Leucocount™ RBC Control

Format	Catalog No.
RBC Control, 3 mL per level	341001
BD Leucocount™ Combo Control (PLT Control and RBC Control), 3 mL per level	341003

23-4959(08)
2022-11
English

CE 2797 IVD

1. INTENDED USE

BD Leucocount™ RBC Control is intended as a two-level process control with quantitative assigned values for use in monitoring the process for enumerating residual white blood cells (rWBC) in leucoreduced red blood cell (RBC) products. It is a control for staining, instrument setup, and white blood cell enumeration on suitably equipped BD flow cytometers when used with the BD Leucocount™ Kit.

2. SUMMARY OF THE TEST

Using stable controls to monitor analytical methods is an established laboratory practice. BD Leucocount™ RBC Control is an internal laboratory quality control material that is intended for use by laboratory professionals to determine the accuracy and precision of methods that measure residual leucocytes in leucoreduced blood products.

Principle of Operation

BD Leucocount™ RBC Control is used in a similar manner as leucoreduced blood products used for transfusion purposes.[1,2,3,4,5,6] The reagent is added to the process control material in a BD Trucount™ Tube and incubated. The BD Leucocount™ Reagent contains the nucleic acid dye, propidium iodide (PI), and RNAse. When used with RNAse, PI stains only cellular DNA. White blood cells are nucleated cells that contain DNA and therefore stain with the dye. Non-nucleated cells, such as erythrocytes, do not stain with PI. BD Trucount™ Tubes contain a lyophilized pellet of fluorescent beads. During incubation of the reagent and the specimen, the bead pellet dissolves, releasing a known number of fluorescent beads, which are distinguished from cells by their fluorescence intensity. The stained sample is acquired on a flow cytometer and the software determines the rWBC count by comparing cellular events to bead events, and reports the counts in the lab report. The control mean values that are obtained by the laboratory should fall within the ranges specified on the BD Leucocount™ RBC Control Residual WBC Assay Values and Expected Ranges sheet provided with the control.

3. REAGENT

Reagent Composition

BD Leucocount™ RBC Control contains mammalian erythrocytes and human leucocytes in a plasma-like fluid with preservatives. Assay ranges can be found in the Residual WBC Assay Values and Expected Ranges sheet

included with the product.

Precautions

- The control should be similar in appearance to fresh whole blood. In unmixed vials the supernatant can appear pink. This is normal and does not indicate deterioration. Dark red supernatant fluid, discoloration of the product, or unacceptable results can indicate deterioration. Do not use the product if deterioration is suspected.
- Go to regdocs.bd.com/regdocs/sdsSearch to download the Safety Data Sheet.

WARNING Treat all blood products as potentially infectious.[7,8] Never pipette by mouth. Wear suitable protective clothing, eyewear, and gloves. Each human donor used in preparation of this product has been tested and found non-reactive for the presence of hepatitis B surface antigen (HBsAg), HIV-1 Ag, and antibodies to hepatitis C virus (HCV) and HIV-1/HIV-2. However, no known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

WARNING When handling or disposing of vials, follow precautions for biohazardous materials in accordance with national and local regulations.

Storage and Handling

- Store vials upright, tightly capped, at 2–8 °C when not in use.
- Unopened vials are stable until the expiration date indicated on each vial and on the Residual WBC Assay Values and Expected Ranges sheet when stored continuously at 2–8 °C. Do not use beyond labeled expiration date.
- Opened vials are stable for 30 days or 21 thermal cycles (uses), whichever comes first, when handled properly. A thermal cycle constitutes one time of performing all steps under Section 4, Procedure.

  In general, stability is limited by the number of times the vial is removed from the refrigerator, warmed, and mixed (defined as a "use"), by the time the vial is first opened, and by the decrease in volume with each use.
- Avoid unnecessary cycles of warming and cooling. Protect from freezing, from temperatures above 30 °C, and from prolonged time (>30 minutes) at room temperature (18–30 °C).
- Follow exactly the steps under Section 4, Procedure.

