BD HLA-B27 Kit

Catalog No. 340183

23-2563(16)
2023-10
English

Rx Only CE IVD

1. INTENDED USE

The BD® HLA-B27 system is a qualitative two-color direct immunofluorescence method for the rapid detection of HLA-B27 antigen expression in erythrocyte-lysed whole blood (LWB) using the BD FACSVia™, BD FACSCanto™, BD FACSCalibur™, BD FACSort™, or BD FACScan™ flow cytometers.

Not for use in tissue typing.

2. SUMMARY AND EXPLANATION

HLA-B27 is a major histocompatibility complex (MHC) class I molecule. MHC class I molecules are cell-surface glycoproteins that are expressed on most nucleated human cells and platelets.[1]

The presence of HLA-B27 antigen is strongly associated with ankylosing spondylitis (AS), a chronic inflammatory disease of the axial musculoskeletal system, and a few other rheumatic disorders (Reiter's syndrome, acute anterior uveitis, and inflammatory bowel disease).[2] HLA-B27 testing is routinely used to screen for AS since 90% of patients with AS have the HLA-B27 surface antigen compared to only 8% of healthy individuals.[3]

3. PRINCIPLES OF THE PROCEDURE

Cell Preparation

When Anti–HLA-B27 FITC/CD3 PE monoclonal antibody reagent is added to human whole blood, the fluorochrome-labeled antibodies bind specifically to leukocyte surface antigens. The stained samples are treated with BD® HLA-B27 BD FACS™ Lysing Solution to lyse erythrocytes and then washed and fixed before flow cytometric analysis.

Flow Cytometer Setup

This section provides guidelines for instrument setup of BD flow cytometers that require instrument setup.

Instrument setup for any of the BD FACSCanto™ family of flow cytometers is done using BD FACS™ 7-Color Setup Beads and BD FACSCanto™ Clinical Software.

The BD FACSCalibur™ flow cytometer is initially set up using BD Calibrite™ Beads with BD FACSComp™ software.

The FITC/FL1 detector voltage is set specifically for the assay using HLA-B27 calibration beads. The suffix on the bead vial is the target value, in units of log median fluorescence (LMF) for 256 channels full scale. **The suffix must be entered correctly in the software or results can be incorrect.** The software then adjusts the detector voltage until the bead attains the target value LMF. For the BD FACSCalibur™ instrument only, the bead is used additionally to set the FSC gain. Reports are produced by the appropriate software to verify correct setup.

Instrument setup is not required for the BD FACSVia™ flow cytometer because test definitions for each assay define default acquisition and gate settings. However, to perform the BD® HLA-B27 test, you must run instrument QC and perform BD® HLA-B27 setup. For instructions on how to run instrument QC on this cytometer, see the *BD FACSVia™ System Instructions For Use* (IFU). For instructions on how to perform the BD® HLA-B27 test, see the *BD®* HLA-B27 *Application Guide For the BD FACSVia™ System*.

Figure 1 shows the Application Setup Report for the BD FACSCanto™ family of flow cytometers. Figure 2 shows the HLA-B27 Calibration Report for the BD FACSCalibur™ instrument. Figure 3 shows the HLA-B27 Setup Report for the BD FACSVia™ instrument.

Sample Acquisition

This section and the following section provide instructions for sample acquisition and analysis using BD FACSCanto™ Clinical Software for the BD FACSCanto™ family of flow cytometers, using BD® HLA-B27 software for the BD FACSCalibur™ flow cytometer, or using BD FACSVia™ clinical software for the BD FACSVia™ flow cytometer. For sample acquisition instructions using other cytometers, see the accompanying IFU.

Approximately 15,000 total events or 2,000 T lymphocytes are acquired.

Sample Analysis

The acquisition software automatically analyzes the acquired sample. T lymphocytes are gated in dot plots of CD3 PE (PE or FL2 detector) versus side scatter (Figure 4, Figure 5, and Figure 6). The T-lymphocyte population is displayed in a FITC/FL1 histogram (Figure 4, Figure 5, and Figure 6), where the LMF is calculated. Samples with an LMF greater than or equal to the decision marker should be considered HLA-B27–positive (see Results for details), and samples with an LMF less than the marker should be considered HLA-B27–negative. The decision marker is set by the suffix on the reagent vial for HLA-B27 FITC/CD3 PE. The suffix is in units of LMF and must be entered correctly into the software before sample acquisition, or assay results might be incorrect.

Figure 1 Example of HLA-B27 Setup Report from BD FACSCanto™ Clinical Software for the BD FACSCanto™ system

Application Setup Report
HLA-B27

Cytometer:	BD FACSCanto	Institution:	
Serial Number:	V03600034	Director:	
Software:	BD FACSCanto v.2.0	Operator:	RD
Date:	05/27/2005 1:23:00 PM	Overall Result:	PASS

Cytometer Setup

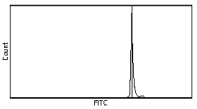
Cytometer Setup Report: 05/27/2005 1:18:47 PM, Overall Result: PASS
Bead Product: BD FACS 7-Color Setup Beads, Catalog Number: 335775
Lot Information: Lot ID 21842, Exp.: 2005-11-30

HLA-B27 Setup

HLA-B27 Bead Lot ID: 16036/141, HLA-B27 Reagent Lot ID: 17616:144

FITC Histogram

FITC Average: 141, Spec.: 140-142, P/F: PASS



Detectors

Detector	Laser	Voltage
FSC	Blue	113
SSC	Blue	410
FITC	Blue	501
PE	Blue	498

Compensation

	Fluorophores (applied % spectral overlap)		PASS	spec: all values ≤ 100%
Detector	FITC	PE		
FITC	100.00	0.42		
PE	30.06	100.00		

