



TRILLIUM DIAGNOSTICS, LLC

INNOVATIVE DIAGNOSTICS FOR CLINICAL CYTOMETRY AND LABORATORY HEMATOLOGY

FETALtrol™

Fetal Red Cell Controls for Fetomaternal Hemorrhage Testing

CE

Product Information

- REF** FH101 3 Levels – two 2mL vials each
FH102 3 Levels – one 2mL vial each (for promotional use only – not for resale)

IVD For *in vitro* Diagnostic Use

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use stabilized controls to monitor the performance of diagnostic tests. Trillium FETALtrol is a tri-level, assayed, human blood control designed to document and monitor values obtained from test methods used to determine fetal RBCs in maternal blood samples. The fetal RBCs in the product are Rh_o or D antigen positive and the adult RBCs are Rh_o or D antigen negative.

APPLICATION

The laboratory determination of the level of fetal cells in maternal circulation remains an important support in the obstetrical management of women with suspected uterine trauma and in the proper dose administration of Rh immune globulin. Trillium FETALtrol provides a means of monitoring preparation techniques, stains, reagents, and methods of data analysis for quantitative and qualitative tests.

INTENDED USE

Product use is intended for hospital clinical laboratories and reference laboratories by trained medical technologists or similar individuals having experience in test methods for fetomaternal hemorrhage. FETALtrol can be used to control both flow cytometry assays and manual stains (KBB) for the detection of RBCs containing HbF or Rh_o (D antigen).

PRODUCT COMPONENTS

Trillium FETALtrol is an *in vitro* diagnostic reagent composed of D-antigen (Rh_o) negative human adult erythrocytes, supplemented with D-antigen (Rh_o) positive human cord blood erythrocytes.

Level 1 (N) - Normal or Negative (Green cap and label)

Level 2 (L) - Low Positive (Blue cap and label)

Level 3 (H) - High Positive (Red cap and label)

SPECIMEN PREPARATION

- 1 Allow tube to warm at ambient temperature for 10 minutes. Do not mix during this period.
- 2 Mix by rolling the vial horizontally between the palms of your hands 10 to 20 times and gently inverting the vial about 10 times. Continue to mix until the cells are completely and evenly resuspended. Do not shake the vial or use a mechanical mixer.
- 3 Handle FETALtrol exactly as you would a patient sample. Pipette an aliquot from the vial and follow your laboratory's established procedure for the detection of fetal cells. (KBB users must dilute FETALtrol).
- 4 After sampling, carefully wipe the rim of the vial and the inside of the cap with a lint-free wipe. Replace the cap, ensuring it is tight. Return the vial to the refrigerator within 30 minutes of use.

Note to KBB users: Since FETALtrol is a stabilized blood product, it may appear to stain darker or be more resistant to elution. While the adult and fetal cells are still distinguishable, using fresh eluting reagent, using room temperature fluids, and increasing the eluting time slightly may improve the stained appearance.

EXPECTED VALUES AND THEIR DERIVATION

Refer to the table of assay values below for expected results. The assay values were obtained from replicate testing on the listed methods. The mean range, where applicable, is an estimate of observed interlaboratory variation due to reagent differences and staining technique.



HANDLING AND STORAGE

Store vials upright, tightly capped, and at 2-8°C when not in use. Unopened vials are stable until the expiration date indicated on each vial and assay sheet. Opened vials are stable for 25 thermal cycles (uses) when handled properly. A thermal cycle constitutes performing all steps under "Instructions for use" once. Avoid unnecessary cycles of warming and cooling. Protect product from freezing, from temperatures above 30°C and from prolonged time at room temperature (18-26°C).

WARNING

Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. Because no known test method can offer complete assurance that infectious agents are absent, consider this product potentially infectious. When handling or disposing of product follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

PRODUCT QUALITY CONTROL

The performance and specificity of reagents contained in this kit are tested using Trillium's in-house quality control methods. Manufacturing of this product is done using quality system and manufacturing production guidelines in compliance with FDA QSR and ISO 13485:2003.

PRODUCT LIMITATIONS

Proper storage and use of this product as indicated above 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 material in the vial.

INDICATIONS OF DETERIORATION

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

PERFORMANCE CHARACTERISTICS

The assay values, with their associated ranges, reflect the expected biological variability of the control materials and the estimated interlaboratory variation.

Each laboratory should establish a mean and acceptable range for each lot of control material. The laboratory mean should fall within the listed range. Laboratories may consider results acceptable when at least 95% of test results are within the laboratory's expected range.

REFERENCES

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- 2 Kleihauer, E., Brown, H., Betke, K., *Klin Wochenschrift* 35; 637, 1957.
- 3 US Department of Labor, Occupational Safety and Health Administration. 29 CFR Parts 1910. 1030, Occupational Exposure to Bloodborne Pathogens; Final Rule. Federal Register 235:64175-82. 1991.
- 4 US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (NIH) 93-8395. Washington: US Government Printing Office. 1993.
- 5 NCCLS. *Fetal Red Cell Detection; Approved Guideline*. NCCLS document H52-A (ISBN 1-56238-452-X), 2001 (Wayne, PA).
- 6 Mundee Y, Bigelow NC, Davis BH, Porter JB: Simplified flow cytometric method for fetal hemoglobin containing red blood cells. *Cytometry* 42:389-393, 2000.
- 7 Chen JC, Davis BH, Wood B, Warzynski MJ: Multi-Center Clinical Experience with Flow Cytometric Method for Fetomaternal Hemorrhage Detection. *Cytometry* 50:285-290, 2002.

TRADEMARKS

Calltag™ is a trademark of Invitrogen Calltag Laboratories. Burlingame, CA 94010.

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