1. INTENDED USE

NOTE This product is CE marked to the IVD directive 98/79/EC and available in Europe for use on the BD FACSVia™ system and the BD FACScalibur™ flow cytometer. The BD FACSVia system is not available in the United States.

BD FACScalibur Flow Cytometer Intended Use

The BD Leucocount™ kit is designed for counting residual white blood cells (rWBCs) in leucoreduced blood products.

BD FACSVia System Intended Use (CE-IVD)

The BD Leucocount kit is for in vitro diagnostic use on the BD FACSVia system using the BD FACSVia™ clinical software. The kit is designed for counting residual white blood cells (rWBCs) in leucoreduced blood products.

2. SUMMARY AND EXPLANATION

The presence of white blood cells (WBCs) in blood and platelet products is associated with an increased incidence of febrile transfusion reactions, transmission of cytomegalovirus, and alloimmunization to HLA antigens in transfusion recipients.1-3 Leucoreduction, the collection of platelets via apheresis, or post-collection processing with special filters, can lower the WBC count to 5 x 10^6 per unit or below, thus minimizing complications associated with transfusions.4-5 The BD Leucocount kit is designed to provide an efficient, sensitive method for enumerating rWBCs using flow cytometry while eliminating limitations associated with other methods.6-7 The BD Leucocount assay incorporates BD Trucount™ tubes to determine absolute cell counts of rWBCs in a single tube. The FDA has
recommended the use of flow cytometry as a counting method for evaluating leucoreduced blood products.8

3. PRINCIPLES OF THE PROCEDURE

The BD Leucocount reagent contains propidium iodide (PI). PI is a nucleic acid dye which, when used with RNAse, stains only cellular DNA. White blood cells are nucleated cells that contain DNA and are therefore stained with the dye. Non-nucleated particles (including platelets and red cells) do not stain with this reagent. BD Trucount™ tubes contain beads that act as an internal reference to accurately determine the absolute count of residual white cells. Appropriate samples are combined with the lyophilized bead pellet in the BD Trucount tubes before staining. After staining rWBCs, samples are acquired on a flow cytometer. Absolute rWBC counts are determined by using a simple calculation based on bead number and sample volume.

4. REAGENTS

The BD Leucocount kit contains BD Leucocount reagent and BD Trucount tubes, sufficient for 50 tests. The BD Leucocount reagent contains:
- PI, a nucleic acid dye
- 0.1% sodium azide
- RNAse, for the enzymatic digestion of RNA in platelets and reticulocytes
- detergent, which permeabilizes the cell membrane to allow for entry of PI
- buffers, to stabilize the stained sample

BD Trucount tubes contain a lyophilized pellet of 4.2-µm fluorescent beads used as an internal standard for calculation of the absolute count.

Precautions
- For In Vitro Diagnostic Use.
- The addition of a precise volume of sample is critical. Pipets must be calibrated to deliver exactly 100 µL of sample. If necessary, perform the reverse pipetting technique according to the pipet manufacturer’s instructions.
- Care should be taken to avoid microbial contamination of the reagent, which could give aberrant results.
- Do not use the reagents if you observe any change in appearance. Precipitation or discoloration indicates instability or deterioration.
- Before use, inspect the BD Trucount tube to make sure the pellet is intact and below the retainer.
- Bead count varies by lot of BD Trucount tubes. It is critical to use the bead count shown on the lot of BD Trucount tubes that you are currently using when calculating absolute cell counts. Do not mix multiple lots of tubes in the same assay.

WARNING All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection9,10 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 BD Leucocount reagent at 2°C–8°C. Do not use after the expiration date shown on the label.
- Avoid unnecessary exposure of the reagent to light.
Do not freeze the reagents or expose them to direct light during storage or incubation with cells. Keep the reagent vials dry.

Store BD Trucount tubes in their original foil pouch at 2°C–25°C. To avoid potential condensation, open the pouch only after it has reached room temperature and carefully reseal the pouch immediately after removing a tube. Examine the desiccant each time you open the pouch. If the desiccant has turned from blue to lavender, discard the remaining tubes. Use tubes within 1 hour after removal from the foil pouch. Once the pouch has been opened, the tubes are stable for 1 month. Do not use beyond the expiration date indicated on the packaging.