Threshold

FSC	20000

Comments

Reviewed By: _____

Figure 2 Example of HLA-B27 Calibration Report from BD FACSComp™ software for the BD FACSCalibur™ system

HLA-B27 Calibration Report

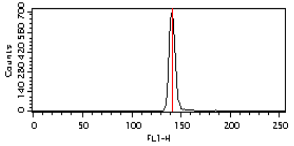
Institution BD
Director: CW
Operator: AA

Date: Friday, July 15, 2005 11:15 AM
Software: FACSComp v 5.2.1
Cytometer: FACSCalibur E0344

Bead Lot ID: 12254/141

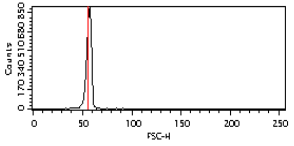
HLA-B27 Lot ID: 12330:146

Average FL1: 141



FSC Histogram:

Average FSC: 56



Instrument Settings:

Parameter	Detector	Amplifier	Threshold
FSC	E00	1.55	52
SSC	405	1.00	
FL1	697	Log	
FL2	616	Log	

Compensation	FL1 - %FL2	FL2 - %FL1	Laser Power	16.10 mWatts
	0.0	24.9		

Results: **Calibration was successful.**

Comments:

Figure 3 Example of HLA-B27 Setup Report from BD FACSVia™ clinical software for the BD FACSVia™ system

ID: HLA-B27 Setup

Report Date: OCT 07, 2015 14:10:07

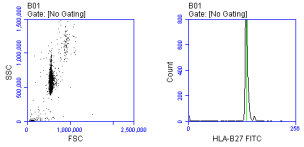
BD FACSVia Serial #: Demo Serial
BD FACSVia Software Version: 1.0

Result: Successful

Date Acquired	OCT 07, 2015 14:09:52	**Operator**	
Setup Bead Lot	4090508	**Lab Director**	LJO
Expiration Date	APR 30, 2016		
Setup Bead Suffix	138		
Reagent Lot	4107738		
Expiration Date	NOV 30, 2015		
Reagent Suffix	150		

Setup Report File Name: C:\Users\Public\Documents\BD Accuri Files\HLA-B27 Setup Reports\HLA-B27 Setup_20151007_140952.pdf

HLA-B27 Setup



	Result
Setup Bead Suffix	138
Setup Bead Median	138

QC Messages

Comments:

Figure 4 Example of HLA-B27 Laboratory Report from BD FACSCanto™ Clinical Software for the BD FACSCanto™ system

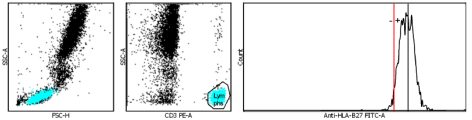
D13

4085 Rep1	**V07300226**		
Director:		Panel:	HLA-B27
		Acquired:	06/01/2005 2:43:03 PM
		Analyzed:	06/01/2005 2:43:03 PM
		Bead Lot ID:	16036/141
		Reagent Lot ID:	17616:144
		Status:	OK
		Operator:	RD
		Reviewer:	
		Results:	01062005.csv

Column #1: Column #2: Column #3:

BD FACSCanto V07300226 BD FACSCanto v.2.0

HLA-B27 Total Events: 10108



4085 Rep1003.001.fcs Reagent Lot ID: 17616:144

Gated Events	2610
Preset HLA-B27 Marker	144
Sample HLA-B27 Median	166
Conclusion	HLA-B27 positive sample

QC Messages
No quality control messages generated.

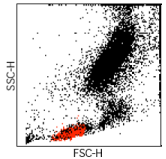
Comments

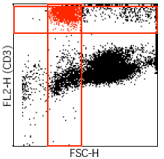
Figure 5 Example of HLA-B27 Laboratory Report from BD® HLA-B27 software for the BD FACSCalibur™ system

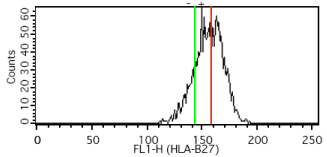
BD

HLA-B27 Laboratory Report

Director: CW		Cytometer: FACSCalibur (E0344)
Operator: RS		Software: HLA-B27 v4.0
Sample Name:	HLA/42/T2/G5/L/C	
Sample ID:	P30782	
Date Acquired:	Fri, Jul 15, 2005 7:59 PM	
Date Analyzed:	Fri, Jul 15, 2005 7:59 PM	
Data File Name:	HLA/42/T2/G5/L/C02.01	
Lab Report Name:	HLA/42/T2/G5/L/C02.lab	
Bead Lot ID:	16036/141	
Reagent Lot ID:	17616:144	
Events Acquired:	15000	
Gated Events:	1731	
Preset FL1 Marker:	144	Sample FL1 Median: 158
Conclusion:	**HLA-B27 positive sample**	







Comments:

Figure 6 Example of an HLA-B27 Laboratory Report from BD FACSVia™ clinical software for the BD FACSVia™ system

ID: 9983514
Report Date: JUN 24, 2015 13:28:58

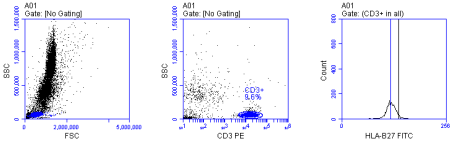
BD FACSVia Serial #: Demo Serial
BD FACSVia Software Version: 1.0

