BD Leucocount™ PLT Control

Residual WBC control for leucoreduced platelet products

Tests	Catalog No.
PLT, 25 Tests per Kit	662417
BD Leucocount Combo Control Kit, (PLT Control and RBC Control, 25 Tests each)	662418

11/2016 23-19383-00

IVD

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

Becton Dickinson Pty Ltd,
4 Research Park Drive,
Macquarie University Research Park,
North Ryde NSW 2113, Australia

Becton Dickinson Limited,
8 Pacific Rise, Mt. Wellington,
Auckland, New Zealand

bdbiosciences.com
ClinicalApplications@bd.com

1. INTENDED USE

The BD Leucocount™ PLT control kit consists of platelet (PLT) Low and PLT High process controls intended for use with the BD Leucocount™ Kit to monitor the process for enumeration of residual leucocytes in leucoreduced platelet products, including dilution, staining, instrument setup, and white blood cell (WBC) enumeration.

For In Vitro Diagnostic Use.

2. SUMMARY AND EXPLANATION

It is an established laboratory procedure to use stable controls to monitor analytical methods. The BD Leucocount PLT control is a stable material that provides a means of determining the accuracy and precision of methods that measure residual leucocytes in platelet products. It is tested in the same manner as platelet products used for transfusion purposes.[1-6]

3. REAGENTS

Reagents Provided

The BD Leucocount PLT control is an in vitro diagnostic reagent composed of mammalian platelets and human leucocytes in a plasma-like fluid with preservatives. Assay ranges can be found in the Assay Values sheet included with the product.

Precautions

WARNING Treat all blood products as potentially infectious. Each human donor sample used in preparation of this product has been tested by an FDA-licensed method and found non-reactive for the presence of HBs Ag, HIV-1 Ag, and antibody to 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 patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29CFR Part 1910.1030) or other equivalent biosafety procedures.

WARNING All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection[7,8] and dispose of with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing, eyewear, and gloves.

Storage and Handling

- Store vials upright, tightly capped, at 2°C–8°C when not in use.
- Unopened vials are stable until the expiration date indicated on each vial and on the Assay Values sheet when stored continuously at 2°C–8°C.
- Opened vials are stable for 30 days or 21 thermal cycles (uses), whichever comes first, when handled properly. A thermal cycle constitutes performing all steps once under Instructions for Use.

  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.
- Protect from freezing, from temperatures above 30°C, and from prolonged time at room temperature (18°C–30°C).
- Follow exactly the steps under Instructions for Use.

Indications of Deterioration

The BD Leucocount PLT 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.**

4. INSTRUCTIONS FOR USE

1. Remove the vial from the refrigerator (2°C–8°C) and allow to stand at room temperature (18°C–30°C) for 15 minutes.

   Do not shake the vial or use a mechanical mixer.
2. Hold the vial vertically between the palms of your hands and roll back and forth 10 times.
3. Gently invert the vial 10 times.
4. Examine the bottom of the vial.

   If the cells are not completely and uniformly suspended, repeat steps 2 and 3.
5. Process the BD Leucocount PLT control exactly as a patient sample.
6. After sampling, carefully wipe the vial rim and the cap with a lint-free tissue.
7. Tightly replace the cap and immediately return the BD Leucocount PLT control to the refrigerator.

5. EXPECTED RESULTS

See the Assay Values sheet for the assay values for each lot of the BD Leucocount PLT control. Select the appropriate table for the method being used. Verify that the

lot number on the Assay Values 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.

NOTE Each laboratory should establish its own ranges.

6. LIMITATIONS

- Incomplete mixing of the vial before use invalidates both the sample withdrawn and the remaining product 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.
- **For US:**

  Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

7. PERFORMANCE CHARACTERISTICS

Assigned values are presented as Assay Mean and Expected Range. The mean value is derived from replicate testing using published methods and manufacturer's instructions.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Compare the existing lot with the new lot when the current quality control lot is still in use and not expired. The laboratory recovered mean should be within the assay Expected Range. For greater control sensitivity each laboratory should establish its own Assay Mean and Expected Range and periodically reevaluate them. The laboratory range can include values outside the assay Expected Range. Target values not listed on the Assay Values sheet can be established by the user if the control is suitable for the method.

REFERENCES

1. Wenz B, Gurtlinger KF, O'Toole AM, Dugan EP. Preparation of granulocyte-poor red blood cells by microaggregate 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 —Third Edition.* Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI document M29-A3.
8. Centers for Disease Control. Perspectives in disease prevention and health promotion update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR*. 1988;37:377-388.