5. INSTRUMENT
The BD Leucocount kit is designed for use on a flow cytometer equipped with appropriate computer hardware and software. The cytometer must have a 488-nm laser capable of detecting forward scatter (FSC) and side scatter (SSC) and at least two-color fluorescence. It must also be able to threshold or discriminate using the FL2 channel.

You can use BD CellQuest™ Pro software for data acquisition and analysis on a BD FACS™ brand cytometer, such as the BD FACS Calibur flow cytometer with the optional BD FACS™ Loader. For these cytometers, use BD Calibrite™ beads to set photomultiplier tube (PMT) voltages, fluorescence compensation, and to check instrument sensitivity before use.

You can also use BD FACSVia clinical software on the BD FACSVia flow cytometer with the optional BD FACSVia Loader. For this cytometer, use BD™ CS&T beads for instrument QC, to check the instrument’s measurements and performance.

Results can be achieved using flow cytometers manufactured by companies other than BD Biosciences. Set up the cytometer for two-color acquisition following the manufacturer’s recommendations.

6. SPECIMEN COLLECTION AND PREPARATION
A minimum of 100 µL of sample is required for this procedure. You can use samples containing an additive. For freshly collected samples without an additive:

1. Collect red blood cell (RBC) and platelet samples according to manufacturer’s instructions.
2. Prepare and run the samples within 48 hours following leucoreduction.

Store RBC samples at 2°C–8°C until ready for staining. Store platelet samples at room temperature (20°C–25°C) until ready for staining.

Interfering Conditions
- The presence of EDTA in the sample can interfere with results.
- Do not use previously fixed and stored samples.
- Samples without additive that are refrigerated before staining could give aberrant results.

7. PROCEDURE
Reagents Provided
BD Leucocount reagent, sufficient for 50 tests, and BD Trucount tubes.
Reagents and Materials Required but Not Provided

- BD Leucocount controls (Catalog Nos. 341001, 341002, 341003) or equivalent. Other control materials may be used, but will need validation by the user.
- Falcon® disposable 12 x 75-mm polypropylene test tubes or equivalent
- Vortex mixer
- Micropipettor with tips

For BD FACS brand cytometers running BD FACSComp™ software:
- BD Calibrite™ beads (Catalog Nos. 349502 or 340486)

For BD FACSVia cytometers:
- BD CS&T beads (Catalog Nos. 656504, 656505)

Staining Procedure

**CAUTION** Pipette the sample and reagents onto the side of each tube just above the metal retainer. If the sample remains on the side of the tube, it will not be stained with the reagent. Do not touch the bead pellet.

1. Carefully dispense 200–400 µL of well-mixed RBC or platelet samples into clean 12 x 75-mm polypropylene tubes.

**NOTE** Use polypropylene tubes for sample storage, not for counting WBCs in RBC or platelets.

2. Remove the BD Trucount tubes from the foil pouch and reseal the pouch immediately.

3. Label each tube. Prepare the samples within 1 hour.

**NOTE** Before use, verify that the bead pellet is intact and under the metal retainer at the bottom of the BD Trucount tube. If not, discard the tube and replace it with another.

4. Add 100 µL of well-mixed sample (platelet, RBC, control) to the labeled BD Trucount tube.

5. Add 400 µL of BD Leucocount reagent to each tube.

6. Cap the tubes and gently vortex. Do not vortex longer than 15 seconds.

7. Incubate the tubes for 5 minutes in the dark at room temperature.

8. Store the tubes in the dark until ready for acquisition. Samples can be acquired up to 24 hours after staining.

Quality Control

We recommend running BD Leucocount controls each day of use to provide absolute residual white cell counts around your laboratory’s critical cut-off values. In addition, it is advisable to run controls on every shift.

1. Stain controls as samples.

2. Acquire the control samples using the procedure described in Sample Acquisition.

The fluorescence intensity of BD Leucocount control cells might differ slightly from that of unpreserved WBCs. See Figure 1, Figure 2, and Figure 6.

