BD Trucount™ Controls

30 Tests—Catalog No. 340335

23-3537(10)
2023-07
English

CE 2797 IVD

1. INTENDED USE

BD Trucount™ Controls are designed for use with BD Trucount™ Tubes and the BD FACSLyric™ flow cytometer as a control for the absolute counting process. Specifically, a control bead value that is outside the expected range could indicate an error in pipetting or a problem with the bead count value from the BD Trucount™ Tubes.

BD Trucount™ Controls can be used with the BD FACS™ Universal Loader.

2. SUMMARY OF THE TEST

BD Trucount™ Controls are fluorescent polystyrene beads supplied at three concentrations – low, medium, or high. BD FACSuite™ Clinical application calculates the absolute counts of the BD Trucount™ Control beads to confirm pipetting accuracy.

BD Trucount™ Controls are intended for use by laboratory professionals.

Principle of Operation

A control bead suspension is added to anticoagulated whole blood in a BD Trucount™ Tube. The lyophilized bead pellet is suspended in the sample, releasing a known number of fluorescent BD Trucount™ beads, and acquired on a BD FACSLyric™ flow cytometer. BD FACSuite™ Clinical application calculates the absolute counts of the BD Trucount™ Control beads by comparing Trucount™ Control Bead events to Trucount™ Bead events.

3. REAGENT

Reagent Composition

BD Trucount™ Controls contain beads with the following concentration ranges:

Table 1 BD Trucount™ Controls concentration ranges

BD Trucount™ Controls	Concentration (beads/mL)
Low Control Beads (A)	4.72×10^4–5.25×10^4
Medium Control Beads (B)	2.351×10^5–2.635×10^5
High Control Beads (C)	9.403×10^5–1.0539×10^6

Precautions

- Calibrate pipets to deliver exactly 50 µL of sample or perform the reverse pipetting technique (see Reverse Pipetting on page 3). See the pipet manufacturer's instructions for more information.
- Bead count varies by lot of BD Trucount™ Tubes. It is critical to use the bead count shown on the current lot of BD Trucount™ Tubes when entering this value in the software. Do not mix multiple lots of BD Trucount™ Tubes in the same run.
- BD Trucount™ Controls are designed for use with a specific lyse/no-wash procedure. Do not attempt to threshold on forward scatter (FSC) for data collection.
- Go to regdocs.bd.com/regdocs/sdsSearch to download the Safety Data Sheet.

Storage and Handling

Store at 2–8 °C. Reagent in opened or unopened vials is stable until the expiration date shown on the vial label. Do not use after this expiration date.

4. INSTRUMENT

The BD FACSLyric™ system is outlined in the following table. See the corresponding reagent or instrument user documentation for details.

Table 2 BD FACSLyric™ system

Flow cytometer	Setup beads	Setup software	Analysis software
BD FACSLyric™	BD® CS&T Beads BD® FC Beads 7-Color Kit	BD FACSuite™ Clinical application	BD FACSuite™ Clinical application

The BD FACS™ Universal Loader can be used with this product.

5. SPECIMEN COLLECTION AND PREPARATION

- Collect blood specimens aseptically by venipuncture into a BD Vacutainer® EDTA blood collection tube, or equivalent.[1]
- Store blood specimens at room temperature (20–25 °C).

WARNING All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection[2,3] 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.

6. PROCEDURE

Reagents and Materials

Reagents and materials provided

BD Trucount™ Controls come with two vials of each of the following:

- BD Trucount™ Low Control Beads (A)
- BD Trucount™ Medium Control Beads (B)
- BD Trucount™ High Control Beads (C)

Each vial of BD Trucount™ Controls is provided in 1.5 mL of buffered saline with <0.1% sodium azide, sufficient for 15 tests.

The lot-specific bead count value (beads/µL) and standard deviation (SD) for each concentration level is found on a label on the inside of the box.