Name: Craft, A
Case #: C556

Date Acquired	JUN 24, 2015 13:26:46	**Operator**	PJT
		Prep	OD
		Tube Rack	
		Lab Director	LJO

BD FACSVia File Name: C:\Users\Public\Documents\BD Accuri Files\FACSVia Workspaces\HLA-B27_0624.cs

HLA-B27

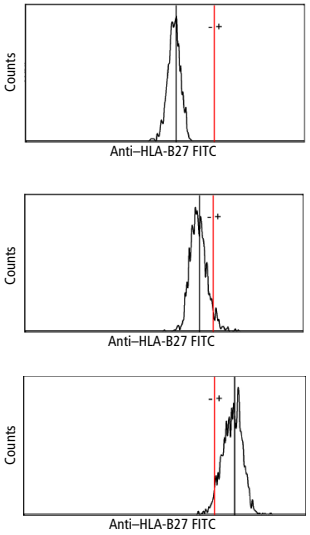


	Result
Total events	23316
CD3+ events	2238
CD3+ Percent of total events	9.60%
Decision Marker/Reagent Suffix	140
Sample Median	120
Conclusion	Negative

QC Messages

Figure 7 shows examples of HLA-B27–positive (bottom histogram) and HLA-B27–negative samples (top and middle histograms). The middle sample is also negative because the LMF is below the decision marker, but it is brighter than the sample in the top histogram. It is brighter because the Anti–HLA-B27-FITC antibody shows some cross-reactivity with some other HLA types, particularly HLA-B7.[4,5]

Figure 7 Examples of HLA-B27–negative (top and middle) and HLA-B27–positive (bottom) samples



4. REAGENTS

Reagents Provided

Sufficient for 50 Tests

The BD® HLA-B27 kit consists of one vial containing a combination of murine monoclonal antibodies, Anti–HLA-B27 conjugated with FITC and CD3 conjugated with PE; one bottle of 10X BD® HLA-B27 BD FACS™ Lysing Solution concentrate; and one vial of BD® HLA-B27 Kit Calibration Beads sufficient for 10 setups.

Reagent A, BD® HLA-B27 Kit Anti–HLA-B27/CD3

Reagent A, sufficient for 50 tests, is provided in 1.5 mL of buffered saline with gelatin and 0.1% sodium azide. It contains FITC-labeled Anti–HLA-B27, clone GS145.2 (IgG_1, kappa),[6] for the identification of the HLA-B27 antigen, and PE-labeled CD3, clone SK7 (IgG_1, kappa),[7-10] for the identification of T lymphocytes. Store at 2–8 °C.

Reagent B, BD® HLA-B27 BD FACS™ Lysing Solution

Reagent B (30 mL) contains 10X buffered BD® HLA-B27 BD FACS™ Lysing Solution with less than 50% diethylene glycol and less than 9.77% formaldehyde. Store at 2–25 °C.

To use, dilute 1:10 with room-temperature (20–25 °C) reagent-grade water. When stored in a glass or high density polyethylene (HDPE) container at room temperature, the prepared solution is stable for 1 month.

Reagent C, BD® HLA-B27 Kit Calibration Beads

Reagent C, sufficient for 10 setups, is provided in 1.5 mL of buffered saline with Tween® 20, gelatin, and 0.1% sodium azide. The beads are used to set up the cytometer specifically for the HLA-B27 assay. Store at 2–8 °C.

Concentration values are listed in the following table:

Reagent	Concentration
CD3	4.2 µg/mL
HLA-B27	5.0 µg/mL
Calibration Beads	2.00 x 10^7 beads/mL

Precautions

CAUTION Federal law restricts this device to sale by or on the order of a licensed practitioner.

CAUTION The operator must not manually change any of the instrument settings after they have been established by the setup procedures. See the information in Flow Cytometry.

- For In Vitro Diagnostic Use.
- Not for use in tissue typing.
- When stored at 2–8 °C, reagents are stable until the expiration date shown on the label. Do not use after the expiration date.
- The reagents must not be frozen or exposed to direct light during storage or incubation with cells. Keep the reagent vials dry.
- Stain within the times specified in Specimen Collection and Preparation. Before staining, store blood at room temperature (20–25 °C). Do not use previously fixed cells. Use of times or temperatures other than those specified can cause errors in results. Blood samples refrigerated before staining can give aberrant results.
- For optimal results, analyze stained samples within 24 hours of staining.
- Alteration in the appearance of the reagents, such as precipitation or discoloration, indicates instability or deterioration. In such cases, the reagents should not be used.
- The antibody reagent and calibration beads contain sodium azide as a preservative; however, care should be taken to avoid microbial contamination which can cause erroneous results.
- Reagent B contains 31.45% 2,2´-oxybisethanol (diethylene glycol), CAS number 111-46-6, EC number 203-872-2, EC number 200-659-6; 9.77% formaldehyde, CAS number 50-00-0, EC number 200-001-8; and 3.43% methanol, CAS number 67-56-1. The lysing solution is classified as hazardous according to the Globally

Harmonized System of Classification and Labelling of Chemicals (GHS). Visit regdocs.bd.com to download the Safety Data Sheet.

	Danger
	H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H314: Causes severe skin burns and eye damage. H317: May cause an allergic skin reaction. H335: May cause respiratory irritation. H341: Suspected of causing genetic defects. H350: May cause cancer. H370: Causes damage to organs. H373: May cause damage to organs through prolonged or repeated exposure. **US only: H402: Harmful to aquatic life.**
Prevention	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust/fume/gas/mist/vapors/spray. P264: Wash face, hands and any exposed skin thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P312: Call a POISON CENTER or doctor/physician if you feel unwell. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P363: Wash contaminated clothing before reuse. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310: Immediately call a POISON CENTER/doctor. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P307+P311: IF exposed: Call a POISON CENTER or doctor/ physician. P308+P313: If exposed or concerned: Get medical advice/attention.
Storage	P405: Store locked up.
Disposal	P501: Dispose of contents/container to an approved facility in accordance with local, regional, national and international regulations.