If you are using a BD FACS brand flow cytometer running BD FACSComp software, and if necessary, create and save an acquisition/analysis template for control samples, with R2 appropriately adjusted. A gating aid sample can be
useful in defining the expected fluorescence intensity of WBCs present in blood products. For details, see the Gating Aid (Optional) section. For BD FACSVia cytometers, gates surround normal and control cells.

Quality control runs should produce results equivalent to the expected values.

**Figure 1** High-level control samples

<table>
<thead>
<tr>
<th>Region</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>10,000</td>
</tr>
<tr>
<td>R2</td>
<td>320</td>
</tr>
</tbody>
</table>

**Figure 2** Low-level control samples

<table>
<thead>
<tr>
<th>Region</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>10,000</td>
</tr>
<tr>
<td>R2</td>
<td>34</td>
</tr>
</tbody>
</table>

**Instrument Setup**

This section provides guidelines for instrument setup.

Setup is not required for the BD FACSVia flow cytometer because test definitions for each assay define default acquisition and gate settings. For instructions on how to run a sample on this cytometer, see the *BD FACSVia System Instructions For Use (IFU)*.

For users of BD FACS brand cytometers that require instrument setup, verify instrument performance using BD Calibrite beads or equivalent. For users of non-BD flow cytometers, follow the manufacturer’s recommendations for performance verification.

For instructions on performing BD Leucocount setup automatically using BD FACSComp software (version 4.1 or later), refer to the *BD FACSComp Software User’s Guide*.

To perform manual setup:
1. Prepare an instrument setup tube by adding 500 µL of phosphate buffered saline (PBS) to a labeled BD Trucount tube.

2. Run the instrument setup tube in Setup mode and make the following adjustments:
   - Turn all compensation settings to 0.0%.
   - Set FSC to LINEAR amplification.
   - Set FL1, FL2, and SSC to LOG amplification. Use channel values.
   - Adjust FL2 threshold to approximately 300 to eliminate debris.
   - Under Acquisition and Storage, verify that the instrument resolution is 1,024.

3. Adjust the SSC, FL1, and FL2 photomultiplier tube (PMT) voltages to place the BD Trucount beads in the appropriate mean channel values as follows.
   - While viewing the SSC histogram (Figure 1), adjust the SSC PMT voltage to place the beads in channel 700 ± 20.

```
Marker Events Mean
All 8,340 696.54
M1 8,249 693.38
```

- While viewing the FL1 histogram (Figure 2), adjust the FL1 PMT voltage to place the beads in channel 800 ± 20.

```
Marker Events Mean
All 8,340 799.46
M1 8,203 797.95
```

- While viewing the FL2 histogram (Figure 5), adjust the FL2 PMT voltage so the beads are in channel 700 ± 20.
4. Save instrument settings.

**Sample Acquisition**

This section provides instructions for sample acquisition using a BD FACS brand cytometer running BD FACSComp software. For sample acquisition instructions using other cytometers, see the accompanying IFU.

1. Create an FL1 vs FL2 dot plot.

2. Begin acquisition of the prepared sample. If using the BD FACS Loader, a 10-second start-of-rack mix and a 3-second interim mix after every tube is recommended. Vortex the tubes immediately before placing them into the BD FACS Loader racks. For complete instructions on the BD FACS Loader, refer to the *BD FACS Loader User’s Guide*.

3. Without storing data, create regions R1 and R2, which contain BD Trucount beads and rWBCs respectively (Figure 6).

4. Confirm that the FL2 threshold is set appropriately.

5. Acquire and store all events. Stop acquisition when 10,000 events have been collected in R1 (the bead region).

**Data Analysis**

This section provides instructions for data analysis using a BD FACS brand cytometer running BD FACSComp software. For data analysis instructions using other cytometers, see the accompanying IFU.

