ALL THE PIECES ARE IN PLACE

CLEARLLAB 10C SYSTEM, INCLUDING APPLICATION SPECIFIC CONTROL CELLS

EMPOWER
life-changing decisions.

BECKMAN COULTER
Life Sciences

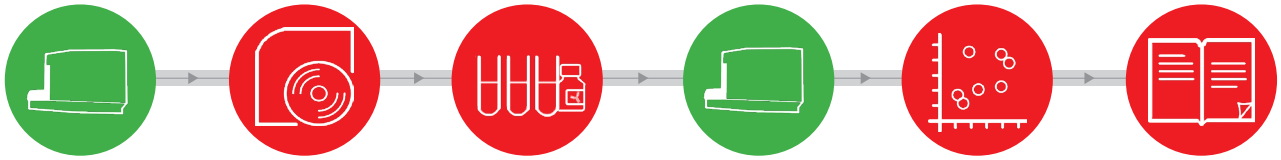
A POWERFUL SOLUTION FOR OPTIMIZING YOUR LAB'S L&L WORKFLOW

Now there's a simple yet powerful way for your lab to expedite and standardize compliant Leukemia and Lymphoma* (L&L) immunophenotyping.

As the **only integrated L&L immunophenotyping solution for lymphoid and myeloid lineages** the ClearLLab 10C system includes:

- ClearLLab CE-IVD 10-color panels
- Fluorescence standardization and color compensation setup kits
- Process controls
- Navios/Navios EX flow cytometer
- Kaluza C analysis software

Standardize & streamline your workflow



Instrument QC
Navios / Navios Ex
Set-up beads
ClearLLab Compensation Kit
ClearLLab Controls
Kaluza C
IQAP

Test Order
Data Innovations
Manual Entry
Software interaction

Sample Preparation
IOTest 3 Lysing Solution
IOTest 3 Fixative solution
ClearLLab 10C Panels
DURA Innovations Technology

Data Acquisition
Navios / Navios Ex
IQAP

Data Analysis
Kaluza C

Review & Reporting
CaseBook
Analysis Templates
Kaluza C

Training
CaseBook, including LMD files
ClearLLab 10C Training

Services
PROservice
Service Contract

Additional Products
ClearLLab LS
Single Color Reagents

Empower your L&L workflow using the power of the ClearLLab 10C system. Deliver important patient information with cost efficiencies, using less steps, fewer tubes, more colors and optimized Kaluza C analysis templates.

* For Non-Hodgkin's lymphoma only

CLEARLLAB 10C CE-IVD PANELS

INTEGRATED L&L* IMMUNOPHENOTYPING SOLUTION FOR BOTH LYMPHOID AND MYELOID LINEAGES

Consensus-compliant with Bethesda and WHO markers, our four dry pre-mixed 10-color antibody tubes eliminate the need to pipette antibodies, improving efficiency while reducing potential for human error.

What's more, **ClearLLab 10C panels** meet applicable compliance requirements and lessen the need for extensive validations.

Because only verification is needed, according to Laboratory Standard ISO 15189, your lab can efficiently generate more data.

Data that's reliable, reproducible and actionable.

Panel specifications:

- Four dry unitized antibody panels:
  - B Cells tube (B)
  - T Cells tube (T)
  - Myeloid Cells tube (M1)
  - Myeloid Cells tube (M2)
- 25 tests/kit, five pouches of five tubes each
- Consensus-compliant markers (Bethesda[1] and WHO[2] recommendations)
- DURA Innovations technology—dry, unitized reagents that can be stored at room temperature

Powered By DURA Innovations Dry Unitized Reagent Assays

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(1) Davis BH, et al. 2006 Bethesda International Consensus Recommendations on the Immunophenotypic Analysis of Hematolymphoid Neoplasia by Flow Cytometry: Optimal Reagents and Reporting for the Flow Cytometric Diagnosis of Hematopoietic Neoplasia. Cytometry Part B (Clinical Cytometry) 2007;72B:S5-S13.

(2) Vardiman JW, Arber DA, Brunning DR et al. The 2008 revision of the World Health Organization (WHO) classification of myeloid neoplasms and acute leukemia: rationale and important changes. Blood 2009;114:937-951.