- All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection[11,12] 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.
- Testing has demonstrated that HLA-B27 expression is decreased over time in acid citrate dextrose solution B (ACD-B) blood collection tubes. This decrease can lead to incorrect results and therefore ACD-B tubes are not recommended for sample collection.

Storage and Handling

- Store Reagent A and Reagent C upright at 2–8 °C. Do not use after the expiration date shown on the label.
- Store Reagent B, undiluted, at 2–25 °C. When diluted, store at room temperature (20–25 °C) for up to one month.
- Do not freeze the reagents or expose them to direct light during storage or incubation with cells. Keep reagent vials dry.

5. INSTRUMENT

For detailed information on use, refer to product-specific documentation.

BD FACSVia™ System

- BD FACSVia™ flow cytometer
- BD FACSVia™ clinical software version 2.0 or later
- BD® HLA-B27 assay module (test definition)

BD FACSCanto™ or BD FACSCanto™ II System

- BD FACSCanto™ family of flow cytometers
- BD FACSCanto™ Clinical Software
- BD® HLA-B27 application module

BD FACSCalibur™ System

- BD FACSCalibur™ flow cytometer
- BD FACStation™ data management system (included in the BD FACSCalibur™ system)
- BD® HLA-B27 software
- BD FACSComp™ software

All performance characteristics were obtained using these instruments and software systems. Other systems can have different characteristics.

6. SPECIMEN COLLECTION AND PREPARATION

Collect blood aseptically by venipuncture, using BD Vacutainer® blood collection tubes.[13] A minimum of 1 mL of whole blood is required for this procedure.

Blood drawn into EDTA, heparin, or ACD solution A (ACD-A) blood collection tubes can be stored up to 48 hours at room temperature (20–25 °C) until ready for staining. Once stained, samples are stable up to 24 hours at 2–8 °C.

Interfering Conditions

Do not use previously fixed and stored cells. Leukocyte samples or whole blood samples refrigerated before staining can give aberrant results. Reject hemolyzed samples or samples with less than 1 mL of whole blood in the collection tube.

7. PROCEDURE

Reagents Provided

See Reagents Provided and Precautions in Section 4, Reagents.

Reagents and Materials Required But Not Provided

- BD Vacutainer® EDTA blood collection tubes or equivalent
- Falcon® disposable 12 x 75-mm polystyrene test tubes or equivalent
- Vortex mixer
- Low-speed centrifuge (minimum speed 200*g*) with swinging-bucket rotor and 12 x 75-mm tube carriers
- Vacuum aspirator with trap
- Micropipettor with tips
- 1X phosphate-buffered saline (PBS)
- BD® CellWASH (Catalog No. 349524) or a wash buffer of phosphate-buffered saline (PBS) with 0.1% sodium azide

  NOTE BD® CellWASH solution is not available in all markets.

- BD CellFIX™ (Catalog No. 340181) or 1% paraformaldehyde solution in PBS with 0.1% sodium azide

  Store at 2–8 °C in amber glass for up to 1 week.

  NOTE BD CellFIX™ solution is not available in all markets.

- Reagent-grade (both distilled and deionized) water
- BD FACSFlow™ Sheath Fluid (Catalog No. 342003) or equivalent

  CAUTION For flow cytometers other than BD FACSVia™ flow cytometers, use only BD FACSFlow™ Sheath Fluid to dilute HLA-B27 calibration beads.

  CAUTION For BD FACSVia™ flow cytometers, use only 1X PBS to dilute HLA-B27 calibration beads.

- Deionized water with BD® Sheath Additive (Catalog No. 660584) for sheath fluid on the BD FACSVia™ flow cytometer. For instructions, refer to the IFU.
- For the BD FACSCanto™ or BD FACSCanto™ II system:
  BD FACS™ 7-Color Setup Beads (Catalog No. 335775). For instructions and warnings, refer to the IFU.

- For the BD FACSCalibur™ system: BD Calibrite™ Beads (Catalog No. 349502 or 340486). For instructions and warnings, refer to the IFU.
- For the BD FACSVia™ system: BD® CS&T Beads (Catalog No. 656504 for 50 Tests, Catalog No. 656505 for 150 Tests). For instructions and warnings, refer to the instructions for use (IFU).

Staining and Fixing the Cells

The following procedure should be performed at room temperature (20–25 °C) using room-temperature reagents. Use care to protect tubes from direct light. See Precautions.

1. For each sample, label a 12 x 75-mm tube with the sample identification number.
2. Place 30 µL of Reagent A into the tube.
3. For each sample tube, use a fresh micropipettor tip and carefully add 50 µL of well-mixed anticoagulated whole blood into the bottom of each tube. The recommended white blood cell (WBC) concentration is 3.5 to 9.4 x 10^3 WBC/µL. Vortex thoroughly at low speed for 3 seconds and incubate for 15 to 20 minutes at room temperature (20–25 °C) in the dark.

   NOTE Protect samples from direct light during this incubation procedure and use care to prevent blood from running down the side of the tube. If whole blood remains on the side of the tube, it will not be stained with the reagent.
4. Dilute 10X BD® HLA-B27 BD FACS™ Lysing Solution to 1X following the instructions in Section 4, Reagents. Add 2 mL of room temperature (20–25 °C) 1X lysing solution to each tube. Immediately vortex thoroughly at low speed for 3 seconds and incubate for 10 to 12 minutes at room temperature (20–25 °C) in the dark. Do not exceed 12 minutes incubation.