Reagents and materials required but not provided

- BD Trucount™ Tubes (Catalog No. 663028)
- BD FACS™ Lysing Solution (Catalog No. 349202)

  The lysing solution is provided as a 10X concentrate and it contains diethylene glycol and formaldehyde. See the *BD FACS™ Lysing Solution* instructions for use (IFU) for precautions and warnings.
- Vortex mixer
- Micropipettor with tips
- Bulk dispenser or pipettor (450 µL) for dispensing 1X BD FACS™ Lysing Solution
- (Optional) BD FACS™ Universal Loader

Diluting BD FACS™ Lysing Solution

Dilute the 10X concentrate 1:10 with room temperature (20–25 °C) deionized water. The prepared solution is stable for 1 month when stored in a glass or high density polyethylene (HDPE) container at room temperature.

Reverse Pipetting

Accurate pipetting is critical when using a BD Trucount™ Tube. Use the reverse pipetting technique to add the sample to a BD Trucount™ Tube. For reverse pipetting, depress the button to the second stop. Release the button to draw excess sample into the tip. Press the button to the first stop to expel a precise volume of sample, leaving excess sample in the tip.

Preparing the Controls

1. Remove three BD Trucount™ Tubes from the foil pouch. Label the tubes Low, Medium, and High.

   NOTE Verify that the BD Trucount™ bead pellet is under the metal retainer at the bottom of the tube. If this is not the case, discard the BD Trucount™ Tube and replace it with another. Do not transfer beads to another tube.

   NOTE Use care to protect the tubes from direct light. Perform the procedure at room temperature (20–25 °C).
2. Gently vortex each control vial for 30 seconds and add 50 µL of the low control beads to the tube labeled Low, 50 µL of the medium control beads to the tube labeled Medium, and 50 µL of the high control beads to the tube labeled High.

   NOTE Do not add antibody reagent.
3. Pipette 50 µL of well-mixed, anticoagulated whole blood from a hematologically normal donor onto the side of the tube just above the retainer.
4. Add 450 µL of 1X BD FACS™ Lysing Solution to each tube.
5. Cap the tubes and vortex gently to mix.

The samples are now ready to be analyzed on the flow cytometer.

Acquiring the Sample

Before you begin:

1. Ensure that Characterization QC (CQC) and lyse/no wash reference settings have not expired.
2. Add bead and reagent lots to library, if needed.

   See the *BD FACSLyric™ Clinical System Instructions For Use* for information.
3. Perform daily Performance QC (PQC) using BD® CS&T Beads.

   See the BD® CS&T Beads IFU and the *BD FACSLyric™ Clinical System Instructions For Use* for information.

To run the assay:

1. Create a worklist.
   - Create a Trucount Control task.
2. Enter information in the worklist table.
   - Enter the lot ID for the BD Trucount™ Tube and the bead count, found on the pouch label, in the appropriate column (Trucount Lot ID and Beads Per Pellet, respectively).
3. Run the control tasks on the worklist.
4. Vortex each tube thoroughly at low speed immediately before acquiring it.[4]

   NOTE If you are using the BD FACS™ Universal Loader, vortex tubes immediately before placing them into the Loader racks.
5. After acquiring the control samples, click **Stop Tube**.
6. Review the lab report for the controls.

7. RESULTS

Representative Data

The lab report for BD Trucount™ Controls is shown in Figure 1.

Figure 1 BD Trucount™ Controls Lab Report

BD Trucount Controls: Lab Report

Sample ID: 313
Sample Name:
Case Number:

Acquired Using: Worklist_003
Cytometer: BD FACSLyric
Sample Preparer:
Operator: Admin User

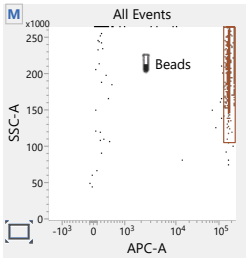
Approved: 10/23/2019 2:50:30 PM P
Cytometer SN: Z654587P021
Sample Preparer SN:
Director:
Department: None

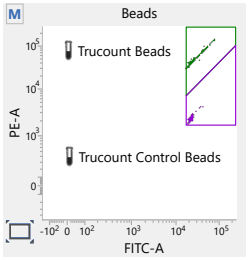
Entry Status: Approved

Software: BD FACSuite Clinical v1.4
Institution: None
Address:

