

FETALtrol™

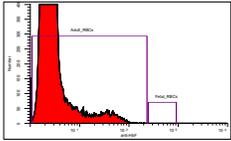
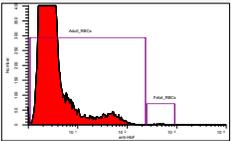
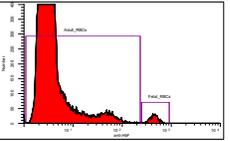
HEMATOLOGY CONTROLS

CONTROL

LOT F23-02

 **2023-07-15**

ASSAY VALUES AND EXPECTED RANGES

Assay Values and Expected Ranges				
Method		Level 1 (green) Lot: F23-02N	Level 2 (blue) Lot: F23-02L	Level 3 (red) Lot: F23-02H
Caltag™ (Flow Cytometry) Fetal Hemoglobin Test	% Fetal Cells	 0.00 - 0.06%	 0.05 - 0.35%	 0.80 - 2.40%
Sure-Tech™ (K-B Manual) Fetal Hemoglobin Stain	% Fetal Cells	0.00 - 0.06%	0.04 - 0.36%	1.10 - 2.80%

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.

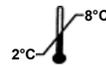


WARNING:

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 (25°C), and increasing the eluting time may improve the stained appearance.

EXPECTED RESULTS

Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

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.

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

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19 Rue Louis Delourmel
35230 Noyal Châtillon / Seiche
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