   CAUTION Avoid prolonged exposure of the cells to lytic reagents, which can cause white cell destruction.
5. Immediately after incubation, centrifuge tubes at 300*g* for 5 minutes at room temperature (20–25 °C).
6. Aspirate the supernatant, leaving approximately 50 µL of residual fluid in the tube to avoid disturbing the pellet.
7. Vortex tubes thoroughly at low speed to resuspend the cell pellet in the residual fluid. Add 2 mL of BD® CellWASH solution or PBS with 0.1% sodium azide to each tube. Vortex thoroughly at low speed for 3 seconds and centrifuge at 200*g* for 5 minutes at room temperature (20–25 °C).
8. Aspirate the supernatant, leaving approximately 50 µL of residual fluid in the tube to avoid disturbing the pellet.
9. Vortex the tube thoroughly at low speed to resuspend the cell pellet in the residual fluid. Add 0.25 mL of BD CellFIX™ solution, or 1% paraformaldehyde in PBS with 0.1% sodium azide to each tube, and vortex thoroughly at low speed for 3 seconds.

Make sure the cells are well mixed with the fixing solution. Fix samples for 30 minutes before acquisition.

10. Samples are now ready to be analyzed on the flow cytometer. Cap or cover and store the prepared tubes at 2–8 °C in the dark until flow cytometric analysis. Analyze the fixed cells within 24 hours of staining. Vortex the cells thoroughly at low speed to reduce aggregation before analyzing them on the flow cytometer.

Flow Cytometry

See Flow Cytometer Setup, and refer to the appropriate instrument and software IFUs for specific setup instructions. Ensure that cytometer setup with BD Calibrite™ Beads, BD FACS™ 7-Color Setup Beads or BD® CS&T Beads has passed instrument quality control criteria on the same day before proceeding with the HLA-B27 setup procedure.

Use the following instructions for flow cytometric analysis. See also Section 5, Instrument.

HLA-B27 Setup for All Supported Instruments

HLA-B27 setup must be performed each day samples are run. Prepare a fresh aliquot of HLA-B27 calibration beads each time the following setup procedure is performed. Dilute beads just before setup.

1. Gently and thoroughly vortex the HLA-B27 calibration bead vial.
2. Add 2 drops of beads to 1 mL of 1X PBS (for BD FACSVia™ flow cytometers) or BD FACSFlow™ diluent (for other flow cytometers) in a 12 x 75-mm test tube.
3. Vortex the bead suspension thoroughly at low speed for 3 seconds.
4. Run the beads with BD FACSComp™ software on the BD FACSCalibur™ flow cytometer, with the BD FACSCanto™ Clinical Software on the BD FACSCanto™ family of flow cytometers, or from the BD® HLA-B27 Setup tab in the Instrument QC section of the BD FACSVia™ clinical software on the BD FACSVia™ flow cytometer.

   The event rate should be at least 400 events/sec before proceeding with setup. If the event rate is less than 400 events/sec, add another drop of beads to the tube.

   The software will produce a report to confirm proper setup (see Figure 1, Figure 2, and Figure 3).

CAUTION Failure to follow the entire instrument setup procedure can cause erroneous results.

CAUTION Do not manually change any of the instrument settings after they have been established by these setup procedures.

Sample Acquisition and Analysis

Acquire all samples on the flow cytometer. For the BD FACSCanto™ family of flow cytometers, use BD FACSCanto™ Clinical Software. For the BD FACSCalibur™ flow cytometer, acquire data using BD® HLA-B27 software. For the BD FACSVia™ flow

cytometer, use BD FACSVia™ clinical software. Refer to the software IFU for detailed instructions. After acquisition, each software automatically analyzes the sample and produces a laboratory report showing details of the analysis and whether the sample is positive or negative for HLA-B27.

Quality Control

For optimal results, BD requires the setup procedure described in the following manuals:

- *BD*® HLA-B27 *Software Reference Manual* (for the BD FACSCalibur™ flow cytometer)
- *BD*® HLA-B27 *Application Guide* (for the BD FACSCanto™ family of flow cytometers)
- *BD*® HLA-B27 *Application Guide* (for the BD FACSVia™ system).

We recommend staining known HLA-B27–positive and HLA-B27–negative control samples and running them as a QC check of the system ***each time*** the BD® HLA-B27 test is run. Results from HLA-B27–positive and HLA-B27–negative subjects are illustrated in Figure 7.

BD FACSCanto™ and BD FACSVia™ clinical software identify $CD3^+$ T-lymphocyte events. There must be adequate separation (as determined by the software) between the CD3-positive and CD3-negative populations. If the gate is misplaced, a QC message will appear. Refer to the software manual for information.

For the BD FACSCalibur™, or BD FACSVia™ flow cytometer, the corresponding software uses the following criteria for evaluation of the dot plots and QC analysis of the data.

- A minimum of 2% of all events must be T lymphocytes (bright FL2 events) to allow the software to position the gate on the FSC vs FL2 dot plot.
- There must be adequate separation (as determined by the software) between the CD3-positive and CD3-negative populations.

If these conditions are not met, an error message appears. See Troubleshooting for additional information. If the QC criteria are not met, results from the BD® HLA-B27 test can be suspect.

Visually inspect the scatter versus CD3 PE (PE/FL2 detector) dot plot to ensure that the T-lymphocyte gate is set correctly.