The power to simplify sample preparation

We can help you standardize sample prep by providing:

- Common method for all four ClearLLab 10C panels
- Versatile methods for bulk- vs. tube-based sample requirements
- All acquisition and analysis protocols (available for download)

The power to provide important patient information faster to clinicians

The ClearLLab 10C Panels are intended for in vitro diagnostic use for qualitative identification of various cell populations by multiparameter immunophenotyping on the Navios and Navios EX flow cytometers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having, or suspected of having, the following hematopoietic neoplasms: chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and/or myeloproliferative neoplasms (MPN). The reagents can be used with peripheral whole blood (collected in K2EDTA, Acid Citrate Dextrose (ACD) or Heparin), bone marrow (collected in K2EDTA, ACD or Heparin) and lymph node specimens. Interpretation of the results should be confirmed by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings.

The first 10-color CE-IVD immunophenotyping reagents for assessing lymphoid and myeloid populations

	Blue laser					Red laser			Violet laser	
	FITC	PE	ECD	PC5.5	PC7	APC	APC-A700[1]	APC-A750[2]	PB [3]	KRo [4]
B Cell Tube Part# **B96805**	Kappa	Lambda	CD10	CD5	CD200	CD34	CD38	CD20	CD19	CD45
T Cell Tube Part# **B96806**	TCRγδ	CD4	CD2	CD56	CD5	CD34	CD7	CD8	CD3	CD45
M1 Cell Tube Part# **B96807**	CD16	CD7	CD10	CD13	CD64	CD34	CD14	HLA-DR	CD11b	CD45
M2 Cell Tube Part# **B96808**	CD15	CD123	CD117	CD13	CD33	CD34	CD38	HLA-DR	CD19	CD45

(1) APC-A700: APC-Alexa Fluor* 700
(2) APC-A750: APC-Alexa Fluor* 750
(3) PB: Pacific Blue*
(4) KRo: Krome Orange

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FLOW-4258SB11.18

CLEARLLAB COMPENSATION KIT & CLEARLLAB COMPENSATION BEADS

THE POWER TO REDUCE YOUR COMPENSATION WORKLOAD

ClearLLab Compensation Kit

ClearLLab Compensation Beads

The ClearLLab Compensation beads, which are antibody capture beads, are used in conjunction with the ClearLLab Compensation Kit to perform color compensation and enhance assay performance of the ClearLLab 10C system. When using this system, compensation is only required on initial set-up of the application, when daily QC fails, after instrument service as needed, or when switching to a new lot of Flow-Set Pro.

These kits:

- Include all required compensation setup reagents
- Simplify sample preparation with ClearLLab compensation beads which are antibody capture beads
- Feature a unitized test format using DURA Innovations dry reagent technology, which requires no refrigeration

Powered By
DURA Innovations
Dry Unitized Reagent Assays

What's more, Navios EX flow cytometers feature software application for enhanced compensation setup for 10 colors.

Part Number	Description
B74074	ClearLLab Compensation Kit
B99883	ClearLLab Compensation Beads

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CLEARLLAB CONTROL CELLS

THE MISSING PIECE YOU'VE BEEN LOOKING FOR

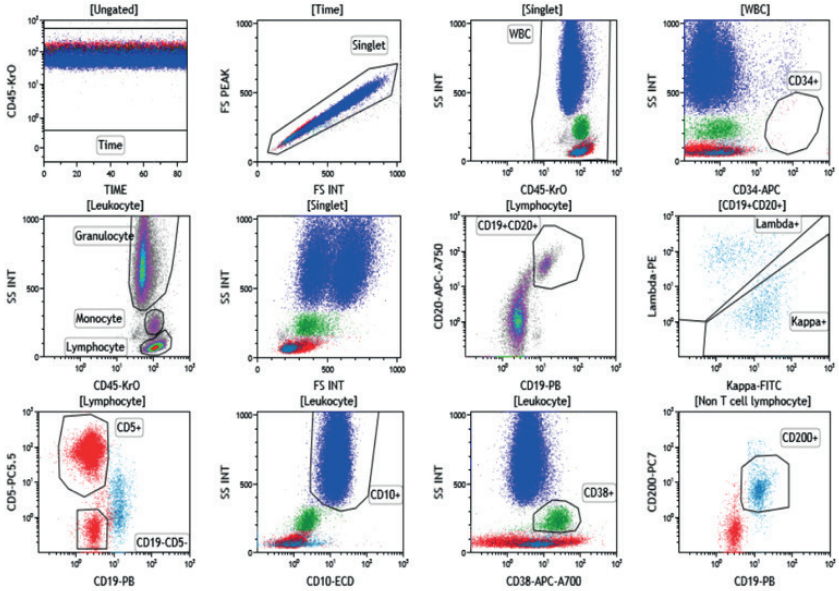
ClearLLab Control Cells, a liquid preparation of stabilized human erythrocytes and leukocytes (lymphocytes monocytes and granulocytes), are the first application specific IVD controls cells for L&L* immunophenotyping. Two types of ClearLLab Control Cells are available one with a normal phenotype and one with an abnormal phenotype. They are intended for use with the ClearLLab 10C panels.

