BD FACSDiva™ CS&T IVD Beads

Catalog No.	Volume
656046	One 3-mL vial
656047	Three 3-mL vials

23-13313(04)
2023-09
English

CE IVD

1. INTENDED USE

BD FACSDiva™ CS&T IVD Beads are intended for in vitro diagnostic use on BD FACSCanto™ II flow cytometers running BD FACSDiva™ software. BD FACSDiva™ CS&T IVD Beads are used to set up the cytometer, to perform daily performance quality control (QC), and to determine lyse/wash (LW) application settings.

2. SUMMARY OF THE TEST

BD FACSDiva™ CS&T IVD Beads allow the software to automatically characterize, track, and report measurements of the cytometer. Automated algorithms in the software define the cytometer baseline. Once baseline mean fluorescence intensity (MFI) target values are defined, the beads are used to run daily performance checks. BD FACSDiva™ CS&T IVD Beads are also used to reset MFI target values when switching to a new lot of beads.

In addition, BD FACSDiva™ CS&T IVD Beads are used to manually determine LW application settings. Once saved, LW application settings are automatically updated after the user performs the daily cytometer performance check, based on the instrument performance that day.

BD FACSDiva™ CS&T IVD Beads are intended for use by laboratory professionals.

Principle of Operation

BD FACSDiva™ CS&T IVD Beads are dyed with fluorochromes which are excited by the cytometer's lasers. The beads emit fluorescence in detectors used for the following fluorochromes (see Table 1).

Table 1 Fluorochromes supported by BD FACSDiva™ CS&T IVD Beads

Fluorochromes	Excitation laser	Emission range (nm)
FITC, PE, PerCP-Cy5.5, PE-Cy7	Blue	500–800
APC, APC-Cy7, APC-H7	Red	650–800
BD Horizon™ V450, BD Horizon™ V500-C	Violet	420–700

BD FACSDiva™ CS&T IVD Beads consist of equal quantities of 3-µm bright, 3-µm mid, and 2-µm dim polystyrene beads. The following figures show BD FACSDiva™ CS&T IVD Beads analyzed by flow cytometry. Data was acquired using a BD FACSCanto™ II flow cytometer and BD FACSDiva™ software. Laser excitation was at 488 nm.

Figure 1 Dot plot showing BD FACSDiva™ CS&T IVD Beads

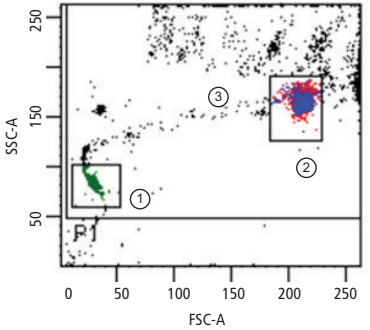
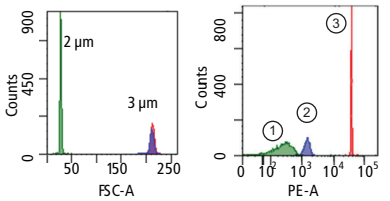


Figure 2 Histograms showing bead size and separation of BD FACSDiva™ CS&T IVD Beads



No.	Description
1	Dim
2	Mid
3	Bright

MFI and robust coefficient of variation (rCV) are measured for each bead intensity in all fluorescence detectors. Algorithms within the software differentiate the fluorescence signal from each bead type based on size and fluorescence intensity in each detector. The software then uses this data to calculate and report a variety of setup measurements, including linearity, relative fluorescence detection efficiency (Qr), relative background (Br), standard deviation of electronic noise (SD_{EN}), and laser delays.

3. REAGENT

Reagent Composition

BD FACSDiva™ CS&T IVD Beads are supplied in phosphate buffered saline (PBS) with bovine serum albumin (BSA) and 0.1% sodium azide.

