FETALtrol™

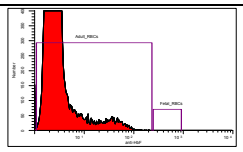
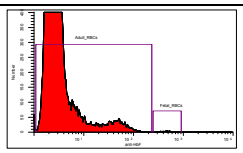
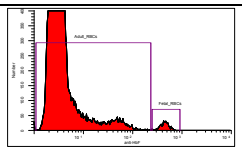
HEMATOLOGY CONTROLS

CONTROL

LOT F16-04

2017-01-15

ASSAY VALUES AND EXPECTED RANGES

Assay Values and Expected Ranges				
Method		Level 1 (green) *Lot: F16-04N*	Level 2 (blue) *Lot: F16-04L*	Level 3 (red) *Lot: F16-04H*
Caltag™ (Flow Cytometry) Fetal Hemoglobin Test	% Fetal Cells	 0.00 - 0.06%	 0.09 - 0.25%	 1.00 – 2.20%
Sure-Tech™ (K-B Manual) Fetal Hemoglobin Stain	% Fetal Cells	0.0 – 0.1%	0.1 – 0.5%	0.9 – 2.5%

INTENDED USE

FETALtrol 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 (KB) for the detection of RBCs containing HbF or Rho (D antigen). Refer to assay table for specific methods.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use stabilized controls to monitor the performance of diagnostic tests. 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.

REAGENTS

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

PRECAUTION

FETALtrol is intended for ***in vitro* diagnostic use** only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested, and yielded non-reactive / negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. Additional details can be found at:
http://www.rndheme.com/TechnicalInformation.aspx.
No test method can offer complete assurance that infectious agents are absent; therefore this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Stability and Storage

Store FETALtrol upright at 2 - 8° C (35 - 46° F) when not in use**. Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 25 thermal cycles (uses), provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear pink or reddish and hemolyzed; this is normal and does not indicate deterioration. Unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**

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INSTRUCTIONS FOR USE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.
   a) Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake. Tubes stored for a long time may require extra mixing. Confirm that cell button on bottom of tube is suspended.
   b) Gently invert the tube 8 - 10 times immediately before sampling.
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. (KB users must dilute FETALtrol).
4. After sampling:
   a) After sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
   b) Return tubes to refrigerator within 30 minutes of use.

   Note to KB 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 (25ºC), and increasing the eluting time may improve the stained appearance.

EXPECTED RESULTS

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

PERFORMANCE CHARACTERISTICS

The mean range reflects 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.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

R&D Systems, Inc.
614 McKinley Place NE
Minneapolis, MN USA 55413

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EC REP **EUROCELL Diagnostics**
19 Rue Louis Delourmel
35230 NOYAL CHATILLON/ SEICHE
France

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