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# **BD Leucocount™ PLT Control**

Format	Catalog No.
PLT Control, 3 mL per level	341002
BD Leucocount™ Combo Control (PLT Control and RBC Control), 3 mL per level	341003

23-4951(08)  
2022-11  
English



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## 1. INTENDED USE

BD Leucocount™ PLT 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 platelet (PLT) 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™ PLT 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™ PLT Control is used in a similar manner as leucoreduced platelet products used for transfusion purposes.<sup>1,2,3,4,5,6</sup> 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 particles, such as platelets 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™ PLT Control Residual WBC Assay Values and Expected Ranges sheet provided with the control.

## 3. REAGENT

### Reagent Composition

BD Leucocount™ PLT Control contains mammalian platelets 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.

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## Precautions

- The control should be similar in appearance to platelet packs. Suspect deterioration if visible clumps cannot be dispersed when the product has been mixed according to the procedure. Do not use the product if deterioration is suspected.
- Go to [regdocs.bd.com/regdocs/sdsSearch](http://regdocs.bd.com/regdocs/sdsSearch) to download the Safety Data Sheet.

**WARNING** Treat all blood products as potentially infectious.<sup>7,8</sup> 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™ PLT Control Low
  - BD Leucocount™ PLT 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™ PLT 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/ $\mu$ L) 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™ PLT 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™ PLT Control were stained using one lot of BD Leucocount™ Kit, in duplicate. Control material was stained and acquired on one BD FACSLytic™ 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)	2.12	84	0.31	0.37
Lot 2 (Low)	2.16	84	0.29	0.29
Lot 3 (Low)	3.03	84	0.35	0.38

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

Lot	Mean	Number	%CV	
			Repeatability	Within-site precision
Lot 1 (High)	20.07	84	4.48	5.30
Lot 2 (High)	18.74	84	4.56	4.73
Lot 3 (High)	24.49	84	4.73	4.85

### Precision (Reproducibility)

A study was performed at three sites to assess reproducibility of BD Leucocount™ PLT Control. One lot of BD Leucocount™ PLT 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	2.07	90	0.34	16.43
High	20.00	90	1.19	5.96

## 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.
	Inappropriate instrument settings.	Follow proper instrument setup procedures. Optimize instrument settings as required.

## REFERENCES

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2. Venglen-Tyler V, ed. Leukoreduction of RBC and platelet units. American Association of Blood Banks. 1996:722-725.
3. Dumont LJ, Dzik WH, Rebullia 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. Rebullia 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

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## HISTORY

Revision	Date	Changes made
23-4951(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](http://bd.com/symbols-glossary)

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorized representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult <i>instructions for use</i>
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	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 <i>instructions for use</i> or consult electronic <i>instructions for use</i>
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	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
	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 marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	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
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier

## CONTACT INFORMATION



**Becton, Dickinson and Company**  
**BD Biosciences**  
2350 Qume Drive  
San Jose, California 95131 USA



**Becton Dickinson Ireland Ltd.**  
Donore Road, Drogheda  
Co. Louth, A92 YW26  
Ireland



**BD Switzerland Sàrl**  
Route de Crassier 17  
Business Park Terre-Bonne  
Bâtiment A4  
1262 Eysins  
Switzerland

**BD Biosciences**  
**European Customer Support**  
Tel +32.53.720.600  
help.biosciences@bd.com

Australian and New Zealand Distributors:

**Becton Dickinson Pty Ltd.**  
66 Waterloo Road  
Macquarie Park NSW 2113  
Australia

**Becton Dickinson Limited**  
14B George Bourke Drive  
Mt. Wellington Auckland 1060  
New Zealand

Technical Service and Support: Contact  
your local BD representative or  
[bdbiosciences.com](http://bdbiosciences.com).

[ClinicalApplications@bd.com](mailto:ClinicalApplications@bd.com)



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