



BD[®] Stem Cell Enumeration Kit

on BD FACSLyric[™] Flow Cytometer



BD® Stem Cell Enumeration (SCE) Kit

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

- **Minimise 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 minimising 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.

- The BD® Stem Cell Enumeration Kit is intended for **in vitro diagnostic** use
- **Enumerate viable dual-positive CD45+/CD34+** hematopoietic stem cell populations to determine **absolute counts** (cells/ μ L) of viable CD34+ and the **percentages** of viable CD45+/CD34+ hematopoietic stem cells (%CD34)
- Analysis consistent with **ISHAGE guidelines**^{1,2,3}
- Utilises **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/ μ L** on the BD FACSLyric™ Flow Cytometer as on the BD FACSCanto™ II Flow Cytometer

Supported sample types



- ▶ Normal and mobilised peripheral blood
- ▶ Fresh leukapheresis product
- ▶ Fresh bone marrow

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



- ▶ 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

Accurate and reproducible results on a single platform



In vitro diagnostic medical device



Enumerate viable dual-positive CD45+/CD34+ cells



Trusted BD Trucount™ Tube technology



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



39% fewer manual operator steps required



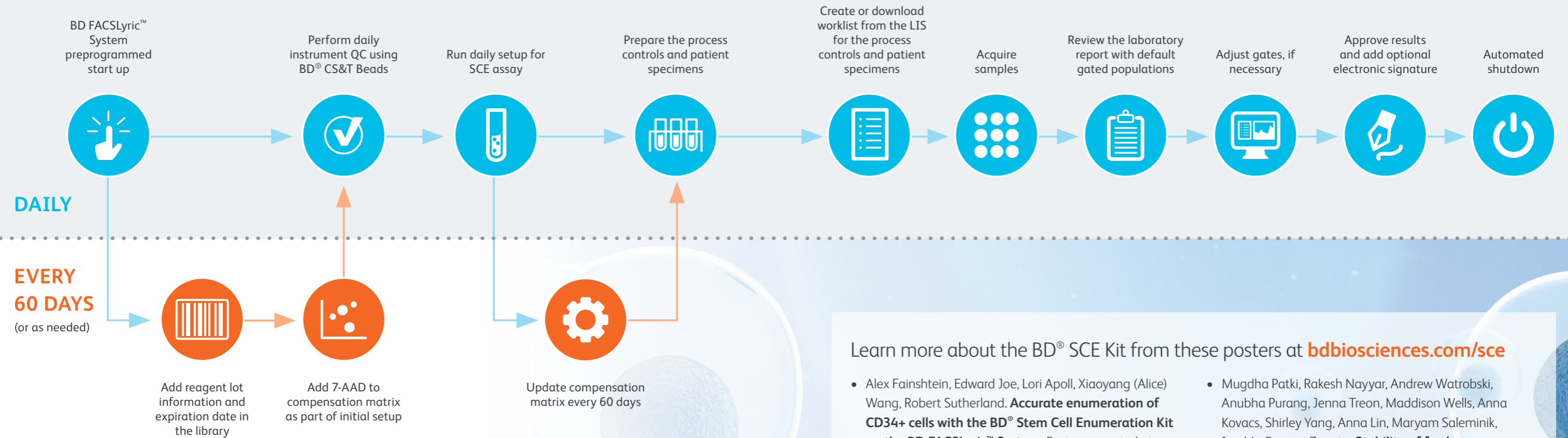
Cost saving on daily assay setup compared to BD FACSCanto™ II Flow Cytometer

Ordering information



Product name	Reg. Status	Catalog number
BD® Stem Cell Enumeration Kit	CE-IVD	664231
BD® Stem Cell Control (Two-Level)	CE-IVD	340991
BD® Stem Cell Enumeration Assay Module for BD FACSLyric™ System	CE-IVD	665005

