Individuals need standards

Approved by
EuroFlow

BD OneFlow™ Solution on BD FACSCanto™ II and BD FACSLyric™ Flow Cytometers

BD - Europe, Terre Bonne Park – A4, Route de Crassier 17, 1262 Eysins, Switzerland

CE

bdbiosciences.com-eu

BD

BD OneFlow™ Solution

EuroFlow™ Strategy for immunophenotypic characterization of hematological malignancies

Approved by EuroFlow

Built on the research and validation work of the EuroFlow™ Consortium on the characterisation of hematological malignancies for improved diagnostic outcomes,[1] the BD OneFlow™ Solution brings the standardisation of leukemia and lymphoma immunophenotyping one step forward. It is a comprehensive set of reagents (BD OneFlow™ LST, B-CLPD T1, PCST, PCD, and ALOT), setup beads, protocols, and assay templates to reproducibly set up the flow cytometer and stain, acquire, and analyse patient specimens for immunophenotyping of normal and aberrant cell populations. The BD OneFlow™ solution improves efficiency by providing a standardised and simplified methodology, increasing reliability and enabling accuracy and confidence in results.[2,3]

The EuroFlow Consortium designed multicolor antibody panels to fully characterise the cell populations in a patient specimen using immunophenotypic markers that are indicative of normal and abnormal cells.[1] In addition to the optimised multicolor antibody panels, the EuroFlow protocol comprises standardised procedures for cytometer setup, determination of assay settings, sample preparation and staining, sample acquisition, and data analysis.[4]

The single-tube screening panels and multi-tube classification panels fit into the EuroFlow diagnostic algorithm for the identification and classification of hematological disorders. Each tube contains a set of backbone-markers and a set of classification markers.[1]

Backbone markers are shared across a particular set of panels and are used to normalise the samples so that data files can be combined and analysed as a single, large data file. They are markers that identify distinct cell populations in a particular cell lineage. Classification markers have been selected for their diagnostic utility in discriminating between cell types within a given lineage and in classifying the abnormal cell type in the sample.

J.J.M. van Dongen et al. LEUKEMIA 2012; 26: 1908-1975. This diagram has been provided courtesy of EuroFlow Consortium.

Efficiency

Optimised workflows improve efficiency

BD OneFlow™ Reagents improve laboratory efficiency by reducing the time spent for sample preparation.[2,3]

Provided in a ready-to-use, dried, single-test tube format, BD OneFlow™ Reagents allow for direct specimen staining, eliminating the need for antibody pipetting, minimising operational mistakes and the risk for testing repetition, thus reducing manual workload.