Precautions

- For In Vitro Diagnostic Use.
- Avoid exposing BD FACSDiva™ CS&T IVD Beads to direct light.
- Do not run BD FACSDiva™ CS&T IVD Beads without first diluting them with BD FACSFlow™ Sheath Fluid, as directed in Preparing a BD FACSDiva™ CS&T IVD Beads suspension. Using a diluent other than BD FACSFlow™ Sheath Fluid may result in inaccurate setups.
- Do not use BD FACSDiva™ CS&T IVD Beads beyond their expiration date or beyond the day-of-use stability period after dilution, as described in Storage and handling. Beads used beyond their stability period begin to lose fluorescence, which may result in inaccurate setups.
- Ensure that you reserve enough of the current lot of BD FACSDiva™ CS&T IVD Beads to reset target values when switching to a new lot of beads (see Table 2). If you do not have enough of the current lot to reset the target values, you must define a new baseline using the new bead lot.
- BD FACSDiva™ CS&T IVD Beads contain sodium azide as a preservative.
- Go to regdocs.bd.com to download the Safety Data Sheet.

Storage and Handling

- Store vials at 2–8 °C and protect from light. Do not use after the expiration date shown on the label.
- After dilution, the beads are stable for 8 hours at 2–25 °C.

  WARNING Keep the diluted beads suspension protected from light. Some of the dyes used to manufacture the beads are very light-sensitive. Fluorescence levels can change if beads are exposed to direct light for longer than 20 minutes.

4. INSTRUMENT

BD FACSDiva™ CS&T IVD Beads are for use on a BD FACSCanto™ II flow cytometer with a 3-laser, 8-color, (4-2-2) (BD-default) configuration (4-2H-2V) running BD FACSDiva™ software, v7.0 or later.

5. PROCEDURE

Reagents and Materials

Reagents and materials provided

BD FACSDiva™ CS&T IVD Beads:

- One 3-mL vial (Catalog No. 656046)
- Three 3-mL vials (Catalog No. 656047)

  Each 3-mL vial contains sufficient beads to run 50 tests (a test equals one drop of beads).
- Card containing the MFI target values for all of the fluorescence detectors

Reagents and materials required but not provided

- Disposable 12 x 75-mm capped polystyrene test tubes
- BD FACSFlow™ Sheath Fluid (Catalog No. 342003)

Preparing a BD FACSDiva™ CS&T IVD Beads suspension

To prepare the BD FACSDiva™ CS&T IVD Beads for acquisition, follow the instructions exactly as described according to the task being performed.

1. Label a 12 x 75-mm capped polystyrene tube according to Table 2 and the task you are performing.
2. Thoroughly mix the BD FACSDiva™ CS&T IVD Beads vial.
3. Prepare the diluted beads according to Table 2 and the task you are performing.

   WARNING Avoid dripping the beads down the side of the tube when diluting them. This can lead to low bead counts during acquisition.
4. Vortex the tube gently before use.

Table 2 BD FACSDiva™ CS&T IVD Beads preparation

	Add...		
Task	**BD FACSFlow™ Sheath Fluid (mL)**	**Beads (number of drops)**	**To the tube labeled...**
Defining a baseline	0.5	3	Setup beads
Running a performance check	0.35	1	Setup beads
Determining LW application settings	1	2	Setup beads
Resetting target values	0.5	3	Old lot
	0.5	3	New lot

NOTE Do not dilute BD FACSDiva™ CS&T IVD Beads more than recommended.

Setting up the cytometer using BD FACSDiva™ CS&T IVD Beads

The following table gives an overview of the procedures needed to perform instrument setup and establish LW application settings using BD FACSDiva™ CS&T IVD Beads: importing and verifying a bead lot file, defining the cytometer baseline, running a cytometer performance check, determining LW application settings, and resetting the target values for a new bead lot. These tasks are described in Table 3.

Table 3 BD FACSDiva™ CS&T IVD Beads tasks

Task	When performed	By whom
Importing a bead lot file	Each time a new bead lot is used	Administrator
Defining a baseline	At initial setup, after performing service maintenance, and whenever the baseline expires	Administrator
Running a performance check	Daily	Any operator
Determining LW application settings	Every 7 days, whenever a new baseline is defined, and whenever you reset target values for a new lot of beads	Any operator
Resetting target values	Each time a new bead lot is used	Administrator

Opening the BD Cytometer Setup and Tracking workspace

1. Start the BD FACSCanto™ II flow cytometer and the computer.
2. Start BD FACSDiva™ software.
3. Perform fluidics startup.
4. Select **Cytometer > CST** after laser warmup is complete.

   The BD® Cytometer Setup and Tracking (CS&T) workspace opens.
5. Run CS&T tasks.

