1. INTENDED USE

BD LeucoCOUNT™ RBC Control is used to monitor methods for enumeration of residual leucocytes in leucoreduced RBC products, including the dilution and staining process, method setup, and WBC enumeration.

2. SUMMARY AND EXPLANATION

It is an established laboratory procedure to use stable controls to monitor analytical methods. 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.

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

1. For In Vitro Diagnostic Use.
2. WARNING: Treat all blood products as potentially infectious. Each human donor 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.
3. 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.

Storage and Handling

1. Store vials upright, tightly capped, at 2–8°C when not in use.
2. Unopened vials are stable until the expiration date indicated on each vial and on the Assay Values sheet when stored continuously at 2–8°C.
3. 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 from first use; and by the decrease in volume with each use.

4. Protect from freezing, from temperatures above 30°C, and from prolonged time at room temperature (18–30°C).

5. Follow exactly the steps under Instructions for Use.

Indications of Deterioration
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 (2–8°C) and allow to stand at room temperature (18–30°C) for 15 minutes before mixing.

2. To mix, hold the vial horizontally between the palms of your hands. Do not pre-mix on a mechanical mixer.
   • Roll the vial back and forth for 20–30 seconds; occasionally invert the vial. Mix vigorously but do not shake.
   • Continue to mix in this manner until the cells are completely suspended. Vials stored for a long time can require extra mixing.
   • Gently invert the vial 8–10 times immediately before sampling.

3. Process the BD LeucoCOUNT RBC Control exactly as a patient sample.

4. After sampling, wipe the vial rim and the cap and replace the cap immediately.

5. Return the BD LeucoCOUNT RBC Control to the refrigerator immediately after sampling.

5. LIMITATIONS

1. Incomplete mixing of the vial before use invalidates both the sample withdrawn and the remaining product in the vial.

2. Do not use beyond labeled expiration date.

3. The BD LeucoCOUNT RBC Control is not intended as a control for hematology whole blood analyzers.

6. EXPECTED RESULTS

Refer to the Assay Values sheet for the assay values for each lot of 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.

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


WARRANTY

The product sold hereunder is warranted only to conform to the quantity and contents stated on the label at the time of delivery to the customer. There are no warranties, expressed or implied, that extend beyond the description on the label of the product. 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, personal injury, or economic loss caused by the product.

CUSTOMER SUPPORT INFORMATION

Manufactured in the USA for:
BD Biosciences
Becton, Dickinson and Company
2350 Qume Drive
San Jose, CA 95131-1807
USA
Tel (877) 232-8995
Fax (408) 954-2347
www.bdbiosciences.com

Distributed by:
BD Biosciences
Centralized European Office
Denderstraat 24
B-9320 Erembodegem-Aalst
Belgium
Tel (32) 53-720211
Fax (32) 53-720450

BD Biosciences
Asia Pacific Division
30 Titans Avenue #2
Singapore 639461
Tel (65) 861-0693
Fax (65) 860-1590

BD Biosciences
Monte Pelvoux 111
Lomas De Chapultepec
11000 Mexico D.F.
Mexico
Tel (52) 5 284-8281
Fax (52) 5 284-8288

BD Biosciences
Nippon Becton Dickinson Company, Ltd.
Akasaka DS Building
5-26, Akasaka 8-chome
Minato-ku, Tokyo 107-0052
Japan
Tel 03-542-8555-90

BD Biosciences
Rua Alexandre Dumas 1976
Santo Amoeno
04717-004 São Paulo
Brasil
Tel (55) 11 5185-9995
Fax (55) 11 5185-9941

23-4958-01
<table>
<thead>
<tr>
<th>Level Lot No.</th>
<th>Low XX000L</th>
<th>High XX000H</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assay Mean (WBC/µL)</td>
<td>Expected Range (WBC/µL)</td>
</tr>
<tr>
<td>BD LeuCOUNT™ RBC Control</td>
<td>Nageotte Chamber</td>
<td></td>
</tr>
</tbody>
</table>