Tube Name: Trucount Control Low

Events Acquired	4,298	Acquisition Date	10/23/2019
Reagent Lot ID	Trucount Control beads Low Lot ID: 91994	Acquisition Time	1:06:08 PM
Trucount Lot ID	18177	Beads Per Pellet	48150





Results Summary

Label	Results
Total Bead Events	4,000
Trucount Bead Events	3,829
Trucount Control Low Bead Events	169
Trucount Control Low Beads Abs Cnt (beads/µL)	43

For In Vitro Diagnostic Use.

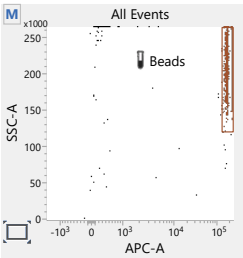
Trucount Controls v1.1
Page 1 of 3

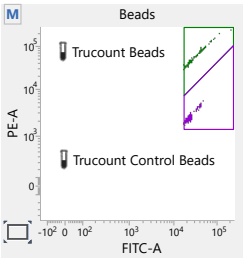
Printed: 10/29/2019 3:23:47 PM

Sample ID: 313
Sample Name:
Case Number:
Acquired Using: Worklist_003
Assay: Trucount Controls

Tube Name: Trucount Control Medium

Events Acquired	4,274	Acquisition Date	10/23/2019
Reagent Lot ID	Trucount Control beads Medium Lot ID: 91995	Acquisition Time	1:07:56 PM
Trucount Lot ID	18177	Beads Per Pellet	48150





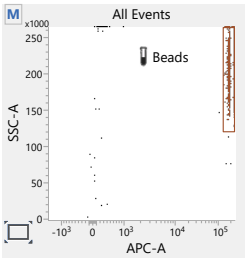
Results Summary

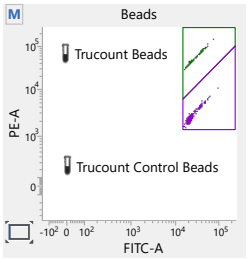
Label	Results
Total Bead Events	4,000
Trucount Bead Events	3,186
Trucount Control Medium Bead Events	811
Trucount Control Medium Bead Abs Cnt (beads/µL)	245

Sample ID: 313
Sample Name:
Case Number:
Acquired Using: Worklist_003
Assay: Trucount Controls

Tube Name: Trucount Control High

Events Acquired	4,127	Acquisition Date	10/23/2019
Reagent Lot ID	Trucount Control beads High Lot ID: 91996	Acquisition Time	1:09:16 PM
Trucount Lot ID	18177	Beads Per Pellet	48150





Results Summary

Label	Results
Total Bead Events	4,000
Trucount Bead Events	1,946
Trucount Control High Bead Events	2,054
Trucount Control High Bead Abs Cnt (beads/µL)	1,016

QC Messages

Showing 0 of 0 QC Messages

For In Vitro Diagnostic Use. Trucount Controls v1.1 Page 3 of 3 Printed: 10/29/2019 3:23:47 PM

Calculating Absolute Counts

BD FACSuite™ Clinical application automatically calculates absolute counts using the following equation:

A = B/C × D/E where:

A = absolute count of Trucount™ Control Beads

B = number of events in the Trucount™ Control Beads region

C = number of events in the Trucount™ Beads region

D = number of beads per test (found on the BD Trucount™ Tubes foil pouch label -– it varies from lot to lot)

E = test sample volume (50 µL)

The number of events in the Trucount™ Control Beads region, the number of events in the Trucount™ Beads region, and the absolute count of the Trucount™ Control Beads are shown in the results summary on the lab report.

8. LIMITATIONS

- BD Trucount™ Controls are not intended for use as a cellular process control.