You can use ClearLLab Control Cells to verify the accuracy/reproducibility of the steps involved in immunophenotyping, including:

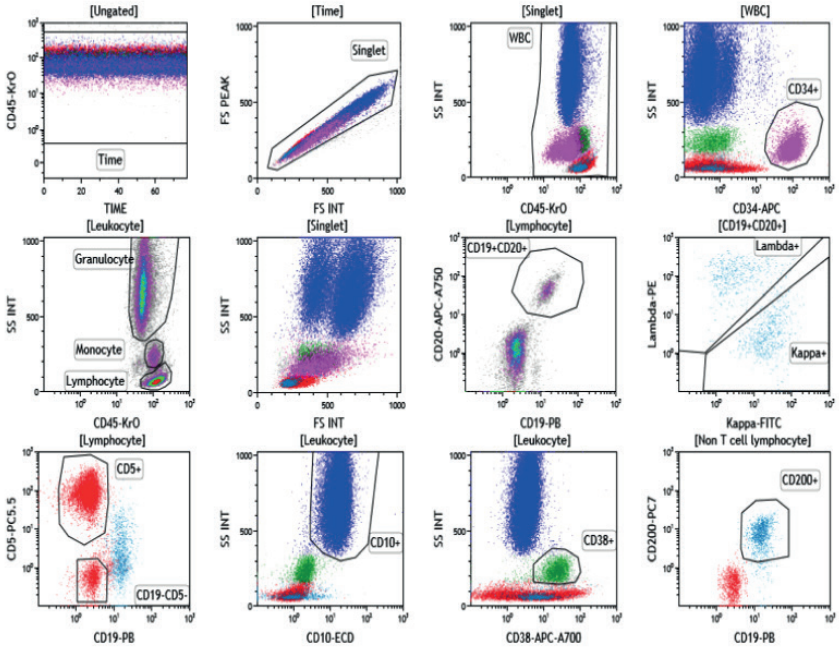
- Validating operator sample preparation technique
- Verifying:
  - Panel reagents
  - Sample prep (including RBC lyse)
  - Instrument settings
- Stability
  - 90 day closed vial stability
  - 30 day open vial stability

Replicating characteristics of clinical specimens (e.g., lysing, light scatter, antigen expression and antibody staining properties), ClearLLab Control Cells provide assay values for up to 27 markers currently available in the four ClearLLab 10C panels both for the normal and abnormal control.

B Panel Normal



B Panel Abnormal



Thus they can reduce the need for your lab to hold/validate patient samples and other materials to use as controls for the markers you want to evaluate.

Part Number	Description
B90002	ClearLLab Control Cells Normal
B90003	ClearLLab Control Cells Abnormal

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KALUZA C DATA ANALYSIS SOFTWARE

A POWERFUL TOOL TO HELP PROTECT YOUR DATA AND STREAMLINE REPORTING

With QC reports to help detect issues that can lead to inaccurate data analysis, to the option to add electronic approval signatures to reports, Kaluza C Data Analysis Software was designed to protect your data and streamline reporting.

Built on the same platform as our successful Kaluza Analysis Flow Cytometry Software*, Kaluza C software helps streamline clinical QC reporting requirements and address standardization issues in flow cytometry.