8. RESULTS

BD instrument systems automatically display results for HLA-B27 antigen expression in the sample as shown in Figure 4, Figure 5, Figure 6, and Figure 7. The sample is reported as either positive or negative for HLA-B27. Results can also be reported as inconclusive for the BD FACSVia™ system.

9. LIMITATIONS

The information obtained from the BD® HLA-B27 test must be combined with other information and interpreted by a medically qualified physician to establish presence or absence of specific disease states.

Anti–HLA-B27 cross-reacts with several of the HLA-B antigens, most commonly with the HLA-B7 antigen.[4,5] The LMF for HLA-B7–positive samples in the FITC/FL1 detector can thus be in the range of HLA-B27–positive samples, resulting in some false-positive results.

Visually inspect the scatter vs CD3 PE dot plot to ensure that the T-lymphocyte gate is set correctly. If the gate is incorrectly set on the granulocyte population, we recommend re-testing the sample.

Performance characteristics of this product have not been established on samples with WBC counts outside the normal range of the participating laboratory. The recommended range of the WBC concentration is 3.5 to 9.4 x 10^3 WBC/µL.

10. PERFORMANCE CHARACTERISTICS

BD FACSVia™ System

Agreement

An agreement study between the BD FACSVia™ and the BD FACSCalibur™ systems was performed at three clinical study sites. A total number of 597 samples were compared and analyzed on both systems (Table 1). Agreement is calculated as follows:

$$100\% \times \frac{\text{(positive on both platforms + negative on both platforms + inconclusive on FACSVia™ and gray zone on FACSCalibur™)}}{\text{(total number of samples)}}$$

Table 1 Agreement study[a]

Test method (BD® HLA-B27 test on BD FACSVia™ system)	**Comparative method (BD® HLA-B27 on BD FACSCalibur™ system)**			
	Positive	Gray Zone	Negative	Total
Positive	72	9	0	81
Inconclusive	3	11	3	17
Negative	0	0	499	499
Total	75	20	502	597

a. Overall agreement is 97.5%.

Precision

Inter-site precision for BD FACSVia™ flow cytometers

A five-day study was conducted at three sites (two external and one site at BD Biosciences) to assess inter-site precision using two donors, an HLA-B27–positive and an HLA-B27–negative donor. Five replicates of donor whole blood samples were stained with one lot of BD® HLA-B27 reagent and then acquired once per day on a BD FACSVia™ flow cytometer. One or more operators were included in the study at each site. The standard deviation (SD) for the mean of the HLA-B27 FITC LMF values for each of the variables was calculated (see Table 2).

Table 2 BD FACSVia™ inter-site precision

Donor Type	Precision	Mean of Sample Median	SD of Sample Median
Negative	Repeatability	136	0.9
	Between site		1.2
	Total reproducibility		1.5
Positive	Repeatability	173	0.9
	Between site		0.1
	Total reproducibility		0.9

Intra-site precision for BD FACSVia™ flow cytometers

BD FACSVia™ system precision was assessed using 42 samples (21 positive for the HLA-B27 antigen and 21 negative). Samples were run in duplicate for 21 days, two runs each day, by three operators using three instruments. The standard deviation (SD) for the mean of the HLA-B27 FITC sample medians for each of the variables was calculated (see Table 3).

Table 3 BD FACSVia™ intra-site precision

Donor Type	Precision	Mean of Sample Median	SD of Sample Median
Negative	Repeatability	124	2.2
	Between run		1.9
	Within site		2.9
Positive	Repeatability	166	0.8
	Between run		1.3
	Within site		1.5

BD FACSCanto™ and BD FACSCanto™ II Systems

Agreement

An agreement study between the BD FACSCanto™ II and the BD FACSCanto™ systems was performed at BD Biosciences. A total number of 125 samples were compared, with each sample collected in duplicate on both systems (Table 4). Agreement is calculated as follows:

$$100\% \times \frac{(\text{positive on both platforms} + \text{negative on both platforms})}{(\text{total number of samples})}$$

Table 4 Agreement study[a,b]

Test method (BD® HLA-B27 test on BD FACSCanto™ II system)	**Comparative method (BD® HLA-B27 test on BD FACSCanto™ system)**		
	Positive	Negative	Total
Positive	54.5	0	54.5
Negative	0	70.5	70.5
Total	54.5	70.5	125

a. Overall agreement is 100%.
b. Both replicates for one sample agreed between the test and comparative methods but disagreed within the method itself (one replicate positive and one replicate negative on each system within two channels).

An agreement study between the BD FACSCanto™ and the BD FACSCalibur™ systems was performed at one reference laboratory. A total number of 397 samples were compared, of which 323 samples were negative for the HLA-B27 antigen and 74 samples were positive (Table 5). There were no discordant samples. Agreement is calculated as follows:

$$100\% \times \frac{(\text{positive on both platforms} + \text{negative on both platforms})}{(\text{total number of samples})}$$

Table 5 Agreement study[a,b]

Test method (BD® HLA-B27 test on BD FACSCanto™ system)	**Comparative method (BD® HLA-B27 test on BD FACSCalibur™ system)**		
	Positive	Negative	Total
Positive	74	0	74
Negative	0	323	323
Total	74	323	397

a. Overall agreement is 100%.

b. Results calculated based on 95% lower confidence interval= 99% agreement

Precision

BD FACSCanto™ II system precision was estimated using ten samples, five positive and five negative for the HLA-B27 antigen. Samples were run in duplicate for two days, two runs each day, using three instruments and three operators. The standard deviation (SD) for the mean of the values for HLA-B27 FITC LMF for each of the variables was calculated. See Table 6.