BD OneFlow™ Instrument setup and ready-to-use single-dose compensation beads simplify instrument standardisation and reduce technical burden and training needs.
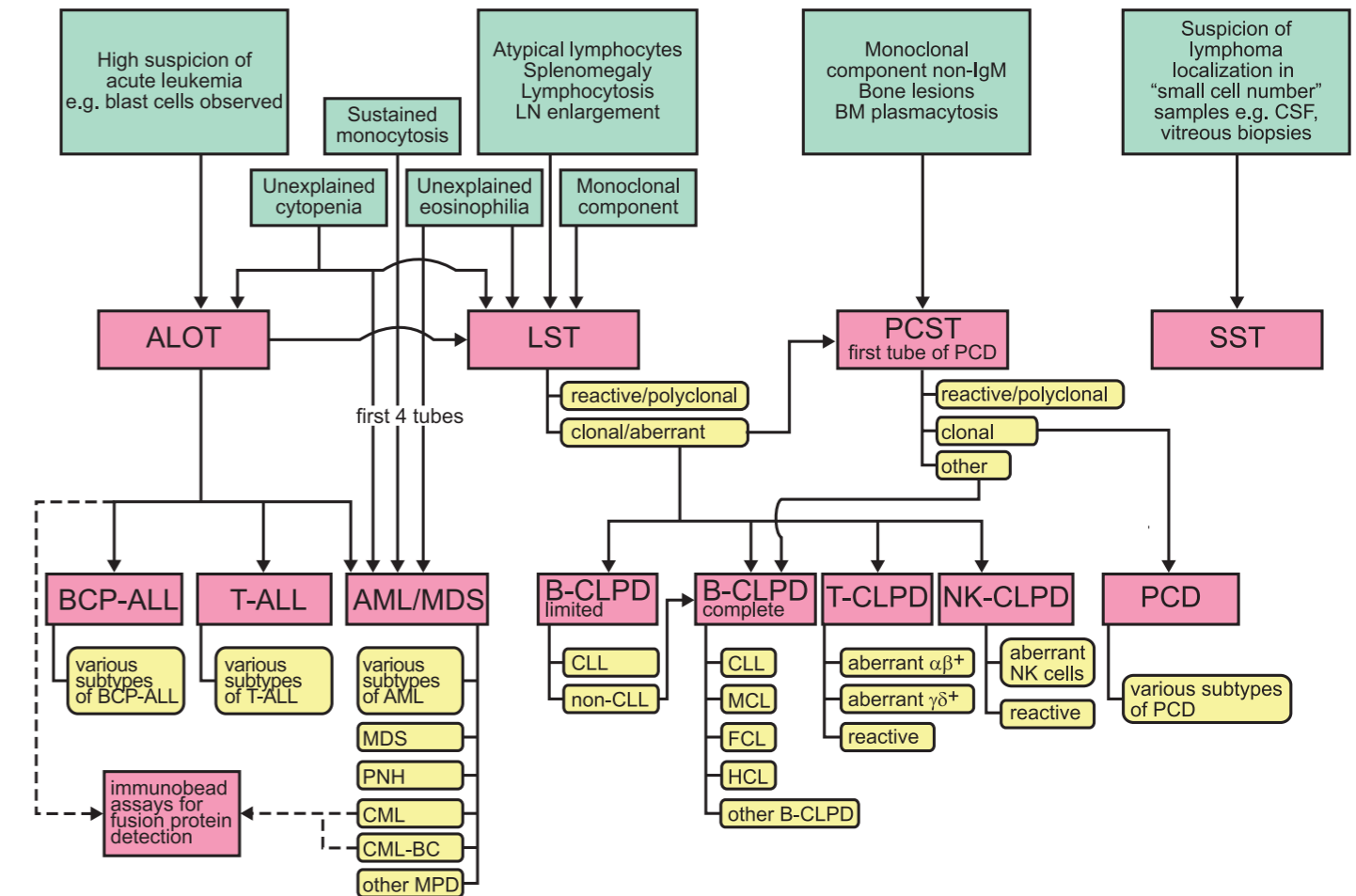
Compliance

Complete CE/IVD system enables compliancy

The BD OneFlow™ Solution is CE marked to the European In Vitro Diagnostic Medical Device Directive 98/79/EC. The BD OneFlow™ solution also helps laboratories in their accreditation process to comply with EN ISO 15189 standard ("Medical laboratories – Requirements for quality and competence").

Accuracy

Standardisation improves data accuracy

Standardisation of processes supports the quality of results and ultimately support the diagnosis and treatment of patients. Built on the standards defined by the EuroFlow™ Consortium, the predefined, disease-specific 8-color reagent panels provide high diagnostic utility delivering accurate and reproducible results.

"The (EuroFlow) LST detected aberrant B-, T- or NK-cells immunophenotypes in 149/150 (99.4%) of B-CLPD and in 78/83 (94%) of T/NK-CLPD with an overall frequency of 97.4%."* [1]

"An unprecedented orientation efficiency of 98.3% for non-ambiguous lineage cases was shown for the (EuroFlow) ALOT combination with a series of 483 newly diagnosed acute leukemia cases, tested prospectively at different centers." [1]