4. PROCEDURE

Reagents and Materials

Reagents and materials provided

- BD Leucocount™ RBC Control Low
- BD Leucocount™ RBC Control High

  Each vial contains 3.0 mL.
- Residual WBC Assay Values and Expected Ranges sheet

Reagents and materials required but not provided

- BD Leucocount™ Kit (Catalog No. 340523)

Setting up the Instrument

1. Ensure that the flow cytometer passes daily quality control.
2. Set up the flow cytometer for the assay being performed.

Resuspending the Control

1. Remove the vials from the refrigerator (2–8 °C) and allow to stand at room temperature (18–30 °C) for 15 minutes.
2. Hold a vial vertically between the palms of your hands and roll back and forth 10 times.
3. Gently invert the vial 10 times.

   CAUTION Do not shake the vial or use a mechanical mixer.

4. Examine the bottom of the vial to determine whether the cells are completely and uniformly suspended.
5. If needed, repeat steps 2 and 3 until the cell pellet on the bottom of the vial is completely resuspended.
6. Remove the amount of control material needed.

   See the *BD Leucocount™ Kit* instructions for use (IFU).

7. Carefully wipe the vial rim and the cap with a lint-free tissue.
8. Tightly replace the cap and immediately return the vials to the refrigerator.
9. Process the BD Leucocount™ RBC Control exactly as a specimen.

   See the *BD Leucocount™ Kit* IFU.

10. Verify that the results are within the ranges provided on the Residual WBC Assay Values and Expected Ranges sheet.

    NOTE Each laboratory should establish its own means and expected ranges.

5. RESULTS

The Residual WBC Assay Values and Expected Ranges sheet reports means and expected ranges for WBC (cells/µL) derived from flow cytometry results using the BD Leucocount™ Kit and from Nageotte chambers.

Select the appropriate table for the method being used. Verify that the lot number on the Residual WBC Assay Values and Expected Ranges sheet corresponds with the lot number on the control vial in use. Ranges for reported values are based on expected variations between laboratories and also take into account expected biological variability of the control material.

6. LIMITATIONS

- Incomplete mixing of the vial before use invalidates both the sample that is withdrawn and the remainder of the material in the vial.
- Do not use beyond the labeled expiration date.
- The BD Leucocount™ RBC Control is not intended as a control for hematology whole blood analyzers.

7. PERFORMANCE CHARACTERISTICS

Precision (Repeatability)

A single-site study evaluated system precision over a period of 21 days. Three lots of BD Leucocount™ RBC Control were stained using one lot of BD Leucocount™ Kit, in duplicate. Control material was stained and acquired on one BD FACSLyric™ flow cytometer two times each day.

The mean and standard deviation (SD) or coefficient of variation (%CV) for repeatability and within-site precision are reported. All values were within the ranges reported on the Residual WBC Assay Values and Expected Ranges sheet.

Table 1 Repeatability and within-site precision of rWBC absolute counts (low)

Lot	Mean	Number	SD	
			Repeatability	Within-site precision
Lot 1 (Low)	2.83	84	0.36	0.39
Lot 2 (Low)	3.34	84	0.34	0.34
Lot 3 (Low)	2.81	84	0.32	0.34

Table 2 Repeatability and within-site precision of rWBC absolute counts (high)

Lot	Mean	Number	%CV	
			Repeatability	Within-site precision
Lot 1 (High)	21.52	84	4.71	5.20
Lot 2 (High)	19.27	84	4.60	5.69
Lot 3 (High)	21.40	84	5.26	5.26

Precision (Reproducibility)

A study was performed at three sites to assess reproducibility of BD Leucocount™ RBC Control. One lot of BD Leucocount™ RBC Control was provided to each of the sites. Five replicates of the control material were stained at each site using the same lot of BD Leucocount™ Kit on 6 non-consecutive testing days. Testing at each site was performed on one BD FACSLyric™ flow cytometer.

The mean, standard deviation (SD), and coefficient of variation (%CV) for reproducibility are reported. All values were within the ranges reported on the Residual WBC Assay Values and Expected Ranges sheet.