Table 6 Precision study–overall

Precision	SD of LMF
Within run	0.62
Between runs	0.99
Between days	0.54
System total	1.18

BD FACSCanto™ system precision was estimated using ten samples, five positive and five negative for the HLA-B27 antigen. Samples were run in duplicate for two days, two runs each day, using three BD FACSCanto™ instruments and three operators. The SD for the mean of the values for HLA-B27 FITC LMF for each of the variables was calculated (Table 7).

Table 7 Precision study–overall

Precision	SD of LMF
Within run	0.7
Between instruments	1.3
Between days	0.8
System total	1.5

Cross-Reactivity Characterization

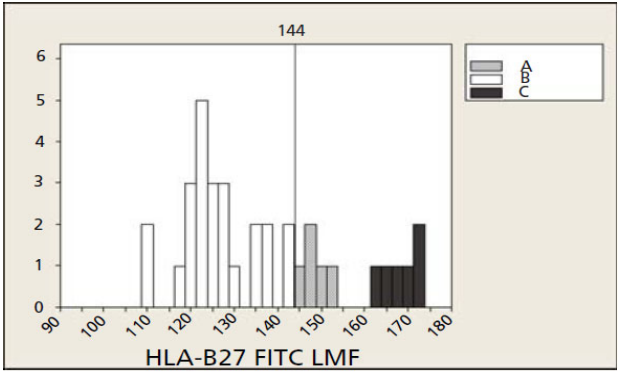
The Anti–HLA-B27 antibody, clone GS145.2, used in the BD® HLA-B27 test, has been shown to cross-react, most commonly with HLA-B7.[4] The LMF for some cross-reacting samples can fall on the positive side of the decision marker, thus resulting in false-positive results.[3-5]

A study was performed to characterize this cross-reactivity. Twenty-nine samples with known HLA-B cross-reactive antigens and six HLA-B27–positive samples, as determined by cytotoxicity or low resolution molecular testing, were stained in triplicate and acquired by each of three operators on two BD FACSCanto™ instruments. Results are shown in Figure 8. All six of the confirmed HLA-B27–positive specimens were above the

decision marker. The five false-positive specimens were predominately HLA-B7, in agreement with published studies.[4] Based on the population tested, the cross-reactive samples that fell on the positive side of the decision marker (LMF channel 144) were within 144 and 154 LMF (Figure 8). This ten-channel zone is also supported by current literature.[3] This zone is referred to as the gray zone for BD FACSCalibur™ and BD FACSCanto™ systems. For the BD FACSVia™ system, samples falling in this zone are labeled inconclusive. Results that fall within this zone should be confirmed by an alternate method.

The prevalence and distribution of HLA-B antigen cross-reactivity can vary.[3-5] We recommend that laboratories confirm this gray zone (inconclusive samples) by performing their own studies.

Figure 8 Cross-reactivity characterization



Results	Description
A	Gray zone (inconclusive)
B	Negative
C	Positive

BD FACSCalibur™ System

Performance of the BD® HLA-B27 test on the BD FACScan™ system was established by testing at three European clinical centers and at BD Biosciences laboratories in Erembodegem, Belgium and in San Jose, California, USA. An in-house study showed equivalency of the BD FACSCalibur™ system with the BD FACScan™ system.

BD® HLA-B27 Test versus Comparative Methods

In these studies, lysed whole blood samples from 1,418 subjects, including 258 HLA-B27–positive subjects, were analyzed on the BD FACScan™ system, using the BD® HLA-B27 test and the microcytotoxicity method (Table 8). Agreement is calculated as follows:

$$100\% \times \frac{(\text{positive on both platforms} + \text{negative on both platforms})}{(\text{total number of samples})}$$

Table 8 BD® HLA-B27 test versus comparative method for HLA-B27 marker validation[a]

Test method (BD® HLA-B27 test on BD FACScan™ system)	**Comparative method (microcytotoxicity method)**		
	Positive	Negative	Total
Positive	258	30	288
Negative	0	1,130	1,130
Total	258	1,160	1,418

a. Overall agreement is 97.9%.

Within-Sample Reproducibility

Lysed whole blood samples from each of five HLA-B27–positive, five HLA-B7–positive/HLA-B27–negative, and five HLA-B27–negative/HLA-B7–negative individuals were obtained. Each sample was divided into three aliquots. Each aliquot was stained with Anti–HLA-B27 FITC/CD3 PE reagent, lysed, washed, and fixed within 6 hours of sample collection. Flow cytometric analysis was performed on a BD FACScan™ flow cytometer within 8 hours of staining. Within-sample variability observed did not alter the determinations for the presence or absence of HLA-B27 antigen. Results demonstrated acceptable within-sample reproducibility.

Between-Instrument Reproducibility

Blood samples from two HLA-B27–positive subjects and two HLA-B27–negative subjects were obtained, aliquoted (three times), stained with Anti–HLA-B27 FITC/CD3 PE reagent, lysed, washed, and fixed within 6 hours of sample collection. Flow cytometric analysis was performed on three BD FACScan™ flow cytometers in the same laboratory within 8 hours of staining. Flow cytometers were set up using a fresh dilution of BD Calibrite™ Beads with Autocomp software and calibrated using a fresh dilution of HLA-B27 calibration beads for FL1 and BD® HLA-B27 software before each stained sample was acquired. There were no differences between instruments in the determination of the presence or absence of the HLA-B27 antigen.