*B-cell chronic lymphoproliferative diseases

Workflow

BD OneFlow™ Reagents can be run on both the BD FACSLyric™ and BD FACSCanto™ II Flow Cytometers for equivalent results.
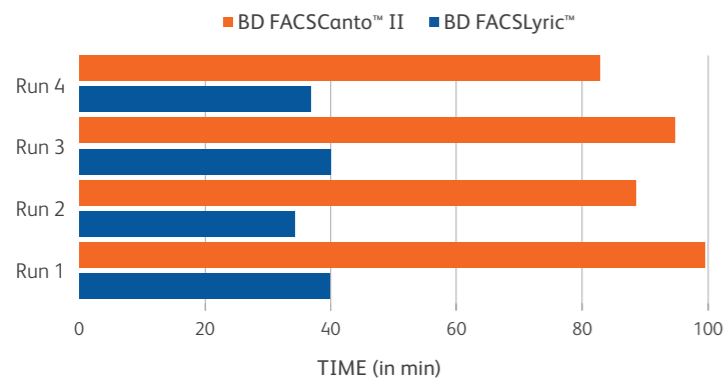
Periodic Setup

🔧 Instrument Setup and QC

BD FACSLyric™

- Characterisation QC with BD® CS&T Beads (6 months or as needed)
- Reference settings update with BD® FC Beads 7-Color and 5-Color Kits (Every 60 days)

BD FACSCanto™ II (monthly)

- Performance check with BD FACSDiva™ CS&T IVD Bead
- PMT voltage adjustment with BD OneFlow™ Setup Beads
- FSC and SSC adjustments with lysed wash blood
- Compensation with BD® FC Beads 8-Color Kit for BD OneFlow™ Assays

Daily Workflow

👆 Startup	🗓 Daily Setup and QC	🧪 Sample Preparation	🔍 Acquisition and Analysis

BD FACSLyric™

Automatic Startup	Performance QC with BD CS&T Beads Assay and Tube Settings Setup with BD CS&T Beads	Standardised sample preparation with BD OneFlow™ Reagents	Sample acquisition and analysis with predefined templates and reports

BD FACSCanto™ II

Instrument Start Up Fluidics Start Up	Performance QC with BD FACSDiva CS&T IVD Beads PMT voltage confirmation with OneFlow Setup Beads	Standardised sample preparation with BD OneFlow™ Reagents	Sample acquisition and analysis with predefined templates and reports

Instrument Setup Time for Operator

■ BD FACSCanto™ II   ■ BD FACSLyric™

TIME (in min)

BD FACSLyric™ Instrument Benefits*

- **69%** annual reduction in periodic instrument setup and QC time
- **95%** annual reduction in instrument set-up hands-on time to less than **30** minutes annually

Daily Setup Time for Operator

■ BD FACSCanto™ II   ■ BD FACSLyric™

TIME (in min)
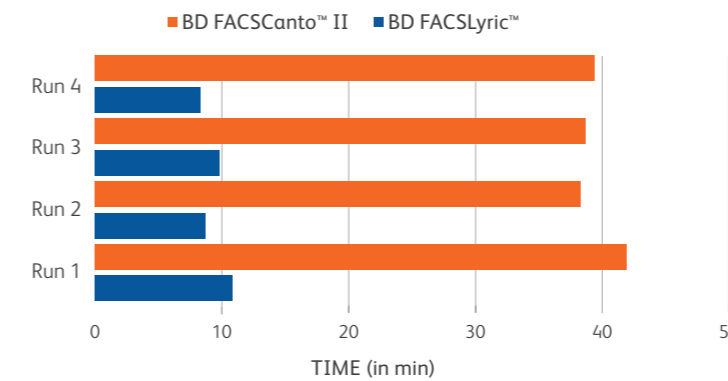
BD FACSLyric™ Instrument Benefits*

- **74%** reduction in manual daily startup and setup steps
- **76%** reduction in daily startup and setup time

*Relative to BD OneFlow™ on BD FACSCanto™ II based upon internal testing. BD FACSLyric™ warmup time is not included as it is pre-programmable and does not impact operator time. Individual lab performance will vary.

BD OneFlow™ LST
Lymphoid Screening Tube

20 tests/box

BD OneFlow™ LST

The BD OneFlow™ LST (Lymphoid Screening Tube) is intended for flowcytometric immunophenotyping of normal and aberrant mature lymphocyte populations of B, T, and NK lineages in peripheral blood, bone marrow, and lymph nodes, as an aid in the diagnosis of hematological disorders.