Table 3 Reproducibility of rWBC absolute counts

Lot	Mean	Number	Reproducibility	
			SD	%CV
Low	2.69	90	0.41	15.40
High	20.86	90	1.36	6.50

8. TROUBLESHOOTING

Problem	Possible Cause	Solution
Values are outside the ones found in the Residual WBC Assay Values and Expected Ranges sheet.	The staining procedure did not work.	Prepare and stain another control sample. Acquire it and confirm that the values are acceptable.
	The cell pellet in the vial was not completely resuspended.	Discard the vial. Use a new vial and thoroughly resuspend the cell pellet according to the IFU.

Problem	Possible Cause	Solution
	Inappropriate instrument settings.	Follow proper instrument setup procedures. Optimize instrument settings as required.

REFERENCES

1. Wenz B, Gurtlinger KF, O'Toole AM, Dugan EP. Preparation of granulocyte-poor red blood cells by micro-aggregate filtration: a simplified method to minimize febrile transfusion reactions. *Vox Sang.* 1980;39:282–287.
2. Venglen-Tyler V, ed. Leukoreduction of RBC and platelet units. American Association of Blood Banks. 1996:722-725.
3. Dumont LJ, Dzik WH, Rebulla P, Brandwein H. Practical guidelines for process validation and process control of white cell-reduced blood components: report of the Biomedical Excellence for Safer Transfusion (BEST) Working Party of the International Society of Blood Transfusion (ISBT). *Transfusion.* 1996;36:11-20.
4. Rebulla P, Porretti L, Bertolini F, et al. White cell-reduced red cells prepared by filtration: a critical evaluation of current filters and methods for counting residual white blood cells. *Transfusion.* 1993:33:128-133.
5. Vachula M, Simpson SJ, Martinson JA, et al. A flow cytometric method for counting very low levels of white cells in blood and blood components. *Transfusion.* 1993:33:262-267.
6. Center for Biologics Evaluation and Research. *Recommendation and Licensure Requirements for Leukocyte-Reduced Blood Products*. Rockville, MD: Food and Drug Administration. 1996.
7. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI document M29-A4.
8. Centers for Disease Control and Prevention. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html. Accessed March 12, 2019.

NOTICE

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

WARRANTY

Unless otherwise indicated in any applicable BD general conditions of sale for non-US customers, the following warranty applies to the purchase of these products.

THE PRODUCTS SOLD HEREUNDER ARE WARRANTED ONLY TO CONFORM TO THE QUANTITY AND CONTENTS STATED ON THE LABEL OR IN THE PRODUCT LABELING AT THE TIME OF DELIVERY TO THE CUSTOMER. BD DISCLAIMS HEREBY ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE AND NONINFRINGEMENT. BD'S SOLE LIABILITY IS LIMITED TO EITHER REPLACEMENT OF THE PRODUCTS OR REFUND OF THE PURCHASE PRICE. BD IS NOT LIABLE FOR PROPERTY DAMAGE OR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING PERSONAL INJURY, OR ECONOMIC LOSS, CAUSED BY THE PRODUCT.

TRADEMARKS

HISTORY

Revision	Date	Changes made
23-4959(08)	2022-11	Updated to meet requirements of Regulation (EU) 2017/746.

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.
US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
EC REP	Authorized representative in the European Community
CH REP	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
STERILE	Sterile fluid path
STERILE EO	Sterile fluid path (ethylene oxide)
STERILE R	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
LATEX	Contains or presence of natural rubber latex
IVD	In vitro diagnostic medical device
CONTROL -	Negative control
CONTROL +	Positive control
Σ	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic

Symbol	Meaning
#	Patient number
	This way up
	Do not stack
	Single sterile barrier system
PHT DEHP BBP	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
CE	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
R_x Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
CC	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
H_2	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
FC	Meets FCC requirements per 21 CFR Part 15
c UL us	UL product certification for US and Canada
UDI	Unique device identifier

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