Importing a BD FACSDiva™ CS&T IVD Beads lot file

Before using a new lot of BD FACSDiva™ CS&T IVD Beads, the administrator must download the appropriate bead lot file. BD FACSDiva™ software uses information in this file to characterize your cytometer and to normalize one bead lot to another when switching bead lots.

To download the bead lot file:

1. Visit our website (http://www.bdbiosciences.com/eu/support) and navigate to the BD FACSDiva™ CS&T IVD Beads Lot Files page.

2. Download the appropriate bead lot file to your workstation or to a USB flash drive and then save the file to:
   - **Windows XP, BD FACSDiva™ v7.0:** C:\ProgramFiles\BD FACSDiva™ Software\CST\BeadLot
   - **Windows 7, BD FACSDiva™ v8.0:** D:\BD\FACSDiva\CST\Bead Lot

   NOTE Ensure that the bead lot file you download corresponds to your current lot of BD FACSDiva™ CS&T IVD Beads.
3. Log in to BD FACSDiva™ software as an administrator.
4. In the BD FACSDiva™ workspace, select **Cytometer > CST**. In the BD FACSDiva™ CS&T workspace, select **Tools > Bead Lots** and do one of the following:
   - Verify that the Setup Beads tab is displayed; the bead lot you are using is selected; and bead part number, lot ID, and expiration date appear in the appropriate fields.
   - If your bead lot does not appear in the Lot IDs list, go to step 5.
5. In the **Bead Lots** dialog, click **Import**.

   An Open dialog for the Bead Lots folder appears.
6. Select the bead lot file (ending in .bls). Click **Open**.

   The bead lot information is automatically entered.
7. Close the **Bead Lots** dialog.
8. **NOTE**If internet access is not available and you are unable to download the bead lot file, please contact BD Biosciences scientific support or your local BD Biosciences representative.

Defining a baseline

At initial setup, after instrument service maintenance, and whenever the baseline has expired (see Table 3), define the cytometer baseline by navigating to the Setup Control window in the BD FACSDiva™ CS&T workspace and doing the following:

1. Select **Define Baseline** from the **Characterize** menu.
2. Select the **Load Tube Manually** checkbox.
3. Verify that the setup beads lot ID selected matches your current lot of BD FACSDiva™ CS&T IVD Beads. If not, select the correct BD FACSDiva™ CS&T IVD Beads lot ID from the **Lot ID** menu.
4. Verify that the 4-2H-2V cytometer configuration is selected.
5. Click **Run.**

   A dialog prompts you to load the BD FACSDiva™ CS&T IVD Beads tube onto the cytometer.

6. Install the tube on the cytometer. Click **OK**.

   The Running Cytometer Baseline window opens.
7. After viewing the Optimized PMTVs Results, click **Continue Setup**.
8. After viewing the Target Values Results, click **Continue Setup**.
9. Remove the tube from the cytometer when prompted.
10. To view the Baseline Report, click **View Report**. To print it, select **File > Print**.
11. To complete the baseline definition and return to the Setup View of the workspace, click **Finish**.
12. Run a performance check.

Running a Performance Check

Run a performance check every 24 hours and after defining a baseline.

1. In the **Setup Control** window, select **Check Performance** from the **Characterize** menu.
2. Select the **Load Tube Manually** checkbox.
3. Verify that the setup beads lot ID selected matches your current lot of BD FACSDiva™ CS&T IVD Beads. If not, select the correct BD FACSDiva™ CS&T IVD Beads lot ID from the **Lot ID** menu.
4. Verify that the 4-2H-2V cytometer configuration is selected.
5. Install the tube on the cytometer.
6. Click **Run**. Click **OK** to confirm that the tube has been loaded.

   The Checking Cytometer Performance window opens. Once the performance check is complete, a dialog opens prompting you to remove the tube. A second dialog opens when setup has completed.
7. To view the Cytometer Performance Report, click **View Report**. To print it, select **File > Print**.
8. To complete the performance check and return to the Setup View of the workspace, click **Finish**.
9. View the status of the baseline and the cytometer performance results in the System Summary view (see Figure 3).

Figure 3 System Summary view of the Cytometer Performance Report

- If the Cytometer Performance Check was successful, the Cytometer Performance Results are shown as Passed. If it was unsuccessful, the results are shown as Failed.

