



BD® Stem Cell Control

CD34⁺ whole blood process control for monitoring the immunophenotyping of CD34⁺ cells

2 mL per level—Catalog No. 340991

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R_x Only

IVD

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1. INTENDED USE

The BD® Stem Cell Control is intended as a complete, two-level, process control for immunophenotyping and enumeration of leucocytes by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis.

2. SUMMARY

Immunophenotyping by flow cytometry is a complex, multi-step process. The BD® Stem Cell Control is a stable control, with assigned values that can be used to monitor the immunophenotyping process for CD34⁺ cells. The BD® Stem Cell Control should be treated in the same manner as whole blood.

3. PRINCIPLES OF THE PROCEDURE

Validity of immunophenotyping results depends on proper technique, efficient RBC lysis, and clear separation of leucocyte subpopulations. Separation of populations is based on such principles as light scatter characteristics, counter staining with nucleic acid binding dyes, CD45 antibody staining, 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 the BD® Stem Cell Control.¹⁻⁴

4. REAGENT

The BD® Stem Cell Control contains stabilized human leucocytes, erythrocytes, and peripheral blood CD34⁺ cells (mobilized or natural, or both) in a preservative medium. The cells have been assayed for CD34 immunoreactivity.

Assay ranges can be found in the Assay Values sheet included with the product.

Precautions

- For In Vitro Diagnostic Use.

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 sheet.
- Opened vials are stable for 12 thermal cycles (uses) when handled properly. A thermal cycle constitutes performing all steps under Section 5, Procedure, once.
- Avoid unnecessary cycles of warming and cooling. Protect this product from freezing, from temperatures above 30°C, and from prolonged time at room temperature (18°C–26°C). Follow exactly the steps in Section 5, Procedure.

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. PROCEDURE

1. Remove the vial from the refrigerator (2°C–8°C) and allow to stand at room temperature (18°C–26°C) for 15 minutes.

CAUTION 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. Repeat steps 2 and 3 until the cell pellet on the bottom of the vial is completely suspended (3 to 4 cycles might be necessary).
5. Invert the vial 5 times immediately before sampling.
6. Set up the flow cytometer and use the monoclonal antibodies according to the manufacturer's directions for patient samples.
7. Process the BD® Stem Cell Control exactly as a patient sample.
8. Return the BD® Stem Cell Control to the refrigerator immediately after sampling.

6. 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. CD34+ events are reported as a percentage of total CD45+ leucocytes.

Ranges for reported values are based on expected variations due to differences in reagents (antibodies and RBC lysing solutions), instruments, staining technique, and data analysis.

NOTE Each laboratory should establish its own acceptable ranges.⁵

The choice of gating strategy for CD34 enumeration will influence the results. It is essential that the results be reviewed to ensure that the events classified as CD34+ cells are consistent with the phenotypic properties of human hematopoietic progenitor cells.⁶⁻⁸

See reference numbers 6, 7, and 8 for guidelines and suggestions for immunophenotypic analysis of lymphocytes and CD34+ cells.

7. LIMITATIONS

- Results are not guaranteed for markers not listed on the assay sheet.
- Some staining parameters of the BD[®] Stem Cell Control might differ from those observed with fresh whole blood. The use of additional fixatives following lysis of the RBC component in the BD[®] Stem Cell Control can affect performance and is not recommended. Do not use beyond the labeled expiration date.
- The BD[®] Stem Cell Control is not intended as a control for hematology whole blood analyzers.
- The BD[®] Stem Cell 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-ADD), with this product is not recommended.

- If values are not obtained by single-platform methods, use the white blood cell count reported in the Assay Values sheet for calculating absolute values.
- Incomplete mixing of the vial before use invalidates both the sample that is withdrawn and the remainder of the material in the vial.

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 NON-INFRINGEMENT. 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.

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