In chronic lymphoproliferative disorders (CLPD), clonogenic events lead to the expansion and accumulation of mature-appearing lymphocytes, which carry a proliferative and/or survival advantage over their normal counterparts.[1] Thus, the detection of phenotypically aberrant and clonal mature lymphocytes is critical to the diagnosis of CLPD.

"The (EuroFlow) LST detected aberrant B-, T-, or NK-cells immunophenotypes in 149/150 (99.4%) of B-CLPD and in 78/83 (94%) of T/NK-CLPD with an overall frequency of 97.4%."[1]

Laser								
Format	BD Horizon™ V450	BD Horizon™ V500-C	FITC	PE	PerCP-Cy5.5	PE-Cy7	APC	APC-H7
Marker	CD20 CD4	CD45	CD8 Igλ	CD56 Igκ	CD5	CD19 TCRγδ-1	CD3	CD38

The antibodies in the BD OneFlow™ LST were chosen for their ability to separate normal lymphocytes into their major subpopulations.

- CD45 identifies mature lymphocytes and B cell precursors.
- CD3 identifies T cells.
- CD3 can also be used to identify B cells and NK cells by exclusion.
- Anti-TCRγ/δ-1, CD5, CD4, and CD8 can separate T cells into a number of subpopulations.
- CD19 and CD20 identify B cells, and together with CD45 can separate B cells into mature B lymphocytes (CD19+, CD20hi, CD45hi) and B-cell precursors (CD19+, CD20-/lo, CD45lo). CD19 and CD20 are also used to identify NK cells by exclusion.

- Anti-Kappa and Anti-Lambda can identify normal and clonally expanded populations of B cells expressing Igκ or Igλ on the surface membrane, respectively.
- CD38 identifies plasma cells and B cell precursors. In addition, it is informative in the evaluation of a wide variety of lymphoid malignancies. CD38 can also aid in the identification of NK cells.
- CD56 identifies NK cells.

BD OneFlow™ B-CLPD T1
B Cell Lymphoproliferative Disorders – Tube 1

20 tests/box

BD OneFlow™ B-CLPD T1

The BD OneFlow™ B-CLPD T1 (B cell Chronic Lymphoproliferative Diseases Tube 1) shall be used for specimens with B-lineage populations needing further investigation in combination with the BD OneFlow™ LST (Lymphoid Screening Tube). The BD OneFlow™ B-CLPD T1 is intended for flow-cytometric immunophenotyping of B cells in peripheral blood and bone marrow as an aid in the diagnosis of chronic lymphocytic leukemia (CLL) and other B cell chronic lymphoproliferative diseases.

Laser								
Format	BD Horizon™ V450	BD Horizon™ V500-C	FITC	PE	PerCP-Cy5.5	PE-Cy7	APC	APC-H7
Marker	CD20	CD45	CD23	CD10	CD79b	CD19	CD200	CD43

The antibodies in BD OneFlow™ B-CLPD T1 were chosen to work in conjunction with the antibodies in BD OneFlow™ LST to distinguish CLL from other B cell chronic lymphoproliferative diseases in patient specimens.

- CD45, CD19, and CD20 are present in both BD OneFlow™ LST and BD OneFlow™ B-CLPD T1 and serve as backbone markers, allowing for the direct comparison of specimens stained using the two tubes.
- CD23, CD200, CD79b, CD43, and CD10 are classification markers and, together with CD5 and CD38 from BD OneFlow™ LST, allow for specimens to be classified as CLL or as other B cell chronic lymphoproliferative diseases.

- Anti-Kappa and Anti-Lambda, present in BD OneFlow™ LST, assess the clonality of the B cell population.

BD OneFlow™ PCST
Plasma Cell Screening Tube

10 tests/box

BD OneFlow™ PCD
Plasma Cell Disorders Tube

10 tests/box

Plasma cell disorders are a group of diseases most often characterised as having a clonal (neoplastic) population of plasma cells in the bone marrow (BM).[1] The cells may secrete a clonal immunoglobulin that can be detected in the circulation. These disorders comprise several distinct diseases, including multiple myeloma and monoclonal gammopathy of undetermined significance.

