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Improved workflow efficiency of BD® Stem Cell Enumeration (SCE) Kit on the BD FACSLyric™ Flow Cytometer as compared to the BD FACSCanto™ II Flow Cytometer

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Introduction

The BD® Stem Cell Enumeration (SCE) Kit provides a single-tube assay for the simultaneous enumeration of total and viable dual-positive CD45+/CD34+ hematopoietic stem cell populations in absolute counts (cells/µL) as well as the subset percentage. Absolute counts and subset percentage for total and viable CD45+ cellular population can also be determined.

Objective

The objective of this study was to identify workflow differences using the BD® SCE Assay between the BD FACSCanto™ II and the BD FACSLyric™ Flow Cytometers through qualitative assessment and quantitative data.

Method

A time-in-motion study was conducted to directly compare the setup and sample acquisition of BD® SCE Assay on BD FACSCanto™ II and BD FACSLyric™ Flow Cytometers. Three runs were performed on each system including instrument warmup, assay setup, SCE high and SCE low control, and sample preparation and acquisition. A single operator proficient on both systems performed all runs. Operator process steps were recorded and timed with total time per process step averaged.

Method Summary	
System in Ready State	Turn on System – Ready State
SCE Set up	Daily Assay Setup
Run Samples:	Whole peripheral blood SCE High Control SCE Low Control
# Sample Reps	1
# Runs	3

Conclusion

BD® SCE Assay setup on BD FACSLyric™ Flow Cytometer (FC) is 15 times faster and requires less operator hands-on time when compared to BD FACSCanto™ II Flow Cytometer. Additionally, BD® SCE Assay on BD FACSLyric™ Flow Cytometer provides users with additional result outputs.

Results on Both Systems:	Additional Results on the BD FACSLyric™ FC
Viable CD45+ Abs Counts	Total CD45+ Abs Count
Viable CD34+ Abs Counts	Total CD 34+ Abs Count
Viable CD45+ Events	Total CD34+ as a % of Total CD45+
Viable CD34+ Events	CD45 Viability %
Bead Events	Viable CD34+ per body weight of recipient cells/kg
Viable CD34+ as a % of Viable CD45+	Viable CD34+ per pack
CD34+ Viability %	

The BD FACSCanto™ II and BD FACSLyric™ Flow Cytometers are Class 1 Laser Products.

Results

SYSTEM READY

Instrument warm up was **15 times faster** on the BD FACSLyric™ System, owing to its preprogrammed warm up that allows the user to schedule laser warm up. With lasers already warmed, the BD FACSLyric™ System averaged two minutes with three manual operator steps to be in ready state while BD FACSCanto™ System requiring laser warm up and fluidic start up averaged 30 minutes with five manual operator steps.

ASSAY SETUP

Daily set up of BD® SCE Assay is **3.5x faster** on the BD FACSLyric™ System than the BD FACSCanto™ II System with a **39% reduction in manual operator steps** over 10.7 minutes involving 20 manual operator steps. This compares to the BD FACSCanto™ II System, which took approximately 37 minutes to complete setup with 33 manual operator steps. This daily time saving is afforded by the every-60-day setup of 7-AAD on the BD FACSLyric™ System compared to the daily optimization tube setup requirement on BD FACSCanto™ II System.

SAMPLE PREPARATION

Both specimens and BD SCE Controls follow the same sample preparation instructions for use and therefore are system independent with no changes from the previous released version of the product.

SAMPLE ACQUISITION

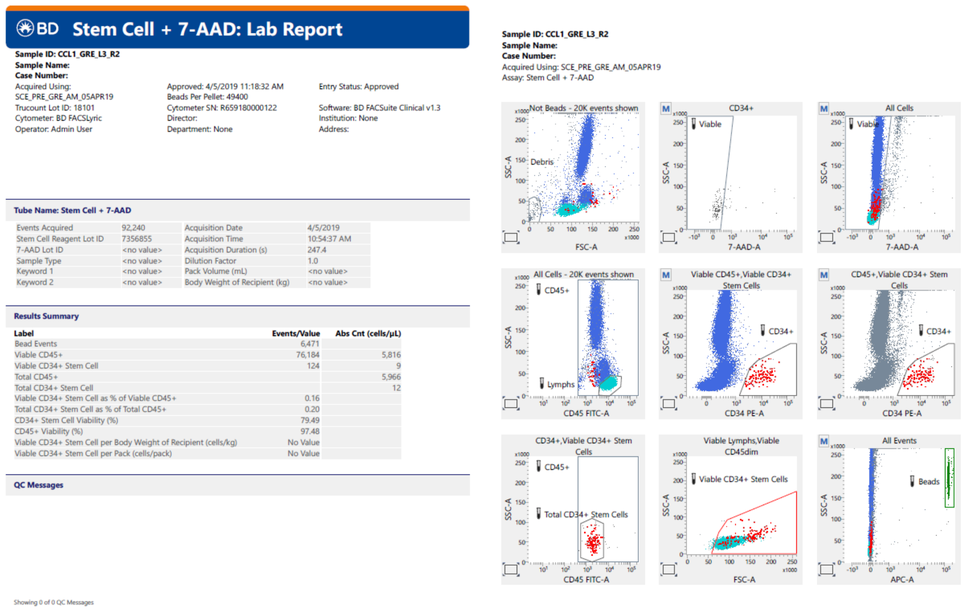
Both BD® SCE Assay control and sample acquisition workflows were similar for time and manual operator steps. Additional regression statistics for viable CD34+ absolute counts and the difference (bias) for %CD34+ in viable CD45+ between the BD FACSLyric™ and BD FACSCanto™ II Systems demonstrate method comparability at a 95% confidence interval.

