BD® Stem Cell Enumeration Kit

on BD FACSLyric™ Flow Cytometer

BD

BD® Stem Cell Enumeration (SCE) Kit

With a simplified, acquisition-to-reporting and standardized workflow, the BD® SCE Kit on the BD FACSLyric™ Flow Cytometer is the IVD solution that enables reliable enumeration of CD34+ stem cells for hematopoietic stem cell transplants, while enhancing lab efficiency.

- **Minimize errors** by automatically calculating relevant results.
- **Use trusted BD Trucount™ Tube technology** for determining absolute CD34+ and CD45+ counts and two-level clinically relevant process controls, providing accurate and reproducible results on a single platform.
- **Enhance workflow efficiency** by reducing compensation frequency and minimizing hands-on time through an intuitive, guided workflow and faster, simpler assay setup.
- **Work with a proven IVD solution** that simplifies acquisition and gating following the International Society of Hematotherapy and Graft Engineering (ISHAGE) guidelines for bone marrow, peripheral blood, cord blood and leukapheresis products.

Accurate and reproducible results on a single platform

For In Vitro Diagnostics

Enumerate viable dual-positive CD45+/CD34+ cells

Trusted BD Trucount™ Tube technology

Daily setup is 3.5x faster than the BD FACSCanto™ II Flow Cytometer

39% fewer manual operator steps required

Cost saving on daily assay setup compared to BD FACSCanto™ II Flow Cytometer

- The BD® Stem Cell Enumeration Kit is for **in vitro diagnostic** use on the BD FACSLyric™ Flow Cytometer
- **Enumerate viable dual-positive CD45+/CD34+** hematopoietic stem cell populations to determine **absolute counts** (cells/µL) of viable CD34+ and the **percentages** of viable CD45+/CD34+ hematopoietic stem cells (%CD34)
- Analysis consistent with **ISHAGE guidelines**[1,2,3]
- Utilizes **BD Trucount™ Tube** technology for an accurate and reproducible single platform assay[1,2]
- Provides **equivalent results and linearity over a range from 1–1,000 CD34+ cells/µL** on the BD FACSLyric™ Flow Cytometer as on the BD FACSCanto™ II Flow Cytometer

Supported sample types

24h

- Normal and mobilized peripheral blood
- Fresh leukapheresis product
- Fresh bone marrow