BD OneFlow™ PCST

The BD OneFlow™ PCST (Plasma Cell Screening Tube) is intended for flow-cytometric immunophenotyping of normal polyclonal and aberrant plasma cell populations in bone marrow as an aid in the diagnosis of hematological disorders.

BD OneFlow™ PCST consists of two single-use tubes containing fluorochrome-conjugated antibodies in an optimised dried formulation. BD OneFlow™ PCST (S) contains antibodies that recognise markers on the surface of cells, and BD OneFlow™ PCST (C) contains antibodies that recognise Igκ and Igλ in the cytoplasm of cells after fixing and permeabilising them.

BD OneFlow™ PCD

The BD OneFlow™ PCD (Plasma Cell Disorders) tube, when run in parallel with the BD OneFlow™ PCST (Plasma Cell Screening Tube), is intended for flow-cytometric immunophenotyping of normal and aberrant plasma cells in bone marrow as an aid in the diagnosis of multiple myeloma and other plasma cell disorders.

Laser								
Format	BD Horizon™ V450	BD Horizon™ V500-C	FITC	PE	PerCP -Cy™ 5.5	PE-Cy™ 7	APC	APC-H7
Marker	CD45 (S)	CD138 (S)	CD38 (S)	CD56 (S)	β2-Microglob. (S)	CD19 (S)	CyIgκ (C)	CyIgλ (C)

The antibodies in the BD OneFlow™ PCST tube were chosen for their ability to identify and characterise plasma cells.

, CD38, CD138, CD45, and CD19 are backbone markers used to identify plasma cells.

, CD56 and β2-Microglobulin are classification markers used to identify aberrant plasma cell populations.

, Anti-Kappa and Anti-Lambda are used to assess the clonality of the plasma cells.

, CD19, Anti-Kappa, and Anti-Lambda are also used to identify and characterise mature B cells.

Laser								
Format	BD Horizon™ V450	BD Horizon™ V500-C	FITC	PE	Per-CP-Cy™5.5	PE-Cy™7	APC	APC-H7
Marker	CD45	CD138	CD38	CD28	CD27	CD19	CD117	CD81

The antibodies in the BD OneFlow™ PCD tube were chosen for their ability to identify plasma cells.

, CD38, CD138, CD45, and CD19 are backbone markers used to identify plasma cells.

, CD27, CD28, CD117, and CD81 are classification markers used to identify aberrant plasma cell populations.

BD OneFlow™ ALOT
Acute Leukemia Orientation Tube

10 tests/box

BD OneFlow™ ALOT

The BD OneFlow™ ALOT (Acute Leukemia Orientation Tube) is intended for flow-cytometric immunophenotyping of aberrant immature populations of hematopoietic cells (lymphoid and non-lymphoid lineage) in bone marrow and peripheral blood as an aid in the diagnosis of acute lymphoblastic leukemia and non-lymphoid acute leukemia.

BD OneFlow™ ALOT consists of two single-use tubes containing fluorochrome-conjugated antibodies in an optimised dried formulation. The BD OneFlow™ ALOT (S) tube contains antibodies that recognise markers on the surface of cells, and the BD OneFlow™ ALOT (C) tube contains antibodies that recognise antigens in the cytoplasm of cells after fixing and permeabilising them.

Acute leukemias are a heterogeneous group of diseases characterised as having a clonal (neoplastic) population of immature hematopoietic cells in the peripheral blood (PB) or bone marrow (BM).[1]

There are two major classes of acute leukemias: lymphoid precursor leukemias and acute myeloid leukemias (AML). The lymphoid precursor leukemias are divided into B cell and T cell precursor lymphoblastic leukemias (BCP-ALL and T-ALL, respectively).

In addition, a small number of neoplasms do not fit into any of these categories because they either show no clear expression of markers indicative of a particular lineage or they express markers specific to more than one lineage. They include acute undifferentiated leukemia (AUL) and mixed phenotype acute leukemia (MPAL).

