1. INTENDED USE

BD™ Multi-Check Control is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis on BD FACSLyric™, BD FACSCanto™ II, BD FACSCanto™, and BD FACSCalibur™ flow cytometers.

2. SUMMARY AND EXPLANATION

Lymphocyte immunophenotyping by flow cytometry is a complex, multistep process. BD Multi-Check Control is a stable control with assigned values that can be used to monitor the immunophenotyping process. BD Multi-Check Control should be treated in the same manner as whole blood.

3. PRINCIPLES OF THE PROCEDURE

Valid immunophenotyping results depend on proper technique, efficient RBC lysis, and clear separation of leucocyte populations. Separation of populations is based on such principles as light-scatter characteristics and reactivity with cell-specific, fluorescent monoclonal antibodies. Reliable intra- and inter-laboratory quality control for the immunophenotyping process can best be achieved with a stable, assayed control such as BD Multi-Check Control.1-4

4. REAGENT

Reagent Provided

BD Multi-Check Control contains stabilized human leucocytes and erythrocytes in a preservative medium. 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 used in preparation of this product has been tested by an FDA-licensed method 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 patient specimens as specified in the OSHA Bloodborne Pathogens Standard (29 CFR Part 1910.1030) or other equivalent biosafety procedures.

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 Assay Values sheet.
- Opened vials are stable for 9 thermal cycles (uses) when handled properly. A thermal cycle constitutes performing all steps under Section 6, Instructions for Use, once.
- Avoid unnecessary cycles of warming and cooling. Protect from freezing, from temperatures above 30°C, and from prolonged time (>30 minutes) at room temperature (20°C–25°C). Follow exactly the steps under Section 6, Instructions for Use.

Indications of Deterioration

The supernatant solution should be straw-colored to light pink. Discoloration of the supernatant fluid due to excessive hemolysis can be caused by heat or freezing.

5. **INSTRUMENTS**

BD Multi-Check Control can be used on the following systems. See Table 1.

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**Table 1 Recommended BD systems**

<table>
<thead>
<tr>
<th>Flow cytometer</th>
<th>Setup software</th>
<th>Analysis software</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD FACS Lyte</td>
<td>BD FACSuite™ Clinical software</td>
<td>BD FACSuite Clinical software</td>
</tr>
<tr>
<td>BD FACS Canto</td>
<td>BD FACS Canto™ clinical software</td>
<td>BD FACS Canto clinical software</td>
</tr>
<tr>
<td>BD FACS Calibur</td>
<td>BD FACSComp™ software v4.0 or later</td>
<td>BD Multiset™ software</td>
</tr>
</tbody>
</table>

6. **INSTRUCTIONS FOR USE**

1. Remove the vial from the refrigerator (2°C–8°C) and allow to stand at room temperature (20°C–25°C) for 15 minutes.

   **CAUTION**  Do not shake the vial or use a mechanical mixer.

2. Verify that the lot number on the vial label matches the lot number on the Assay Values sheet.

3. Hold the vial vertically between the palms of your hands and roll back and forth 10 times.

4. Gently invert the vial 10 times.
5. Repeat steps 2 and 3 until the cell pellet on the bottom of the vial is completely resuspended (3 to 4 cycles might be necessary).

6. Invert the vial 5 times immediately before sampling.

7. Set up the flow cytometer and use the monoclonal antibodies according to the manufacturer’s directions for patient samples.

8. Process the BD Multi-Check Control sample exactly as a patient sample.

   **NOTE** When using a lyse/wash sample preparation method, resuspend the final BD Multi-Check Control cell pellet in phosphate-buffered saline with 0.1% sodium azide (PBS/NaN₃) solution instead of a fixative solution.

9. Return the BD Multi-Check Control vial to the refrigerator immediately after sampling.

10. Confirm that the values obtained for each population fall within the ranges specified on the Assay Values sheet.

7. LIMITATIONS

   - Results are not guaranteed for markers not listed on the Assay Values sheet.
   - Some staining parameters of BD Multi-Check Control can differ from those observed with fresh whole blood. The use of additional fixatives following lysis of the RBC component in the BD Multi-Check Control sample can affect performance and is not recommended. Do not use beyond labeled expiration date.
   - BD Multi-Check Control is not intended as a control for hematology whole blood analyzers.
   - BD Multi-Check Control is not designed to act as an indicator of cellular viability. Use of vital staining dyes, such as propidium iodide (PI) and 7-aminoactinomycin D (7-AAD), with this product is not recommended.
   - If values are not obtained by single-platform methods, use the lymphocyte and white blood cell counts reported in the Assay Values sheet for calculating absolute values.
   - Expected values are listed as percent of total lymphocytes or as number of each phenotype. Number/µL is calculated by multiplying the percent of each phenotype by total lymphocyte counts obtained through independent analysis using a combination of technologies.
   - Incomplete mixing of the vial before use invalidates both the sample that is withdrawn and the remainder of the material in the vial.

8. EXPECTED RESULTS

The assay values reported in the Assay Values sheet are derived from flow cytometry results with immunophenotyping reagents used according to reagent manufacturer recommendations. Ranges for reported values are based on expected variations due to differences in reagents (antibodies and lysis buffers), instruments, technique, and data analysis.

Values are corrected, where appropriate, for lymphocyte purity as defined by CD45+ staining. With proper gating and lysis, lymphocyte purity and recovery should match the Centers for Disease Control (CDC) guidelines.
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.

REFERENCES