Stain within 24 hr of collection
Acquire within 1 hr of lysing

48h

- Fresh cord blood

Stain within 48 hr of collection
Acquire within 1 hr of lysing

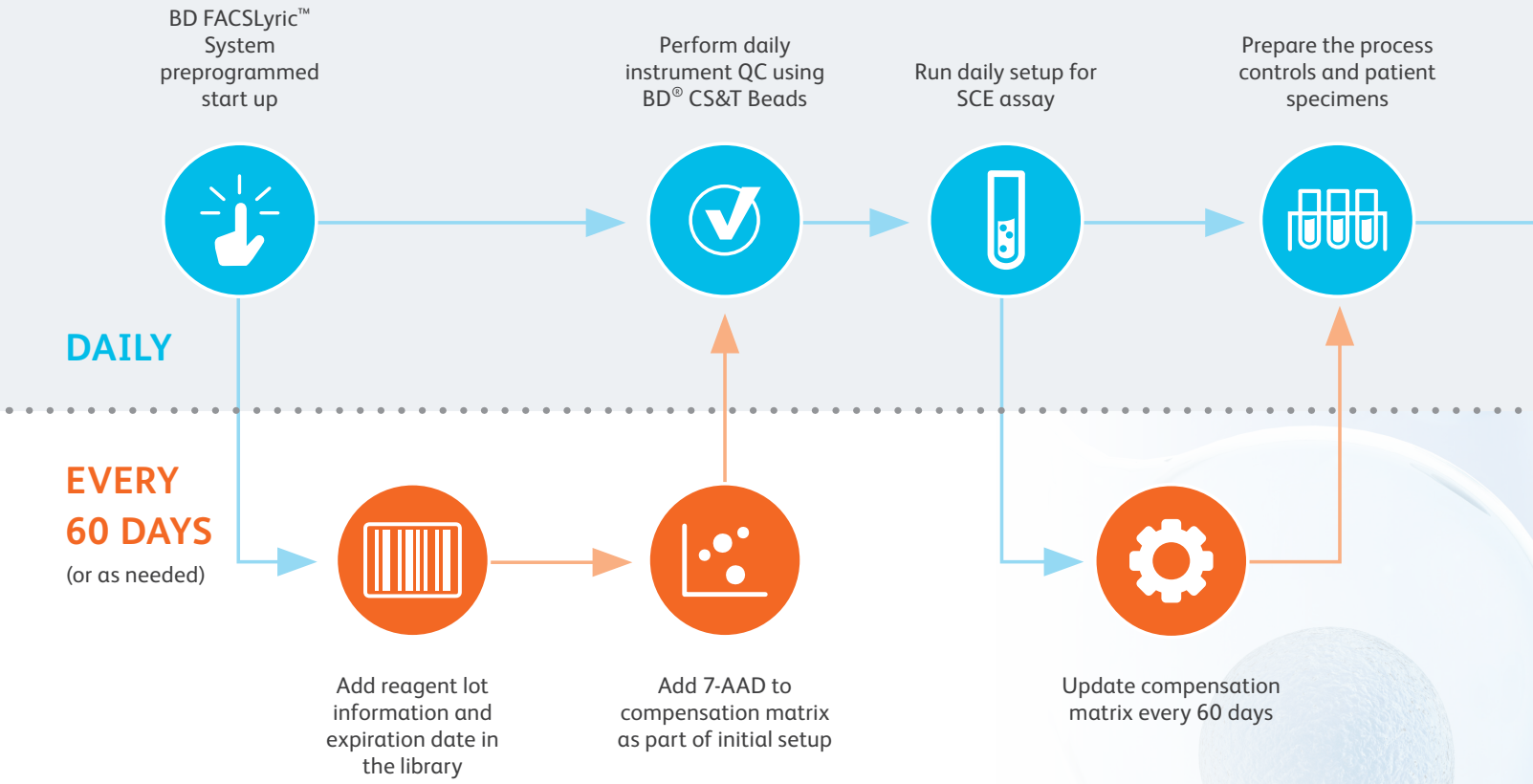
- Thawed leukapheresis product
- Thawed bone marrow
- Thawed cord blood

Stain immediately after thawing
Acquire immediately post-lysis

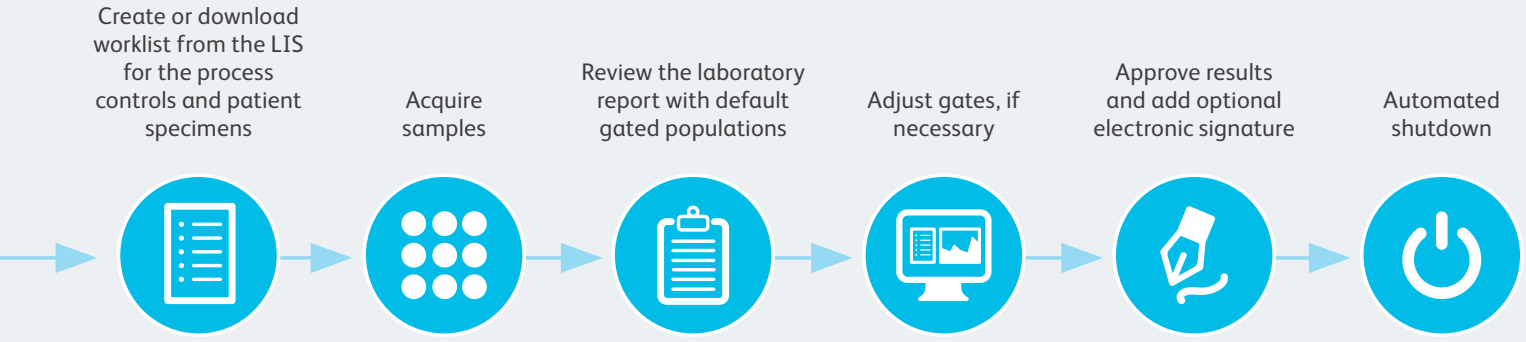
Ordering information

Product name	Reg. Status	Catalog number
BD® Stem Cell Enumeration Kit	IVD	344563
BD® Stem Cell Control (Two-Level)	IVD	340991
BD® Stem Cell Enumeration Assay Module for BD FACSLyric™ System	IVD	665006

