

ASSAY VALUES AND EXPECTED RANGES

VALEURS CIBLES ET INTERVALLE DE VARIATIONS

LOT 111

 2012-01-05

BGT LeukoReduced RBC™ Control

UNITS / UNITES WBC/μL		Control 1		Control 2	
		LOT NO	1111	LOT NO	1112
		MEAN	RANGE	MEAN	RANGE
Flow Cytometer	WBC/uL	2.0	0.5 - 3.5	21.5	16.0 - 27.0
Nageotte Chamber	WBC/uL	1.8	0.3 - 3.3	18.5	13.5 - 23.5

BGT LeukoReduced PLT™ Control

UNITS / UNITES WBC/μL		Control 1		Control 2	
		LOT NO	1111	LOT NO	1112
		MEAN	RANGE	MEAN	RANGE
Flow Cytometer	WBC/uL	2.1	0.5 - 3.7	21.4	16.0 - 26.8
Nageotte Chamber	WBC/uL	1.8	0.2 - 3.4	19.0	14.0 - 24.0

INTENDED USE

BGT **LeukoReduced RBC™ & PLT™** Control is used as a complete process control to monitor leukoreduced red blood cell products, including the dilution and staining process, method setup and WBC enumeration.

SUMMARY AND PRINCIPLE

It is an established laboratory procedure to use stable controls to monitor analytical methods. BGT **LeukoReduced RBC™ & PLT™** Control is a stable material that provides a means of determining the accuracy and precision of methods that measure residual leukocytes in blood products. It is tested in the same manner as blood products used for transfusion purposes.

REAGENTS

BGT **LeukoReduced RBC™ & PLT™** Control contains mammalian erythrocytes and human leukocytes in a plasma-like fluid.

PRECAUTIONS

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL.

BGT **LeukoReduced RBC™ & PLT™** Control is intended solely for *in vitro* diagnostic use by trained personnel. 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.

STABILITY AND STORAGE

Store the vials/tubes upright at 2 to 8°C (35 to 46°F) when not in use. DO NOT FREEZE. Unopened vials/tubes are stable until the expiration date. When handled properly, opened vials/tubes are stable for 30 days or 21 thermal cycles (uses), whichever comes first. A thermal cycle constitutes performing all steps once, under Instructions for Use.

INDICATIONS OF DETERIORATION

BGT **LeukoReduced RBC™ & PLT™** Control should be similar in appearance to fresh whole blood. In unmixed vials/tubes, the supernatant may appear pink; this is normal and does not indicate deterioration. Dark red supernatant fluid, discoloration of the product or unacceptable results may indicate deterioration. Do not use the product if deterioration is suspected.

INSTRUCTIONS FOR USE

1. Remove vial/tube from the refrigerator and allow to warm at room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
2. To mix, hold the vial/tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.
 - a) Roll the vial/tube back and forth for 20-30 seconds; occasionally invert the vial/tube. Mix vigorously but do not shake.
 - b) Continue to mix in this manner until the red cells are completely suspended. Vials/tubes stored for a long time may require extra mixing.
 - c) Invert the vial/tube 8-10 times immediately before each sampling.
3. After sampling:
 - a) Clean residual material from the cap and vial/tube rim with a lint-free tissue. Replace the cap tightly.
4. Return the vial/tube to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the vial/tube matches the lot number on the Assay Sheet. Refer to the assay table specified for your instrument.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean Value and Range. The Mean Value 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 expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before they are 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-recovered mean should be within the Assay Range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically re-evaluate the mean. The laboratory range may include values outside of the Assay Range. The user may establish target

values not listed on the Assay Sheet if the control is suitable for the method.

LIMITATIONS

1. Incomplete mixing of the vial/tube before use invalidates both the sample withdrawn and the remaining product in the vial/tube.
2. BGT **LeukoReduced RBC™ & PLT™** Control is not intended as a control for hematology whole blood analyzers.

The performance of this product is ensured only if properly stored and used as described in this insert.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, call our Technical Service Department at (02551) 4090. For additional information on BGT Systems hematology controls and calibrators, or to place an order, call our Customer Service Department at (02551) 4090.

QUALITY CONTROL PROGRAM

If you submit data to BGT Systems Hematology Quality Control Program, note the QCP data months on the Assay Sheet. Submit data at the end of each month and record the month of use on the data submission form. For information on our Hematology Quality Control Program, call (02551) 4090.



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Printed in Germany

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Printed in Germany
AIS095-001 Rev 6/02



**Aktuelle Wertebblätter zu den Chargen von
LeukoReduced RBC™ & PLT™ Control finden Sie
im Internet unter
www.wertebblatt.de**