

BD Leucocount™ Kit

on the BD FACSLyric[™] Flow Cytometer

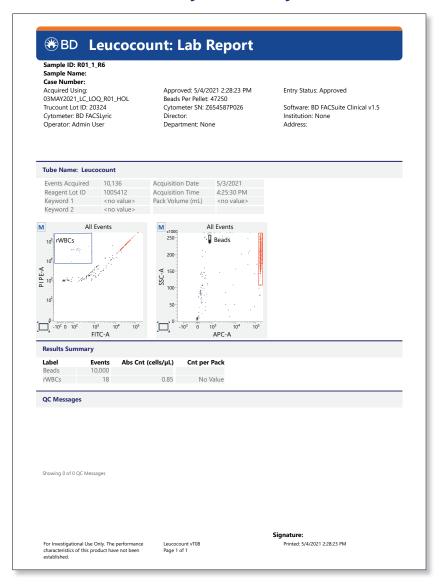






Deliver safety of blood transfusion products

Simplifying enumeration of residual white blood cells (rWBCs) with an IVD assay for the quality control of leucoreduced blood products on the BD FACSLyric^{**} Flow Cytometer.



IVD Assay Daily Workflow on the BD FACSLyric™ Flow Cytometer

BD FACSLyric System preprogrammed start up

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







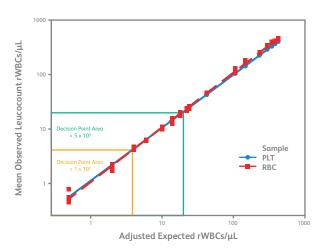


with the trusted BD Leucocount™ Kit

Trusted performance

- Providing sensitivity (Limit of Quantitation of 0.7 rWBC cells/µL) that aligns with leukoreduction guidelines¹
- Offering linear results over a range from 0.7 to 350 rWBC cells/µL

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
- Supporting 21 CFR Part 11 compliance with audit trails and e-signatures

Five easy-to-follow steps for using the BD Leucocount™ Kit



Add 100 μL of well-mixed specimen in α

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 for 5 minutes in the dark at room temperature



Acquire sample



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.

Approve results and add optional electronic signatures

Send results through the lab information system









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



bdbiosciences.com/usr-leucocount-kit

Product Description	Catalog number
BD Leucocount* Kit	662415
BD Leucocount ⁻ Assay Module for BD FACSLyric ⁻ Flow Cytometer	665732
BD Leucocount® RBC Control	662416
BD Leucocount* PLT Control	662417
BD Leucocount Combo Control (RBC Control and PLT Control)	662418

References

1 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-wholeblood-and-blood-components-intended-transfusion

BD FACSLyric™ Flow Cytometers are Class 1 Laser Products.

The BD FACSLyric $^{\text{\tiny{IM}}}$ Flow Cytometer is for In Vitro Diagnostic Use with BD FACSuite $^{\text{\tiny{IM}}}$ 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® Leucocount™ Kit is for In Vitro Diagnostic Use with the, BD FACSLyric™ Flow Cytometer BD FACSVia™ Flow Cytometer and BD FACSCalibur™ Flow Cytometer.

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