Laser								
Format	BD Horizon™ V450	BD Horizon™ V500-C	FITC	PE	PerCP -Cy 5.5	PE-Cy7	APC	APC-H7
Marker	cyCD3 (C)	CD45 (S)	cyMPO (C)	cyCD79a (C)	CD34 (S)	CD19 (S)	CD7 (S)	CD3 (S)

The antibodies in the BD OneFlow™ ALOT were chosen for their ability to identify and characterise aberrant immature populations of hematopoietic cells.

- CD45, CD34, and CD19 are the backbone markers for the BCP-ALL panel.

- CD45, cytoplasmic CD3 (cyCD3), and CD3 are the backbone markers for the T-ALL panel.

- CD45 and CD34 are the backbone markers for the AML panel.

- CD34 and negative or dim expression of CD45 (CD45$^{neg/dim}$) are markers for immature cells.

- Cytoplasmic myeloperoxidase (cyMPO) is a myeloid lineage marker.

- cyCD3 and CD7 are T cell lineage markers.

- CD3 is used as a maturity marker for T cells.

- CD19 and cytoplasmic CD79a (cyCD79a) are B cell lineage markers

BD OneFlow™ setup on the BD FACSCanto™ II

BD FACSDiva™ CS&T IVD Beads

, Standardise setup and monitoring for consistent performance.

BD OneFlow™ Setup Beads

, Ensure data accuracy and reproducibility by providing assay-specific target values, as per EuroFlow™ SOPs.[4]

, Enable lab efficiency by minimising the technical burden and training needs.[3]

BD® FC Beads 8-Color-Kit for BD OneFlow™ Assays

, Eliminate the need for using single vial reagents with ready-to-use single-test dye-coupled beads.

, Enable lab efficiency with a simplified procedure for standardised compensation.[3]

, Support consistency of results, eliminating need for using cells for compensation.[2,3]

BD OneFlow™ Assays System for the BD FACSCanto™ II

, Standardise acquisition and analysis in BD FACSDiva™ v8.0.1, v8.02, v8.0.3, and v9.0 with predefined templates for consistency of results.
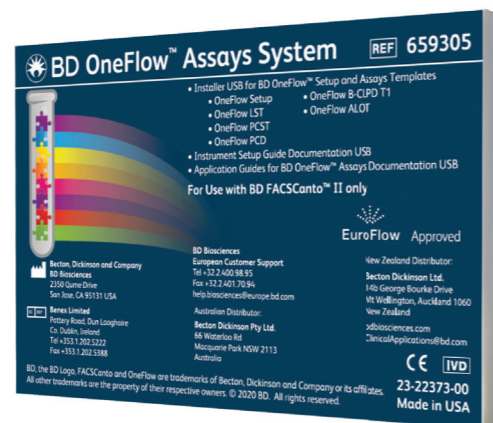
BD OneFlow™ setup on the FACSLyric™

BD® CS&T IVD Beads

, Standardise setup and monitoring for consistent performance.

, Enables single-tube QC for daily setup and performance checks.

BD® FC Beads 7-Color and 5-Color Kits

, Ready-to-use single-test dye-coupled beads for compensation every 60 days.

, No need for using single vial reagents for label-specific compensation.

, Enable lab efficiency with automated compensation.

BD OneFlow™ Assays Installers

, Standardise acquisition and analysis in BD FACSuite™ Clinical Application v1.4 with predefined templates for consistency of results

, Supplemental analysis reports for flexibility in examining additional cell populations