BD® Stem Cell Enumeration Assay workflow on BD FACSLyric™ Flow Cytometer



- 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
- **Saving time every day** on the BD FACSLyric™ Flow Cytometer is possible as 7-AAD requires setup every 60 days versus daily on the BD FACSCanto™ II Flow Cytometer
- A **streamlined workflow** on BD FACSLyric™ Flow Cytometer removes the need for separate SCE optimisation 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 minimise or remove the need for offline calculations, adding convenience and reducing likelihood of 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	Approved: 06/10/2021 5:34:50 PM	Entry Status: Approved	
Trucount Lot ID: 23534	Beads Per Pellet: 52000		
Cytometer: BD FACSLyric	Cytometer SN: SN1	Software: BD FACSuite Clinical v1.4.1	
Operator: Admin User	Director:	Institution: None	
	Department: 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/ μ L)	
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			

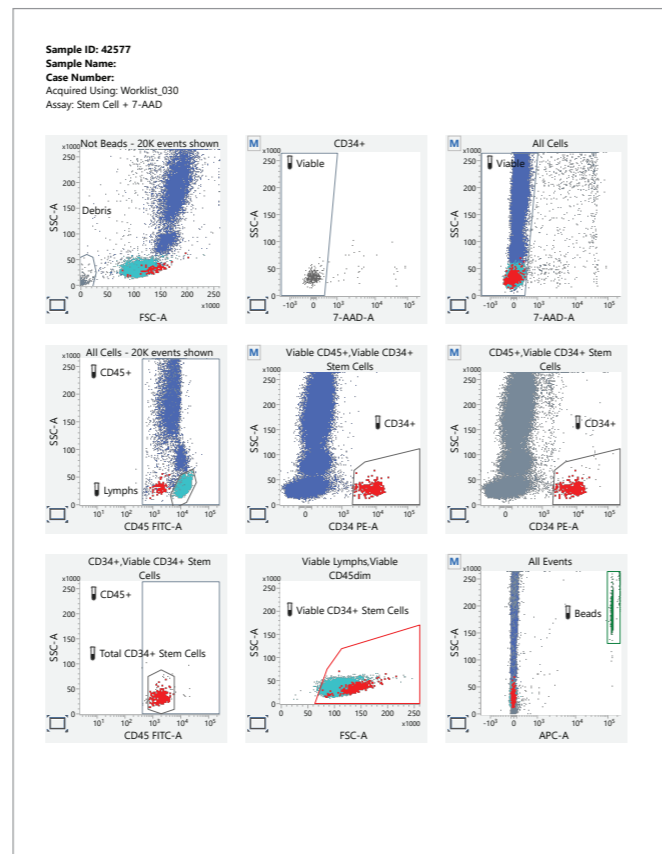
Measured

- ▶ 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 that can be used to monitor the immunophenotyping process for CD34+ cells and consists of:

- Stabilised human leucocytes, erythrocytes, and peripheral blood CD34+ cells (mobilised or natural, or both) in a preservative medium
- Two levels, 2-mL vial per level
- Ready-to-use controls
- CD34+ low control is approx. 10 cells/ μ L*
- CD34+ high control is approx. 35 cells/ μ L*

BD[®] SCE Kit sample preparation—A few simple steps in a single tube**

- Add 20 μ L of BD[®] Stem Cell Reagent, 20 μ L of 7-AAD, and 100 μ L of specimen (by reverse pipetting) to a BD Trucount[™] Tube
- Cap and vortex. Incubate in the dark at room temperature for 20 min
- Add 2 mL of 1X ammonium chloride lysing solution
- Cap and vortex. Incubate in the dark at room temperature for 10 min
- Immediately place tubes on wet ice in the dark until ready to acquire samples
- Acquire samples within 1 hour after lysing for fresh specimens and immediately for thawed specimens.

* Assay ranges can be found in the Assay Values sheet included with the product.

** Please refer to the Instructions For Use (IFU) for a detailed description of the different steps.

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.



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