1. To begin analysis, create an FL1 vs FL2 dot plot with statistics and regions R1 and R2 (Figure 6).

2. Obtain region statistics on sample data.

3. Perform the calculations as discussed in the Results section.

<table>
<thead>
<tr>
<th>Marker</th>
<th>Events</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>8,340</td>
<td>701.04</td>
</tr>
<tr>
<td>M1</td>
<td>8,121</td>
<td>698.72</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Region</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>10,000</td>
</tr>
<tr>
<td>R2</td>
<td>83</td>
</tr>
</tbody>
</table>
Gating Aid (Optional)

NOTE  The BD FACSVia flow cytometer does not use gating aids.

A gating aid sample can be prepared by making a 1:100 dilution of an ABO-matched, non-leucoreduced RBC segment using filtered red cells, plasma, PBS with 2% fetal bovine serum (FBS), or BD FACSFlow™ sheath fluid as the diluent. (We recommend ABO matching to avoid red-cell agglutination).

1. Follow the BD Leucocount staining procedure to prepare the gating aid sample.
2. Install the gating aid sample on the sample injection port.
3. Acquire the gating aid sample in setup mode.
4. As events are displayed, adjust R1 and R2, as needed.

8. RESULTS
The absolute number of rWBCs (A) in the sample is determined by the following calculation:

\[ A = \left( \frac{B}{C} \right) \times \left( \frac{D}{E} \right) \]

where:
\[ A = \text{absolute number of rWBC/µL} \]
\[ B = \text{WBC events for R2} \]
\[ C = \text{bead events for R1} \]
\[ D = \text{bead count per tube}^1 \]
\[ E = \text{stained sample volume} \]

Multiplying this result by the volume of the pack (in µL) results in the total number of WBCs in the entire pack.

Some systems, such as the BD FACSVia system, perform this calculation automatically. In the BD FACSVia system, R2 contains rWBC events, and R1 contains bead events.

9. LIMITATIONS

- The addition of a precise volume of blood is critical when BD Trucount tubes are used. The pipet used should be calibrated to deliver 100 µL of sample.
- Gently vortex samples immediately prior to running them on the flow cytometer to ensure thorough resuspension of cells and beads.
- Nucleated red cells contain nucleic acid and could be detected as rWBCs in this assay. However, nucleated red cells are not present in detectable quantities in blood from normal individuals.\(^1\)
- The use of EDTA with the BD Leucocount reagent is not recommended.
- For US:
  
  **CAUTION**  Federal Law restricts this device to sale by or on the order of a licensed practitioner.

10. PERFORMANCE CHARACTERISTICS

**Precision for BD FACSCalibur Flow Cytometers**

A study was conducted at two sites to assess stain-to-stain precision. Red blood cell samples and platelet samples were

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\(^1\) The lot-specific bead count is provided on the BD Trucount foil pouch.
prepared and then acquired. Results are shown in Table 1.

Table 1 Stain-to-stain precision of the BD Leucocount kit in RBC and platelet units

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Range of WBC/µL</th>
<th>No. of Samples</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–1</td>
<td>15</td>
<td>0.4</td>
<td>0.17</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>22</td>
<td>2.2</td>
<td>0.4</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>5–25</td>
<td>13</td>
<td>9.5</td>
<td>1.1</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>25–300</td>
<td>19</td>
<td>97.0</td>
<td>5.6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–1</td>
<td>21</td>
<td>0.4</td>
<td>0.13</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>13</td>
<td>2.4</td>
<td>0.35</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>5–25</td>
<td>13</td>
<td>11.0</td>
<td>0.87</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>25–300</td>
<td>16</td>
<td>96.0</td>
<td>4.96</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

a. SD = standard deviation
b. CV = coefficient of variation

Stability for BD FACSCalibur Flow Cytometers

A study at one site was conducted to assess sample and stained stability. Sample stability was evaluated by comparing the baseline sample (stained and acquired within 1 hour after leucoreduction) to a sample aliquot held for 24 or 48 hours (stained and acquired within 5 minutes). These results are shown in Table 2.