NOTE Additional information can be obtained from the Cytometer Performance line in the System Summary view (see Figure 3). If the Cytometer Performance line displays the message *completed with warnings* along with the date, review the report to troubleshoot issues, then continue (see Troubleshooting).

10. To track the performance of the cytometer, navigate to the **Performance Tracking** tab in the BD FACSDiva™ CS&T workspace.

    NOTE The data from the Cytometer Performance Report is displayed as Levey-Jennings plots. You can choose to view up to 30 criteria at one time.

11. Select **File > Exit.**

12. The BD FACSDiva™ CS&T workspace closes and returns to the BD FACSDiva™ workspace.

Determining lyse/wash (LW) application settings

Determine LW application settings every 7 days, whenever a new baseline is defined, and whenever you reset target values (see Table 3).

NOTE To set the LW application settings, you will need a tube of BD FACSDiva™ CS&T IVD Beads, a tube of prepared cells, and the card containing the MFI target values for the lot ID of BD FACSDiva™ CS&T IVD Beads used.

1. Prepare the BD FACSDiva™ CS&T IVD Beads as described in Table 2.
2. In the BD FACSDiva™ workspace, confirm that the 4-2H-2V cytometer configuration is selected.
3. Create a new experiment in the Browser or within a specific folder in the Browser. Confirm that BD FACSDiva™ CS&T Settings have been applied.

   NOTE If the CST Mismatch dialog is displayed, click **Use CST Settings**.

4. Add a specimen to the experiment.

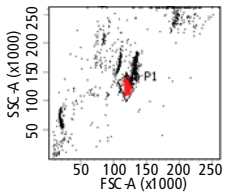
5. Create the following analysis elements on the global worksheet.
   - Display an FSC-A vs SSC-A dot plot with a polygon gate (P1) (see Figure 4).
   - Display eight histograms (one for each fluorescence parameter) using the area measurement, with a single interval gate on each histogram, showing only P1 events (see Figure 5).

   NOTE To show only P1 events, select all the histograms, right-click, and select **Show Populations > P1**.

   - Select bi-exponential display for each histogram and set the plots to display cumulative events.
   - Create a single Statistics View. Edit the Statistics View to display median values for each parameter.
6. Determine detector voltages to place the BD FACSDiva™ CS&T IVD Beads at target values.
   - Install the BD FACSDiva™ CS&T IVD Beads tube on the cytometer.
   - Set the flow rate to Medium.
   - Click **Acquire** and adjust the P1 gate around the 3-µm single bead population (see Figure 4).

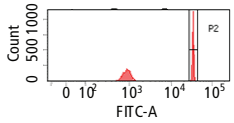
   NOTE Ensure that the P1 gate contains only 3-µm singlet beads. If necessary, zoom in on the FSC-A vs SSC-A plot, adjust the gate, and then zoom out.

Figure 4 FSC-A vs SSC-A dot plot showing the P1 gate around the 3-µm singlet bead population



   - Adjust the fluorescence detector voltages to place the BD FACSDiva™ CS&T IVD Beads 3-µm bright beads peak within the defined range of MFI target values for each parameter on the card provided by BD. Make sure that the bead lot number on the card matches the lot ID of the BD FACSDiva™ CS&T IVD Beads used.
   - Examine each histogram to ensure that the interval gate tightly brackets the 3-µm bright bead peak (see Figure 5). If the peak has a shoulder, do not include it inside the gate, because it contains aggregates, not single beads.

Figure 5 Histogram showing the 3-µm bright bead peak for FITC



- Click **Stop**. Print a copy of the worksheet for your records.

7. Determine FSC, SSC, and threshold settings for cells that will be acquired using these application settings.
   - Install the tube containing a sample of the cells on the cytometer.
   - In the Experiment Browser, set the current tube pointer to the tube that was used to set the PMT voltages, click **Acquire,** and adjust the FSC and SSC detector voltages to place the cells of interest on scale.

   NOTE To see the cells on scale, initially adjust the FSC detector voltage to below 400.

   - Adjust the FSC threshold to minimize debris.
   - Click **Stop**. Print a copy of the worksheet for your records.
8. Save the instrument settings as LW application settings. Right-click the experiment-level **Cytometer Settings** and select **Application Settings > Save.**
9. Name the application settings, for example, *4-2H-2V LW*.