REVIEW RESULT

BD FACSLyric™ System automatically provides **additional result outputs** not available on the BD FACSCanto™ II FC as follows: Total CD45+ Absolute Count, Total CD34+ Stem Cell Absolute Count, Total CD34+ Stem Cell as % of Total CD45+, CD45+ Viability (%), Viable CD34+ per body weight (cells/kg) and Viable CD34+ per pack.

SCE Assay Outputs: BD FACSLyric™ vs BD FACSCanto™ Flow Cytometers

Example: BD FACSLyric™ System SCE Report



BD Stem Cell + 7-AAD: Lab Report

Sample ID: CCL1_GRE_L3_R2
Sample Name:
Case Number:
Acquired Using: SCE_PRE_GRE_AM_05APR19
Trucount Lot ID: 18101
Cytometer: BD FACSLyric
Operator: Admin User
Approved: 4/5/2019 11:18:32 AM
Beads Per Pellet: 49400
Cytometer SN: R65918000122
Director:
Department: None
Entry Status: Approved
Software: BD FACSuite Clinical v1.3
Institution: None
Address:

Tube Name: Stem Cell + 7-AAD

Events Acquired	92,240	Acquisition Date	4/5/2019
Stem Cell Reagent Lot ID	7356855	Acquisition Time	10:54:37 AM
7-AAD Lot ID	<no value>	Acquisition Duration (s)	247.4
Sample Type	<no value>	Dilution Factor	1.0
Keyword 1	<no value>	Pack Volume (mL)	<no value>
Keyword 2	<no value>	Body Weight of Recipient (kg)	<no value>

Results Summary

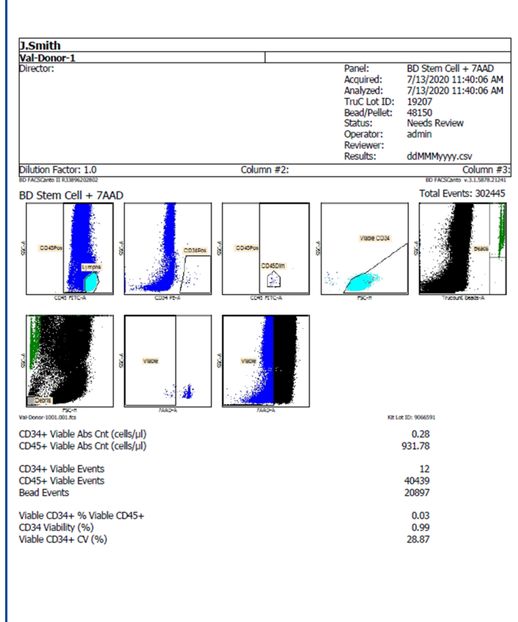
Label	Events/Value	Abs Cnt (cells/µL)
Bead Events	6,471	
Viable CD45+	76,184	5,816
Viable CD34+ Stem Cell	124	9
Total CD45+		5,966
Total CD34+ Stem Cell		12
Viable CD34+ Stem Cell as % of Viable CD45+	0.16	
Total CD34+ Stem Cell as % of Total CD45+	0.20	
CD34+ Stem Cell Viability (%)	79.49	
CD45+ Viability (%)	97.48	
Viable CD34+ Stem Cell per Body Weight of Recipient (cells/kg)	No Value	
Viable CD34+ Stem Cell per Pack (cells/pack)	No Value	

QC Messages

Showing 0 of 0 QC Messages

Sample ID: CCL1_GRE_L3_R2
Sample Name:
Case Number:
Acquired Using: SCE_PRE_GRE_AM_05APR19
Assay: Stem Cell + 7-AAD

Example: BD FACSCanto™ II SCE Report



J.Smith
Val-Donor-1
Director:

Panel:	BD Stem Cell + 7AAD
Acquired:	7/13/2020 11:40:06 AM
Analyzed:	7/13/2020 11:40:06 AM
TruC Lot ID:	19207
Bead/Pellet:	48150
Status:	Needs Review
Operator:	admin
Reviewer:	
Results:	ddMMMyyyy.csv

Dilution Factor: 1.0 Column #2: Column #3

BD Stem Cell + 7AAD Total Events: 302445

CD34+ Viable Abs Cnt (cells/µl)	0.28
CD45+ Viable Abs Cnt (cells/µl)	931.78
CD34+ Viable Events	12
CD45+ Viable Events	40439
Bead Events	20897
Viable CD34+ % Viable CD45+	0.03
CD34 Viability (%)	0.99
Viable CD34+ CV (%)	28.87

For BD FACSLyric CE-IVD, the BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications are CE marked in compliance with the European In Vitro Diagnostic Medical Device Directive 98/79/EC.

BD® SCE Kit is CE marked in compliance with the European In Vitro Diagnostic Medical Device Directive 98/79/EC

BD® SCE Kit is not available for use with BD FACSLyric™ Flow Cytometer in the United States.