner until the contents are resuspended. DO NOT SHAKE THE VIAL OR USE A MECHANICAL MIXER.
3. Immediately prior to sampling, gently invert the vial 10 times. Pipette the required volume of sample from the vial and proceed according to your laboratory's established procedure for the detection of foetal RBCs in patient samples. To

guarantee accuracy of sampling it is recommended that a minimum of 10 μ L be taken per use.

4. Following sampling carefully wipe the rim of the vial and the interior of the cap with a lint free tissue. Replace the cap, ensuring a tight seal.
5. Return the vials to the refrigerator within 30 minutes of use.



Fluorescence intensity histogram plots of FITC conjugated anti HbF using Foetal Control Kit. The vertical axes have been scaled so that the HbF positive populations can be visualised.

WARNINGS AND PRECAUTIONS

Correct storage and use of this product as indicated is required for optimal performance. Incomplete mixing of the vial prior to use invalidates both the sample that is withdrawn and the remainder of the contents of that vial.

WARRANTY:

The highest standards of quality control are used in the manufacture of all CHEMICON Australia products. CHEMICON Australia will not be liable for any incidental, consequential or contingent damages arising from the use of the product.

No warranty is provided that the sale or use of this product either alone, in combination with other products, or in the operation of any process, will not infringe patent, intellectual property or any other rights of third parties.

REFERENCES:

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2. Nance SJ, Nelson JM, Arndt PA, Lam H-TC and Garratty G. 1989. Quantitation of fetal-maternal hemorrhage by flow cytometry. *Am. J. Clin. Pathol.* 91:288-292.
3. Bayliss KM, Kueck BD, Johnson ST, Fueger JT, McFadden PW, Mikulski D and Gottschall JL. 1991. Detecting fetomaternal hemorrhage: a comparison of five methods. *Transfusion* 31: 303-307.
4. Nelson M, Popp H, Horky K, Forsyth C and Gibson J. 1994. Development of a flow cytometric test for the detection of D-positive cells after fetomaternal hemorrhage and survey of the prevalence in D-negative women. *Immunohaematology* 10:55-59.
5. Lloyd-Evans P, Kumpel BM, Bromelow I, Austin E and Taylor E. 1996. Use of a directly conjugated monoclonal anti-D (BRAD-3) for quantification of fetomaternal hemorrhage by flow cytometry. *Transfusion* 36: 432-437.
6. Sebring ES, Polesky HF. 1990. Foetomaternal Hemorrhage: Incidence, Risk Factors, Time of Occurrence, and Clinical Effects. *Transfusion* 30: 344-357.
7. Davis BH. 1993. *Flow Cytometric Analysis of Red Blood Cells. Clinical Flow Cytometry: Principles and Application*, pp. 378-387. Williams & Wilkins, 1993.
8. Nance SJ, Neslon JM, Arndt PA et al. 1989. Quantitation of Fetal-Maternal Hemorrhage by Flow Cytometry. *American J. Clinical Pathology* 91: 288-292.

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