   NOTE We recommend that you use the same name whenever you update the LW application settings. This overwrites the current settings, avoiding any confusion over which application settings to use.
10. Set compensation as needed.

Resetting target values

Before switching to a new lot of BD FACSDiva™ CS&T IVD Beads, reset the target values using the current bead lot and the new bead lot. The software uses this information to reset the target values of the new lot to the same PMTVs as the current lot.

NOTE Ensure that you have enough of the current lot of BD FACSDiva™ CS&T IVD Beads to reset the target values for the new lot (see Table 2). If you do not have enough of the current lot to reset the target values, you must define a new baseline using the new bead lot.

Start the computer, cytometer, and software. Log in to BD FACSDiva™ software as an administrator.

Before you begin, download the lot-specific file for the new bead lot. See Importing a BD FACSDiva™ CS&T IVD Beads lot file.

1. In the **Setup Control** window, select **Reset Target Values** from the **Characterize** menu.
2. Select the **Load Tube Manually** checkbox.
3. Verify that the setup beads lot IDs for the old (current) BD FACSDiva™ CS&T IVD Beads bead lot and the new bead lot are correct.
4. Verify that the 4-2H-2V cytometer configuration is selected.
5. Install the tube containing the old (current) bead lot on the cytometer.
6. Click **Run**.

   The Resetting Target Values window opens.
7. When prompted, remove the tube containing the old bead lot and install the tube containing the new bead lot.
8. When prompted, remove the tube containing the new bead lot.

   When the task is complete, a dialog opens, prompting you to view the Reset Target Values Report.
9. To view the report, click **View Report**. To print it, select **File > Print**.
10. To complete resetting the target values and return to the Setup View of the workspace, click **Finish**.
11. Select **File > Exit**.
12. The CS&T workspace closes and returns to the BD FACSDiva™ workspace.

6. RESULTS

Reviewing the Cytometer Performance Report

The Cytometer Performance Report contains cytometer information, BD FACSDiva™ CS&T IVD Beads lot information, detector and laser settings, specifications, cytometer settings from the detector settings section of the Performance Report, and pass/fail results. Descriptions of measurements taken for the detector settings are provided in Table 4.

Table 4 Detector settings

Measurement	Description
Laser	Laser name
Detector	Scatter or fluorescence detector
Parameter	Fluorochrome name (assigned)
Target Value	Target MFI value defined by the baseline
Actual Target Value	MFI value measured during the performance check

Table 4 Detector settings

Measurement	Description
% Difference Target Value	Percent difference between the baseline target MFI value and the MFI value determined during the performance check
Bright Bead % Robust CV	Percent robust coefficient of variation of the bright beads
Mid Bead Median Channel	MFI value of the mid beads, used in the calculation of photon detection efficiency (Qr) and linearity
Mid Bead % Robust CV	Percent robust coefficient of variation of the mid beads, a value used in the calculation of photon detection efficiency (Qr)
Dim Bead Median Channel	MFI value of the dim beads, used in the calculation of relative optical background fluorescence (Br) in the detector
Dim Bead % Robust CV	Percent robust coefficient of variation of the dim beads, a value used in the determination of relative optical background (Br) in the detector
PMTV	The photomultiplier tube (PMT) voltage value from the current performance check
ΔPMTV	The difference between the PMT voltage from the baseline check and the current performance check
Qr	Relative fluorescence detection efficiency, a measurement used for tracking the light collection efficiency of a detector
Br	Relative optical background signal, a measurement used for tracking optical background levels in a detector
P/F	Pass or Fail: the cytometer performance check passes if the difference between the baseline PMT setting and the current PMT setting is within 50 volts, the laser power and sheath pressure are within range, and the bright bead %rCVs in the primary channels (FITC, APC, V450) are below 6%

7. LIMITATIONS

- BD FACSDiva™ CS&T IVD Beads are intended for use with BD FACSDiva™ software v7.0 or later, running on a BD FACSCanto™ II flow cytometer set with the 4-2H-2V configuration.
- BD FACSDiva™ CS&T IVD Beads do not perform as a fluorescence calibrator and should not be used for setting up a flow cytometer for quantitative fluorescence measurements.

