

BD Leucocount™ Kit

on the BD FACSLyric™ Flow Cytometer

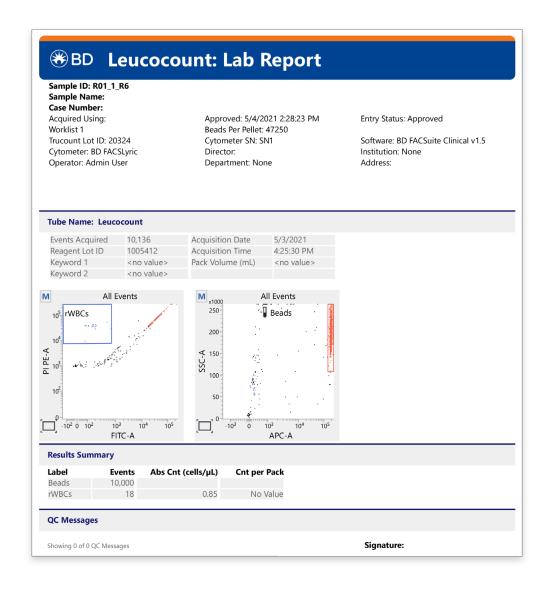






Deliver safety of blood transfusion products with the trusted BD Leucocount™ Kit

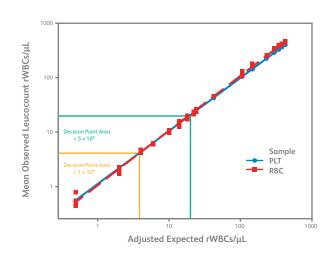
Simplifying enumeration of residual white blood cells (rWBCs) with an CE-IVD assay for the quality control of leucoreduced blood products on the BD FACSLyric[™] Flow Cytometer.



Trusted performance

- Providing sensitivity (Limit of Quantitation of 0.7 rWBC cells/µL) that aligns with leukoreduction guidelines12
- Offering linear results over a range from 0.7-350 rWBC cells/uL

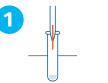
Linearity of the BD Leucocount™ Kit in the analysis of RBC (red) and platelet (blue) samples



Efficient workflow

- Enabling an efficient and intuitive workflow when used with the BD Leucocount™ Kit and BD Leucocount™ **RBC** and PLT Controls
- Delivering high-throughput capability with acquisition using the BD FACS[™] Universal Loader
- Simplifying analysis with predefined templates, lab reports, automated gating and LIS integration
- Features relevant to 21 CFR Part 11 with audit trails and e-signatures

Easy-to-follow steps for using the BD Leucocount[™] Kit



Add 100 µL of wellmixed specimen in a **BD Trucount**[™] Tube



Add 400 µL of BD Leucocount⁻⁻ Reagent to the tube



Cap the tube and gently vortex for no more than 15 seconds



Incubate the tube fo 5 minutes in the dark at room temperature





Samples stained within 24 hours of leucoreduction can be acquired up to 24 hours after staining



Samples stained within 48 hours of leucoreduction should be acquired within 60 minutes of staining.

CE-IVD Assay Daily Workflow on the BD FACSLyric™ Flow Cytometer

BD FACSLyric System preprogrammed



Perform daily instrument QC and assay setup using **BD® CS&T Beads**

Acquire samples using Manual port or the BD FACS™ Universal Loader Review lab report and adjust gates if necessary

Approve results and add optional electronic signatures

Send results through the lab information system



Automated

shutdown













Visit our website for more information on the BD Leucocount™ Kit



bdbiosciences.com/leucocount

Product Description	Catalog number
BD Leucocount ⁻ Kit	340523
BD Leucocount ⁻ Assay Module for BD FACSLyric ⁻ Flow Cytometer	665731
BD Leucocount ⁻ RBC Control	341001
BD Leucocount ⁻ PLT Control	341002
BD Leucocount ^a Combo Control (RBC Control and PLT Control)	341003

References

- 1. European Directorate for the Quality of Medicines & HealthCare and the Council of Europe. *Guide to the preparation, use and quality assurance of blood components.* 20th Edition, 2020. Accessed on March 3, 2023, at https://freepub.edqm.eu/publications/AUTOPUB_48/detail
- 2. U.S. Food & Drug Administration. *Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion*. 2012. Accessed on March 3, 2023, at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pre-storage-leukocyte-reduction-whole-blood-and-blood-components-intended-transfusion

The BD FACSLyric™ Flow Cytometer is a Class 1 Laser Product.



BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Applications, BD FACS™ Universal Loader, BD Leucocount™ Assay Module and BD® CS&T Beads are in vitro diagnostic medical devices bearing a CE mark.



BD Leucocount™ Kit, BD Leucocount™ RBC and PLT Controls and BD Leucocount™ Combo Control are in vitro diagnostic medical devices bearing a CE mark and are CE certified by BSI Group the Netherlands B.V. (Notified Body Number = 2797).

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