BD Multi-Check™ CD4 Low Control

Form	Catalog No.
One 2.5-mL vial	349703
Two 2.5-mL vials	349704
Five 2.5-mL vials	349705

23-19823(03)
2023-08
English

℞ Only IVD

1. INTENDED USE

BD Multi-Check™ CD4 Low 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.

The BD Multi-Check™ CD4 Low Control is also intended to be a CD4 and %CD4 process control for antibody staining, instrument performance, and data analysis on the BD FACSPresto™ system, an imaging cytometer.

2. SUMMARY AND EXPLANATION

BD Multi-Check™ CD4 Low Control is a stable control with assigned values that can be used to monitor the immunophenotyping process. BD Multi-Check™ CD4 Low 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 (flow cytometry only), and clear separation of leukocyte 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™ CD4 Low Control.[1,2]

4. REAGENT

Reagent Provided

BD Multi-Check™ CD4 Low Control contains stabilized human leukocytes 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 2–8 °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 (20–25 °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™ CD4 Low Control can be used on the following systems. See Table 1.

Table 1 Recommended BD systems

Flow cytometer	Setup software	Analysis software
BD FACSLyric™	BD FACSuite™ Clinical application	BD FACSuite™ Clinical application
BD FACSCanto™ BD FACSCanto™ II	BD FACSCanto™ Clinical Software	BD FACSCanto™ Clinical Software
BD FACSCalibur™	BD FACSComp™ software v4.0 or later	BD Multiset™ software
BD FACSPresto™	BD FACSPresto™ integrated software	BD FACSPresto™ integrated software

6. INSTRUCTIONS FOR USE

1. Set up the instrument and ensure that it is ready to run samples.

   See the appropriate Instructions for Use (IFU) for the instrument.

2. Remove the vial from the refrigerator (2–8 °C) and allow to stand at room temperature (20–25 °C) for 15 minutes.
3. Verify that the lot number on the vial label matches the lot number on the Assay Values sheet.
4. Hold the vial vertically between the palms of your hands and roll back and forth 10 times.

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

5. Gently invert the vial 10 times.

6. Repeat steps 4 and 5 until the cell pellet on the bottom of the vial is completely resuspended (3 to 4 cycles might be necessary).
7. Invert the vial 5 times immediately before sampling.

   Insufficient mixing may cause inaccurate results.
8. Remove an aliquot from the vial.

   For flow cytometers, use the sample volume recommended for the reagent used to stain the sample and place it in a 12 × 75-mm tube. See the reagent IFU for details.

   For BD FACSPresto™, dispense the control sample into the cartridge inlet port. See the *BD FACSPresto™ System Instructions For Use* for details.
9. Return the BD Multi-Check™ CD4 Low Control vial to the refrigerator immediately after sampling.
10. Process the BD Multi-Check™ CD4 Low Control sample exactly as a patient sample.

    NOTE When using the lyse/wash sample preparation method, resuspend the final BD Multi-Check™ CD4 Low Control cell pellet in phosphate-buffered saline with 0.1% sodium azide (PBS/NaN_3) solution instead of a fixative solution.
11. 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.
- Do not use BD Multi-Check™ CD4 Low Control beyond the labeled expiration date.
- Do not use BD Multi-Check™ CD4 Low Control beyond the recommended 9 thermal cycles.
- When used on flow cytometers, some staining parameters of BD Multi-Check™ CD4 Low Control can differ from those observed with fresh whole blood. The use of additional fixatives following lysis of the RBC component in BD Multi-Check™ CD4 Low Control can affect performance and is not recommended.
- BD Multi-Check™ CD4 Low Control is not intended as a control for hematology whole blood analyzers.
- BD Multi-Check™ CD4 Low 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.
- When used on flow cytometers, 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.
- For flow cytometers, 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.
- For the BD FACSPresto™ system, expected values are listed as %CD4 and absolute CD4 count.
- Incomplete mixing of the vial before use compromises 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 or BD FACSPresto™ 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

1. *Enumeration of Immunologically Defined Cell Populations by Flow Cytometry—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI document H42-A2.
2. Centers for Disease Control. 1997 Revised guidelines for performing $CD4^+$ T-cell determinations in persons infected with human immunodeficiency virus (HIV). *MMWR*. 1997;46:1-29.

PATENTS AND TRADEMARKS

For US patents that may apply, see bd.com/patents.

Symbols Glossary

Please refer to product labeling for applicable symbols.

Symbol	Meaning
	Manufacturer
EC REP	Authorized representative in the European Community
CH REP	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
STERILE	Sterile fluid path
STERILE EO	Sterile fluid path (ethylene oxide)
STERILE R	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
LATEX	Contains or presence of natural rubber latex
IVD	In vitro diagnostic medical device
CONTROL -	Negative control
CONTROL +	Positive control
Σ	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic
#	Patient number
	This way up
	Do not stack

Symbol	Meaning
	Single sterile barrier system
PHT DEHP BBP	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
CE	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
Rx Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
CC	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
12	Collection date
	Keep away from light
H_2	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
/	<Box #> / <Total Boxes>
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
FC	Meets FCC requirements per 21 CFR Part 15
c UL us	UL product certification for US and Canada
UDI	Unique device identifier
	Importer
	Place patient label in framed area only
MR	Magnetic resonance (MR) safe
MR	Magnetic resonance (MR) conditional
MR	Magnetic resonance (MR) unsafe
For use with	For use with
This Product Contains Dry Natural Rubber	This Product Contains Dry Natural Rubber
For Export Only	For Export Only
Instruments	Instruments

Note: Text layout in symbols is determined by label design.

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HISTORY

Revision	Date	Changes made
23-19823(03)	2023-08	Updated legal manufacturer address. Added symbols glossary. Added History section. Added Patents and Trademarks section.