BD® Stem Cell Enumeration Assay workflow



- Daily setup of the BD FACSLyric™ Flow Cytometer is **3.5x faster** than the BD FACSCanto™ II Flow Cytometer with **39% less** manual operator steps required
- Easily integrated into existing assay menu and workflow on the BD FACSLyric™ Flow Cytometer
- The **daily time saving** on the BD FACSLyric™ Flow Cytometer is possible as 7-AAD requires setup every 60 days versus daily on the FACSCanto™ II Flow Cytometer
- A **streamlined workflow** on BD FACSLyric™ Flow Cytometer removes the need for separate SCE optimization required on the BD FACSCanto™ II Flow Cytometer thereby **reducing the cost** of daily assay setup and allowing you to **get more tests out of the BD® SCE Kit**
- **Intuitive user-interface, predefined assay template and automatic gating** within the BD FACSuite™ Clinical Application simplifies analysis
- **Lab report** includes multiple electronic signatures and calculated results. Automatically calculated results minimize or remove the need for offline calculations, adding convenience and reducing error



Learn more about the BD® SCE Kit from these posters at bdbiosciences.com/sce

- Alex Fainshtein, Edward Joe, Lori Apoll, Xiaoyang (Alice) Wang, Robert Sutherland. **Accurate enumeration of CD34+ cells with the BD® Stem Cell Enumeration Kit on the BD FACSLyric™ System.** Poster presented at: ESCCA; September 17, 2017; Thessaloniki, Greece
- Ranjani Iyer, Mugdha Patki, Rekha Kannan, Anna Lin, Josh Zollett. **Evaluation of viable dual-positive CS45+/CD34+ stem cells on BD FACSLyric™ System using BD® Stem Cell Enumeration Kit**. Poster presented at: ICCS; October 4, 2019; Atlanta, GA.
- Patricia Cleary, Lori Apoll. **Improved efficiency of BD® Stem Cell Enumeration (SCE) Kit on the BD FACSLyric™ Flow Cytometer as compared to BD FACSCanto™ II Flow Cytometers.** Poster presented at: CYTO; June 7, 2021; virtual
- Angela Chen, Farzad Oreizy, Harshada Rohamare, Yang Zeng, Michelle McNamara. **CD34+ cell analysis on the BD FACSLyric™ System using UK NEQAS samples and the BD® Stem Cell Enumeration Kit.** Poster presented at ICCS, October 8, 2021; Baltimore, MD.
- Mugdha Patki, Rakesh Nayyar, Andrew Watrobski, Anubha Purang, Jenna Treon, Maddison Wells, Anna Kovacs, Shirley Yang, Anna Lin, Maryam Saleminik, Imelda Omana-Zapata. **Stability of fresh leukapheresis, fresh cord blood and fresh bone marrow specimens using the BD® Stem Cell Enumeration Kit on the BD FACSLyric™ Flow Cytometer.** Poster presented at ICCS, October 8, 2021; Baltimore, MD.
- Maurice O'Gorman, Ruba Hsen, Rakesh Nayyar, Anubha Purang, Yang Zeng, Angela Chen, Denis-Claude Roy, Martin Giroux, Caren Mutschmann, John S. Carabott, Maryam Saleminik, Anna Lin, Yuanyuan Yang, Imelda Omana-Zapata. **Multi-site evaluation of the BD® Stem Cell Enumeration Kit for CD34 cell enumeration on BD FACSLyric™ and BD FACSCanto™ II Flow Cytometers.** Poster presented at ICCS, October 8, 2021; Baltimore, MD.