8. PERFORMANCE CHARACTERISTICS

Reproducibility of LW setup

LW application settings were determined using 3 lots of BD FACSDiva™ CS&T IVD Beads on each of 4 separate BD FACSCanto™ II flow cytometers. Whole blood cells were stained in triplicate with each single-color fluorochrome-conjugated antibody, and acquired using each of the LW application settings on each cytometer.

Reproducibility was determined for the MFI values of the stained cell populations as two separate components. The first component (lot-to-lot reproducibility) is shown in

Table 5. The second component (instrument-to-instrument reproducibility) is shown in Table 6.

Table 5 Reproducibility of MFI values (lot-to-lot)

Parameter	%CV
FITC	1.9
PE	1.2
PerCP-Cy5.5	4.8
PE-Cy7	1.6
APC	1.9
APC-H7	1.2
V450	1.1
V500	3.8

Table 6 Reproducibility of MFI values (instrument-to-instrument)

Parameter	%CV
FITC	8.7
PE	3.6
PerCP-Cy5.5	14.0
PE-Cy7	1.9
APC	4.4
APC-H7	3.1
V450	6.3
V500	3.7

Repeatability of performance checks

Ten replicate performance checks were run on each of 3 lots of BD FACSDiva™ CS&T IVD Beads using 3 separate BD FACSCanto™ II flow cytometers. The %CV of the bright bead %rCVs and the %CV of the bright bead MFIs were calculated for each detector. The intra-assay precision (tube-to-tube repeatability) is shown in Table 7.

Table 7 Repeatability of performance checks

Parameter	%CV of bright bead %rCV	%CV of bright bead MFI
FSC	15.5	0.33
SSC	9.6	0.52

Table 7 Repeatability of performance checks

Parameter	%CV of bright bead %rCV	%CV of bright bead MFI
FITC	5.3	0.48
PE	7.6	0.36
PerCP-Cy5.5	3.7	0.48
PE-Cy7	2.1	0.71
APC	2.2	0.48
APC-H7	3.2	0.45
V450	2.8	0.65
V500	3.1	0.68

9. TROUBLESHOOTING

Problem	Possible Cause	Solution
No beads detected	Beads not mixed prior to diluting, beads too dilute, debris in the beads suspension, incorrect beads used	Vortex the beads vial, prepare a fresh suspension of beads, and re-run the tube.
	Air bubbles in the flow cell or sheath filter	Check the fluidics for bubbles and debris. See the cytometer IFU for more information.
	Clogs within the sample tubes and lines	Check the fluidics for clogs and debris. See the cytometer IFU for more information.
	Backpressure in the waste lines	Check the waste tank vent for obstructions. See the cytometer IFU for more information.
	High scatter noise (FSC or SSC)	Perform monthly maintenance. See the cytometer IFU for more information. Call BD Biosciences.
Performance check completed with warnings	A relative change in the performance of the cytometer	Review the Cytometer Performance Report to determine whether the specific warnings impact the experiment, then continue.
		Prepare a fresh suspension of beads and re-run the performance check.
		Perform the monthly cleaning procedure. See the cytometer IFU for more information.

Problem	Possible Cause	Solution
Performance check failure	The rCV ratio of dim to mid beads is less than 1.5	Prepare a fresh suspension of beads and re-run the performance check.
		Perform the monthly cleaning procedure. See the cytometer IFU for more information.
	Value(s) for any of the measurements used to check the cytometer performance (see Table 4) are out of spec	Prepare a fresh suspension of beads and re-run the performance check.
		Perform the monthly cleaning procedure. See the cytometer IFU for more information. Call BD Biosciences.

For additional troubleshooting assistance, contact BD Biosciences scientific support or your local BD Biosciences representative.

NOTICE

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

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.

PATENTS AND TRADEMARKS

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

Cy™ is a trademark of GE Healthcare.

HISTORY

Revision	Date	Changes made
23-13313(03)	2022-04	Updated to meet requirements for Regulation (EU) 2017/746.
23-13313(04)	2023-09	Updated legal manufacturer address and symbols glossary. Added US patents link, EU and Swiss importer addresses and importer symbol.

SYMBOLS GLOSSARY

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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-PYROGENIC	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
n	Contains sufficient for *<n>* tests
	For IVD performance evaluation only
	Non-pyrogenic
#	Patient number
	This way
	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."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
i	<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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