



# BD Leucocount™ RBC Control

Residual WBC control for leucoreduced RBC products

## Tests

RBC Control, 25 Tests per Kit  
BD Leucocount Combo  
Control Kit (PLT Control and  
RBC Control, 25 Tests each)

## Catalog No.

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662418

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## 1. INTENDED USE

The BD Leucocount™ RBC control kit consists of red blood cell (RBC) Low and RBC High process controls intended for use with the BD Leucocount™ Kit to monitor the process for enumeration of residual leucocytes in leucoreduced RBC 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 RBC control is a stable material that provides a means of determining the accuracy and precision of methods that measure residual leucocytes in blood products. It is tested in the same manner as blood products used for transfusion purposes.<sup>1-6</sup>

## 3. REAGENTS

### Reagents Provided

The BD Leucocount RBC control is an in vitro diagnostic reagent composed of mammalian erythrocytes 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<sup>7,8</sup> 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, temperatures above 30°C, and prolonged time at room temperature (18°C–30°C).
- Follow exactly the steps under Instructions for Use.

### Indications of Deterioration

The BD Leucocount RBC 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.**

### 4. INSTRUCTIONS FOR USE

1. Remove the vial from the refrigerator (2°C–8°C) and allow it 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 RBC 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 RBC control to the refrigerator.

### 5. EXPECTED RESULTS

See the Assay Values sheet for the assay values for each lot of the BD Leucocount RBC 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 assay 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 RBC 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 of 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

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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.
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