BD® Stem Cell Enumeration Kit laboratory report

BD Stem Cell + 7-AAD: Lab Report

Sample ID: 42577
Sample Name:
Case Number:
Acquired Using: Worklist_030
Trucount Lot ID: 23534
Cytometer: BD FACSLyric
Operator: Admin User

Approved: 06/10/2021 5:34:50 PM
Beads Per Pellet: 52000
Cytometer SN: SN1
Director:
Department: None

Entry Status: Approved
Software: BD FACSuite Clinical v1.4.1
Institution: None
Address:

Tube Name: Stem Cell + 7-AAD

Events Acquired	84,582	Acquisition Date	06/10/2021
Stem Cell Reagent Lot ID	2344	Acquisition Time	4:31:14 PM
7-AAD Lot ID	568	Acquisition Duration (sec)	42.3
Sample Type	Fresh Cord Blood	Dilution Factor	1.0
Keyword 1	Test keyword 1	Pack Volume (mL)	30.0
Keyword 2	Test keyword 2	Body Weight of Recipient (kg)	70.0

Results Summary

Label	Events/Value	Abs Cnt (cells/µL)
Bead Events	3,486	
Viable CD45+	75,001	11,188
Viable CD34+ Stem Cell	343	51
Total CD45+		11,367
Total CD34+ Stem Cell		55
Viable CD34+ Stem Cell as % of Viable CD45+	0.46	
Total CD34+ Stem Cell as % of Total CD45+	0.48	
CD34+ Stem Cell Viability (%)	92.95	
CD45+ Viability (%)	98.43	
Viable CD34+ Stem Cell per Body Weight of Recipient (cells/kg)	21,928	
Viable CD34+ Stem Cell per Pack (cells/pack)	1,534,940	

QC Messages

Showing 0 of 0 QC Messages

Measured

- Bead Events
- Viable CD45+
- Viable CD34+ Stem Cell
- Total CD45+
- Total CD34+ Stem Cell

Calculated

- Viable CD34+ Stem Cell as % of Viable CD45+
- Total CD34+ Stem Cell as % of Total CD45+
- CD34+ Stem Cell Viability (%)
- CD45+ Viability (%)
- Viable CD34+ Stem Cell per Body Weight of Recipient (cells/kg)
- Viable CD34+ Stem Cell per Pack (cells/pack)