Table 2 Change from baseline of samples stained up to 48 hours following leucoreduction

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>n</th>
<th>Mean WBC/µL at Baseline</th>
<th>Mean Change (WBC/µL) at Sample Age of 24 Hours</th>
<th>Mean Change (WBC/µL) at Sample Age of 48 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs</td>
<td>7</td>
<td>15.5</td>
<td>–0.45</td>
<td>–0.8</td>
</tr>
<tr>
<td>Platelets</td>
<td>7</td>
<td>14.8</td>
<td>0.71</td>
<td>0.53</td>
</tr>
</tbody>
</table>

Both platelet and RBC samples can be tested up to 48 hours post leucoreduction. Platelets should be stored at room temperature, and RBCs should be refrigerated. Fresh to 24-hour old samples can be acquired up to 24 hours after staining. Alternatively, samples stored for 48 hours, and then stained, are stable for at least 60 minutes.

Accuracy for BD FACSCalibur Flow Cytometers

The BD Leucocount assay and the Nageotte method were compared for accuracy of residual white cell enumeration. This comparison was performed using both RBC and platelet samples at three blood bank sites. The results are shown in Figure 7, where n = 226 for RBCs and Figure 8 where n = 217 for platelets.

Stained sample stability was evaluated by comparing the baseline sample (stained and acquired within 1 hour of leucoreduction) to samples stained at 24 hours and then held for 24 hours prior to acquisition (Table 3).

Table 3 Change from baseline of samples stained up to 48 hours following leucoreduction

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>n</th>
<th>Mean WBC/µL at Baseline</th>
<th>Mean Change (WBC/µL) at Stain Age of 24 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs</td>
<td>7</td>
<td>15.5</td>
<td>–0.25</td>
</tr>
<tr>
<td>Platelets</td>
<td>7</td>
<td>14.8</td>
<td>0.33</td>
</tr>
</tbody>
</table>
Comparison of Flow Cytometers

BD FACSCalibur flow cytometers

A study was conducted at one site to compare performance of the BD Leucocount kit on flow cytometers from two different manufacturers. Thirty each of RBC and platelet samples were evaluated by regression analysis. Table 4 illustrates the results of that analysis.

Table 4 Comparison of BD Leucocount results on BD FACSCalibur flow cytometer vs another marketed flow cytometer

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs</td>
<td>30</td>
<td>1.06</td>
<td>-5.65</td>
<td>0.998</td>
</tr>
<tr>
<td>Platelets</td>
<td>30</td>
<td>0.99</td>
<td>-0.28</td>
<td>0.999</td>
</tr>
</tbody>
</table>

Linearity for BD FACSCalibur Flow Cytometers

The BD Leucocount kit provides linear results from 1 to 350 WBCs/µL.

Stability for BD FACSVia Flow Cytometers

A study at one clinical site was conducted to assess leucoreduced sample and stained sample stability. Sample stability and stained sample stability were evaluated by comparing the baseline sample (stained within 6 hours after leucoreduction and acquired within 30 minutes after staining) to a sample aliquot held for 24 or 48 hours, as shown in Table 5.

Table 5 Platelets and RBC time points

<table>
<thead>
<tr>
<th>Age of Sample</th>
<th>Age of Stain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 24 hours</td>
<td>24 hours ± 15 minutes</td>
</tr>
<tr>
<td>Within 48 hours</td>
<td>1 hour ± 15 minutes</td>
</tr>
</tbody>
</table>

Figure 7  Accuracy of the BD Leucocount assay vs Nageotte in RBC product

Figure 8  Accuracy of the BD Leucocount assay vs Nageotte in platelet product
These stability results are shown in Table 6 and Table 7.