Between-Laboratory Reproducibility

Samples from 1,418 subjects, including 258 HLA-B27–positive subjects, were evaluated at three European centers in Bremen, Germany; Gent, Belgium; and Strasbourg, France. Among these sites, the HLA-B27–positive populations were tested for agreement of mean fluorescence intensity (MFI) by flow cytometry. Since the analytical procedure requires a predetermined lot-specific marker value, separating negative from positive results, the stability of the MFI of a stained sample is critical to reproducibility. The site-to-site determinations were found to be similar based on the mean and standard deviation estimates of B27-positive sample MFI for the three sites.

Day-to-Day Reproducibility

Day-to-day (longitudinal) reproducibility was assessed at Bremen, Germany. Blood samples were collected from five HLA-B27–positive donors, five HLA-B27–negative/B7–positive donors and five HLA-B27–negative/B7–negative donors. Samples from each donor were collected and analyzed on three separate days to assess the longitudinal variability for this assay.

Results demonstrate acceptable day-to-day reproducibility. No variability observed in donor samples altered the determinations for the presence or absence of the HLA-B27 antigen.

White Blood Cell Concentration

All lots of the BD® HLA-B27 reagent are tested against cell suspensions (whole blood sample) to ensure optimal performance at 50 µL of whole blood. For this study, the normal range was 3.5×10^3 to 9.4×10^3 WBC/µL. Results are shown to be accurate from 3.5×10^3 to 9.4×10^3 WBC/µL.

Blood samples were collected from four HLA-B27–positive donors. To validate that a blood sample with a total leukocyte (WBC) count within the normal concentration range of 3.5 to 9.4×10^3 WBC/µL would yield accurate and reproducible results, a range of concentrations was tested from 100 WBC/µL to 3.3×10^5 WBC/µL of each sample and compared to the result for the whole blood sample from that donor. All samples still tested positive in the cell concentration range of 100 WBC/µL to 4.6×10^4 WBC/µL. Results indicate accuracy within the normal range of peripheral WBC counts.

Whole Blood Stability and Stained Stability

BD FACSVia™ System

A study was performed on the BD FACSVia™ system with 46 donors (18 positive, 2 inconclusive, and 26 negative) using EDTA, ACD-A, and Heparin blood collection tubes. Results showed that samples stored at room temperature (20–25 °C) were stable up to 48 hours before staining. Once stained and stored at 2–8 °C, samples were stable up to 24 hours.

BD FACSCanto™ and BD FACSCalibur™ Systems

A study was performed on BD FACSCanto™ and BD FACSCalibur™ systems with 30 donors (11 of whom were positive) using EDTA and ACD-A blood collection tubes. Results showed that EDTA and ACD-A samples stored at room temperature (20–25 °C) were stable up to 48 hours before staining. Once stained and stored at 2–8 °C, samples were stable up to 24 hours. Testing has shown that HLA-B27 expression is decreased over time in ACD-B blood collection tubes, which can lead to incorrect results. Therefore, ACD-B tubes are not recommended for sample collection.

A second study was performed on the BD FACSCanto™ system with 16 donors (five of whom were positive) using EDTA and heparin blood collection tubes. Results showed that EDTA and heparin samples stored at room temperature (20–25 °C) were stable up to 48 hours before staining. Once stained and stored at 2–8 °C, samples were stable up to 24 hours.

These studies demonstrate that the use of EDTA, heparin, and ACD-A as anticoagulants produces equivalent results across both platforms.

BD FACScan™ System

A study was performed on the BD FACScan™ system with ten donors (five of whom were positive) collected in either EDTA, heparin, or citrate phosphate dextrose (CPD) blood collection tubes. Results showed that EDTA, heparin, and CPD samples stored at room temperature (20–25 °C) were stable up to 24 hours before staining. Once stained and stored at 2–8 °C, samples were stable up to 24 hours.

TROUBLESHOOTING

Observation	Possible Causes	Recommended Solutions
No acceptable gate found	Fewer than 2% of events are T lymphocytes, which can be due to:	
	• Incorrect instrument settings	Verify that all instrument settings agree with current setup report.
	• Incomplete red blood cell lysis	Verify that all steps in the procedure were followed correctly. See item 4 under Staining and Fixing the Cells.
	• Incorrect reagents used	Check that correct reagents are being used; prepare fresh sample.
	• Instrument failure	Recalibrate the instrument.
	• Too few T lymphocytes acquired	Acquire more events; change software stopping criteria, if necessary.
	Inadequate separation between $CD3^+$ and $CD3^-$ populations due to:	
	• Improper sample preparation	Prepare a fresh sample.
	• Blood sample too old (see Specimen Collection and Preparation)	Obtain a fresh blood sample from the subject and restain.
	• Stained preparation too old (>24 hours after staining)	Prepare and stain fresh samples; analyze within 24 hours of staining.
	Reagent expired or not used according to instructions	Check the reagent expiration date; make sure the reagent has been stored and handled according to conditions stated in this IFU.
	Incorrect instrument setup	Verify that all instrument settings agree with current setup report. Verify that the correct suffix for the HLA-B27 calibration beads was used.
Failed control samples	Setup not performed	Perform instrument setup.
	Improper sample preparation	Prepare a fresh sample.
	Incorrectly entered bead or reagent suffixes, or both	Re-enter correct suffix numbers and rerun BD® HLA-B27 Setup.

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.

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PATENTS AND TRADEMARKS

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

HISTORY

Revision	Date	Changes made
23-2563(15)	2023-10	Revision number amended for document management alignment.
23-2563(16)	2023-10	Updated legal manufacturer address. Added EU and Swiss importer addresses. Updated symbols glossary. Updated hazard and precautionary statements.

SYMBOLS GLOSSARY

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 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.

L006715(08) 2023-03

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