, Reports available in 25 languages
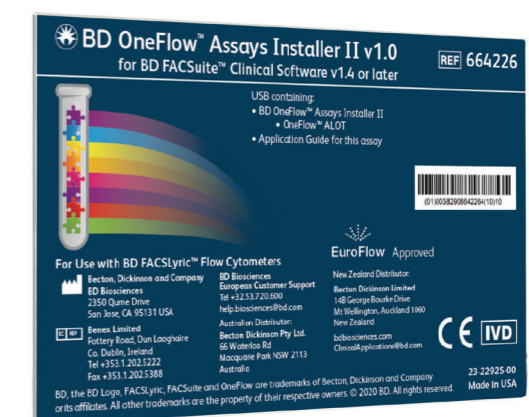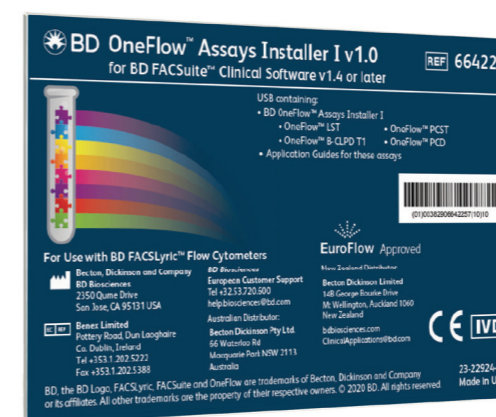
Ordering Information

Product name	Tests	Description	Reg. Status	Product number
BD OneFlow™ LST	20 tests	4 pouches/box – 5 tubes/pouch	CE-IVD	658619
BD OneFlow™ B-CLPD T1	20 tests	4 pouches/box – 5 tubes/pouch	CE-IVD	659293
BD OneFlow™ PCST	10 tests	4 pouches/box (2 S and 2 C) – 5 tubes/pouch	CE-IVD	659912
BD OneFlow™ PCD	10 tests	2 pouches/box – 5 tubes/pouch	CE-IVD	659913
BD OneFlow™ ALOT	10 tests	4 pouches/box (2 S and 2 C) – 5 tubes/pouch	CE-IVD	660228
BD FACSCanto™ II related products				
BD OneFlow™ Assays System Installer	–	3 USB cards: one each for assays installer, setup guide, and application guides	CE-IVD	659305
BD FACSDiva™ CS&T IVD Beads	50 tests	1 vial	CE-IVD	656046
	150 tests	3 vials of 50 tests each		656047
BD OneFlow™ Setup Beads	25 tests	1 vial + 2 MFI target value cards	CE-IVD	658620
BD™ FC Beads 8-Color Kit for BD OneFlow Assays	5 tests	8 pouches/box (1 pouch/color) - 5 tubes/pouch	CE-IVD	658621
BD FACSLyric™ related products				
BD OneFlow™ Assays Installer I	–	1 USB card containing BD OneFlow™ LST, BD OneFlow™ B-CLPD T1, BD OneFlow™ PCST, and BD OneFlow™ PCD assay installers and assays application guides	CE-IVD	664225
BD OneFlow™ Assays Installer II	–	1 USB card for BD OneFlow™ ALOT assay installer and assay application guide	CE-IVD	664226
BD® CS&T IVD Beads	50 tests	1 vial	CE-IVD	656504
	150 tests	3 vials of 50 tests each		656505
BD® FC Beads 7-Color Kit	5 tests	7 pouches/box (1 pouch/color) - 5 tubes/pouch	CE-IVD	656867
BD® FC Beads 5-Color Kit	5 tests	5 pouches/box (1 pouch/color) - 5 tubes/pouch	CE-IVD	661564

Visit our website for more information on BD OneFlow™ Solution

eu.bd.com/oneflow

References

1. van Dongen, J.J., Lhermitte, L., Bottcher, S., et al. EuroFlow antibody panels for standardised n-dimensional flow cytometric immunophenotyping of normal, reactive and malignant leukocytes. *Leukemia.* 2012; 26: 1908-1975.

2. van der Velden, V., Flores-Montero, J., Perez-Andres, M., et al. Optimisation and testing of dried antibody tube: The EuroFlow LST and PIDOT tubes as examples. *J Immunol Methods.* 2019;475:112287.

3. Moloney, E., Watson, H., Barge, D., et al. Efficiency and Health Economic Evaluations of BD OneFlow™ Flow Cytometry Reagents for Diagnosing Chronic Lymphoid Leukemia. *Cytometry Part B (Clinical Cytometry).* 2019.

4. Kalina, T., Flores-Montero, J., van der Velden, V.H., et al. EuroFlow standardisation of flow cytometer instrument settings and immunophenotyping protocols. *Leukemia.* 2012; 26:1986-2010.