Table 6: Change from baseline of samples stored up to 24 hours following leucoreduction

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>n</th>
<th>Mean rWBC/µL at Baseline</th>
<th>Mean Change (rWBC/µL) at Stained Sample Age of 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs</td>
<td>50</td>
<td>57.3</td>
<td>-0.3</td>
</tr>
<tr>
<td>Platelets</td>
<td>48</td>
<td>60.1</td>
<td>1.8</td>
</tr>
</tbody>
</table>

Table 7: Change from baseline of samples stored up to 48 hours following leucoreduction

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>n</th>
<th>Mean rWBC/µL at Baseline</th>
<th>Mean Change (rWBC/µL) at Stained Sample Age of 1 hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs</td>
<td>50</td>
<td>57.3</td>
<td>0.8</td>
</tr>
<tr>
<td>Platelets</td>
<td>48</td>
<td>60.1</td>
<td>-0.3</td>
</tr>
</tbody>
</table>

Both platelet and RBC samples can be tested up to 48 hours post leucoreduction. Platelets should be stored at room temperature (20°C–24°C), and RBCs should be stored at 1°C–6°C. Fresh to 24-hour old samples can be acquired up to 24 hours after staining. Alternatively, samples stored up to 48 hours, and then stained, are stable for 60 minutes after staining.

Accuracy for BD FACSViaFlow Cytometers

The BD Leucocount assay on the BD FACSVia and BD FACSCalibur flow cytometers was compared for accuracy of residual white cell enumeration. This comparison was performed using both RBC and platelet samples at four clinical sites. The results are shown in Figure 9 for RBC samples (n = 278) and Figure 10 for platelet samples (n = 252).
Linearity for BD FACSVia Flow Cytometers

Linearity of the BD Leucocount Kit was determined using triplicate measurements of 11 evenly spaced concentrations of autologous rWBCs spiked into leucoreduced platelet and RBC. The BD Leucocount Kit provides linear results from 0–350 WBCs/µL (platelets) and 0–350 WBCs/µL (RBCs).

Intrasite precision for BD FACSVia Flow Cytometers

A 20 day study was conducted at one site, BD Biosciences, to assess intrasite precision. Performance for the enumeration of rWBC absolute counts was determined across three BD FACSVia flow cytometers (two with an automated loader and one manual) and three operators by acquiring two levels of manipulated BD Leucocount RBC Control and BD Leucocount PLT Control cells as test samples stained in duplicate with two lots of BD Leucocount reagent.

Table 8 rWBCs in leucoreduced platelets

<table>
<thead>
<tr>
<th>Sample Level</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet Low</td>
<td>7.32</td>
<td>0.58</td>
<td>7.96</td>
</tr>
<tr>
<td>Platelet High</td>
<td>15.11</td>
<td>0.92</td>
<td>6.12</td>
</tr>
</tbody>
</table>

a. SD = standard deviation
b. CV = coefficient of variation

Table 9 rWBCs in leucoreduced RBCs

<table>
<thead>
<tr>
<th>Sample Level</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC Low</td>
<td>7.58</td>
<td>0.68</td>
<td>9.03</td>
</tr>
<tr>
<td>RBC High</td>
<td>16.50</td>
<td>1.12</td>
<td>6.81</td>
</tr>
</tbody>
</table>

a. SD = standard deviation
b. CV = coefficient of variation

Intersite precision for BD FACSVia Flow Cytometers

A 20 day study was conducted at three sites (two external sites and one site at BD Biosciences) to assess intersite precision. Two levels of manipulated BD Leucocount RBC Control and BD Leucocount PLT Control were stained in duplicate and then acquired each day on a BD FACSVia flow cytometer. Two operators were included in the study at each site. Results are shown in Table 10 and Table 11.

Table 10 rWBC in leucoreduced platelets

<table>
<thead>
<tr>
<th>Sample Level</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet Low</td>
<td>7.30</td>
<td>0.69</td>
<td>9.49</td>
</tr>
<tr>
<td>Platelet High</td>
<td>16.49</td>
<td>1.07</td>
<td>6.46</td>
</tr>
</tbody>
</table>

a. SD = standard deviation
b. CV = coefficient of variation

Table 11 rWBC in leucoreduced RBCs

<table>
<thead>
<tr>
<th>Sample Level</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC Low</td>
<td>6.76</td>
<td>0.73</td>
<td>10.76</td>
</tr>
<tr>
<td>RBC High</td>
<td>17.10</td>
<td>1.28</td>
<td>7.51</td>
</tr>
</tbody>
</table>

a. SD = standard deviation
b. CV = coefficient of variation

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.

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REFERENCES