9. PERFORMANCE CHARACTERISTICS

Precision

System performance of the BD FACSLyric™ flow cytometer with BD Trucount™ Controls was evaluated in 4 separate 20-replicate runs prepared from 1 of 3 donors, by 1 of 3 operators, using 1 of 4 lots of BD Trucount™ Controls (Low, Medium, or High), and acquired on 1 of 4 BD FACSLyric™ flow cytometers. The mean bead count for each lot is compared to the expected count printed on the box label to determine accuracy, and the standard deviation (SD) of each level is evaluated for precision. The mean, mean %bias, and SD results for each lot of control beads are shown in the following table.

Table 3 Control bead absolute counts vs expected counts

Level	Lot No.	N, reps	Mean (beads/µL)	Mean %Bias	SD
Low	1	20	50.5	3.06	7.8
	2	20	52.1	4.10	8.1
	3	20	54.4	6.67	8.2
	4	20	51.7	7.71	7.7
Medium	1	20	260.3	5.81	21.4
	2	20	260.0	1.54	22.2
	3	20	259.4	1.73	22.2
	4	20	256.6	4.71	21.3
High	1	20	1,002.3	2.17	63.8
	2	20	1,054.1	2.44	66.9
	3	20	1,050.9	2.53	66.6
	4	20	1,029.8	4.87	63.9

10. TROUBLESHOOTING

Problem	Possible Cause	Solution
Absolute count is incorrect	Bead count from a different lot of BD Trucount™ Tubes was used.	Confirm the lot number and bead count for the BD Trucount™ Tubes. Repeat staining in a new tube.
	Cell concentration is abnormal.	Stain a fresh specimen.
	The bead pellet was not under the metal retainer in the bottom of the tube.	Stain a fresh specimen after confirming that the bead pellet is intact under the metal retainer.
Few or no cells	The metal retainer blocks the aspiration tube when using the BD FACS™ Universal Loader.	Troubleshoot the cytometer.

REFERENCES

1. *Collection of Diagnostic Venous Blood Specimens*, *7th ed.* Wayne, PA: Clinical and Laboratory Standards Institute; 2017. CLSI document GP41.
2. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI document M29-A4.
3. Centers for Disease Control and Prevention. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html. Accessed March 12, 2019.
4. Jackson AL, Warner NL. Preparation, staining, and analysis by flow cytometry of peripheral blood leukocytes. In: Rose NR, Friedman H, Fahey JL, eds. *Manual of Clinical Laboratory Immunology*. 3rd ed. Washington, DC: American Society for Microbiology; 1986:226-235.

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.

Refer to the Eudamed website: https://ec.europa.eu/tools/eudamed for Summary of Safety and Performance.

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.

HISTORY

Revision	Date	Changes made
23-3537(09)	2023-01	Updated to meet requirements of Regulation (EU) 2017/746.
23-3537(10)	2023-07	Updated legal manufacturer address. Added EU and Swiss importer addresses and importer symbol. Updated 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-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
	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.

L006715(08) 2023-03

CONTACT INFORMATION

Becton, Dickinson and Company
BD Biosciences
155 North McCarthy Boulevard
Milpitas, California 95035 USA

EC REP **Becton Dickinson Ireland Ltd.**
Donore Road, Drogheda
Co. Louth, A92 YW26
Ireland

Becton Dickinson Distribution Center NV
Laagstraat 57
9140 Temse, Belgium

CH REP **BD Switzerland Sàrl**
Route de Crassier 17
Business Park Terre-Bonne
Bâtiment A4
1262 Eysins
Switzerland

Becton Dickinson AG
Binningerstrasse 94
4123 Allschwil
Switzerland

BD Biosciences
European Customer Support
Tel +32.53.720.600
help.biosciences@bd.com

Australian and New Zealand Distributors:

Becton Dickinson Pty Ltd.
66 Waterloo Road
Macquarie Park NSW 2113
Australia

Becton Dickinson Limited
14B George Bourke Drive
Mt. Wellington Auckland 1060
New Zealand

Technical Service and Support: In the United States contact BD at 1.877.232.8995 or bdbiosciences.com.
For regions outside the United States, contact your local BD representative or bdbiosciences.com.

ClinicalApplications@bd.com

eifu.bd.com