

R&D Body Fluid

HEMATOLOGY CONTROLS

CONTROL
LOT BF1224

2025-03-05

ASSAY VALUES AND EXPECTED RANGES

Method	Parameter	LEVEL 1		LEVEL 2	
		LOT	BF1224-1	LOT	BF1224-2
		MEAN	RANGE	MEAN	RANGE
Hemocytometer Count	WBC/uL	8	1 - 15	310	185 - 435
Hemocytometer Count	RBC/uL	0	-	1105	805 - 1405

INTENDED USE

R&D Body Fluid Control is a control designed to monitor values obtained using a hemocytometer to validate the quantitation of red and white blood cells in patient body fluid samples.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials which provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS

R&D Body Fluid is an *in vitro* diagnostic reagent composed of mammalian erythrocytes and leukocytes suspended in a plasma-like fluid with preservatives.



PRECAUTION

R&D Body Fluid Control 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 by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA), HIV-1/2 and Anti-HTLV I/II. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, 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 R&D Body Fluid upright at 2 - 8° C when not in use. Protect tubes from overheating and freezing. Unopened tubes are stable through the expiration date. Opened tubes are stable 90 days or 31 thermal cycles (uses), whichever comes first, provided they are handled properly.

INDICATIONS OF DETERIORATION

R&D Body Fluid Control should be similar in appearance to cerebrospinal fluid. In unmixed vials the supernatant should appear clear and colorless. Discoloration of the vials may indicate deterioration or contamination. **Do not use the product if deterioration is suspected.**



INSTRUCTIONS FOR USE

- Remove vials from the refrigerator and allow to warm to room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
- To mix, hold a vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
 - Roll the vial back and forth for 20 - 30 seconds; occasionally invert the vial. Mix vigorously, but do not shake.
 - Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may require extra mixing.
 - Gently invert the vial 8 - 10 times immediately before sampling.
- Prepare a sample of R&D Body Fluid for analysis with the same technique used for a patient specimen.
- After sampling:
 - If vial has been open for sampling, clean residual material from the cap and vial rim with a lint-free tissue. Replace the cap tightly.
 - Return vials to refrigerator within 30 minutes of use.

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EXPECTED RESULTS

Verify that the lot number on the vial matches the lot number on the table of assay values. Operating technique may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean Value is derived from replicate testing analysis of hemocytometer counts. The Range is an estimate of variation between laboratories and also takes into account 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. 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

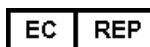
For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

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