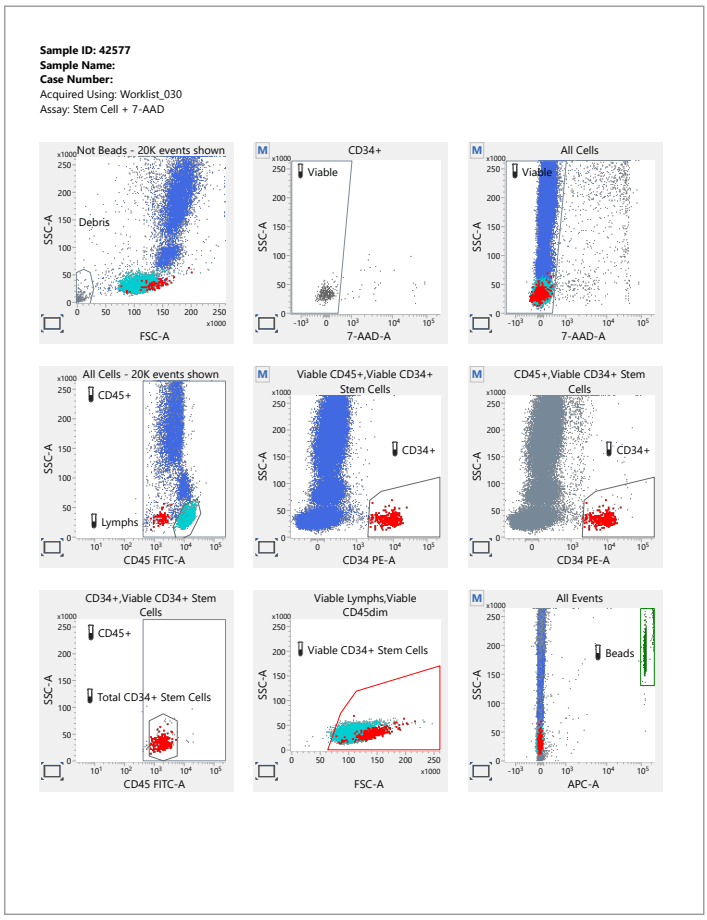


Figure 1: BD® Stem Cell Enumeration Kit lab report from BD FACSuite™ Clinical Application. Results for fresh bone marrow are displayed in the report. Gating strategy follows the ISHAGE protocol.

The BD® Stem Cell Enumeration Kit is sufficient for 50 tests and consists of:

- 50 BD Trucount™ Tubes to determine absolute counts by comparing beads to cell events
- BD® Stem Cell Reagent containing CD45 FITC and CD34 PE for the identification of leukocytes and hematopoietic precursor cells
- 7-Aminoactinomycin D (7-AAD) nucleic acid dye to assess the cell viability
- 10X Ammonium chloride lysing solution for red blood cell lysis

The BD® Stem Cell Control is a complete process control for monitoring CD34+ cells and consists of:

- Whole blood
- Two levels, 2-mL vial per level
- Ready-to-use controls
- CD34+ low control is approx. 10 cells/µL
- CD34+ high control is approx. 35 cells/µL

BD® SCE Kit sample preparation–A few simple steps in a single tube

1

BD Trucount™ Tube

Add 20 µL of BD® Stem Cell Reagent, 20 µL of 7-AAD, and 100 µL of specimen (by reverse pipetting) to a BD Trucount™ Tube

2

Cap and vortex. Incubate in the dark at room temperature for 20 min

3

Add 2 mL of 1X ammonium chloride lysing solution

4

Cap and vortex. Incubate in the dark at room temperature for 10 min

5

Immediately place tubes on wet ice in the dark until ready to acquire samples

6

Acquire samples within 1 hour after lysing for fresh specimens and immediately for thawed specimens.

References

1. Sutherland DR, Anderson L, Keeney M, Nayar R, Chin-Yee I. The ISHAGE guidelines for CD34+ cell determination by flow cytometry. International Society of Hematotherapy and Graft Engineering. *J Hematother*. 1996;5(3):213-116.
2. Keeney M, Chin-Yee I, Weir K, Popma J, Nayar R, Sutherland DR. Single platform flow cytometric absolute CD34+ cell counts based on the ISHAGE guidelines. : *The Cytometry*. 1998;34(2):61-70.
3. Sutherland DR, Nayyar R, Acton E, Giftakis A, Dean S, Mosiman VL. Comparison of two single-platform ISHAGE-based CD34 enumeration protocols on BD FACSCalibur and FACSCanto flow cytometers. *Cytotherapy*. 2009;11(5):595-605.
4. Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI document H42-A2.

Visit our website for more information on the BD® Stem Cell Enumeration Kit

bdbiosciences.com/sce

BD Flow Cytometers are Class 1 Laser Products.
The BD® Stem Cell Enumeration Kit is for In Vitro Diagnostic Use with the BD FACSLyric™ Flow Cytometer, BD FACSCanto™ II Flow Cytometer and the BD FACSCalibur™ Flow Cytometer. The BD FACSLyric™ Flow Cytometer is for In Vitro Diagnostic Use with BD FACSuite™ Clinical Application for up to six colors. The BD FACSLyric™ Flow Cytometer is for Research Use Only with BD FACSuite™ Application for up to 12 colors. Not for use in diagnostic or therapeutic procedures. The BD FACSCanto™ II Flow Cytometer is for In Vitro Diagnostic Use for up to six colors. Seven and eight colors are for Research Use Only. The BD FACSCalibur™ Flow Cytometer is discontinued.

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