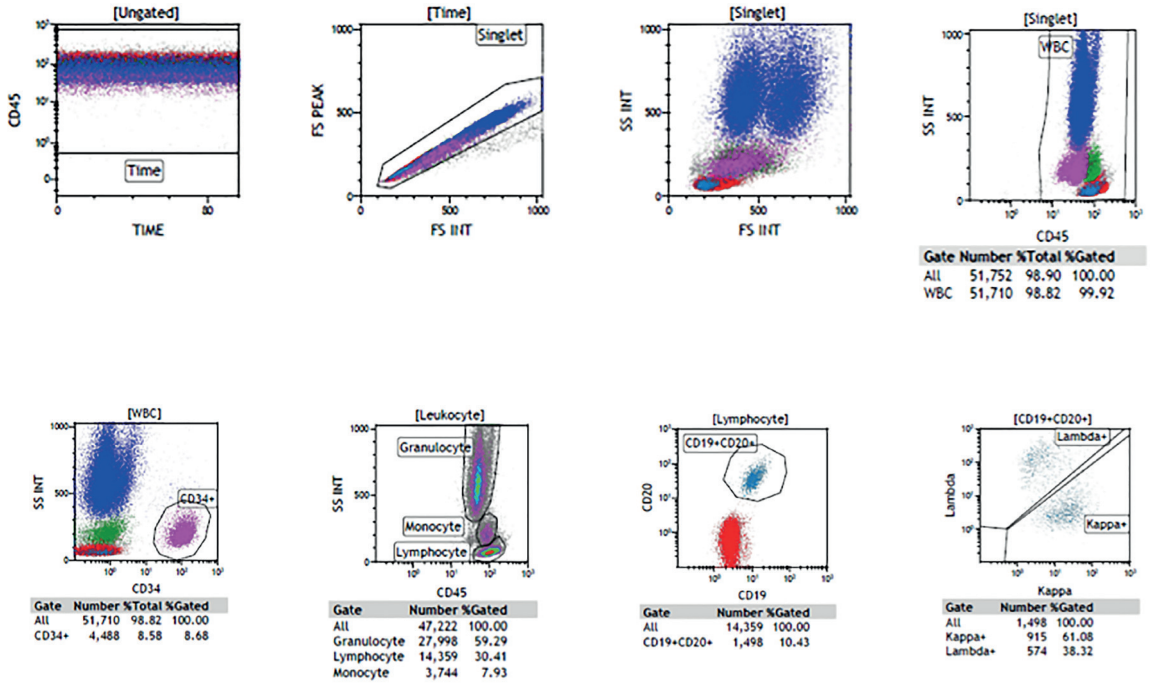
To help ensure consistent data quality, this standalone software product generates reports and Levey-Jennings charts to verify the reliability of instruments/assays—and makes it easy to save your data for future audits.

In addition, Kaluza C software makes it easy to:

- Load listmode files compliant with the FCS standard up through version 3.1
- Reduce time to prepare reports by linking plots from workspace to report sheets
- Features supporting visualization of rare events (merge files, rare event display, etc.)
- Easily compare reports
- Integrate with a Laboratory Information System (LIS)
- Provide traceability through user management

* For Research Use Only - Not for use in Diagnostic procedures

See the power of Kaluza C software



Kaluza C software enables rapid and clear clinical data review and offers LIS integration and audit trails with E-Signature

Part Number	Description
C10574	Kaluza C Software

Visit beckman.com to download a 30-day free trial.

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NAVIOS EX FLOW CYTOMETER

FOR POWERFULLY DEPENDABLE FLOW CYTOMETRY

With the 10-color capabilities of a Navios EX flow cytometer, you can collect additional data points from each sample, thereby reducing the number of samples to prepare (along with the possible errors that result in manual preparation processes).

Navios systems

- Simultaneously measure forward scatter, side scatter, and up to 10 fluorescent dyes using three solid-state lasers (488 nm, 638 nm and 405 nm)
- Simplify compensation by providing a compensation setup software for the ClearLLab 10C system
- Sample ID to track and maintain sample identification from order entry to report generation
- Network ready and can be bi-directionally interfaced with a Laboratory Information System (LIS)
- Enables you to manage test orders, minimize manual data entry, track samples via barcodes throughout the testing process, and eliminate transcription errors in the reporting process

All these benefits—and more—are packaged in a compact instrument that delivers stable performance over long periods of time and across a wide range of operating temperatures.

Navios is CE marked for 10-color in-vitro diagnostic use. In the U.S., Navios is intended for use as an in vitro diagnostic device for immunophenotyping with Navios tetra software and CYTOSTAT tetraCHROME reagents. All other uses are for research use only.

The device is not available for sale in all markets, please contact your Beckman Coulter representative for availability.

CLASS 1 LASER PRODUCT

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INTERLABORATORY QUALITY ASSURANCE PROGRAM (IQAP)

THE POWER TO LEARN HOW YOUR QC PROGRAM COMPARES TO OTHERS

IQAP is a comprehensive, easy-to-use program to complement and enhance your laboratory's in-house quality control (QC) program. It's available globally to users of flow cytometry cell controls from Beckman Coulter Life Sciences.

An IQAP Report helps you correlate IQAP results with other in-house QC techniques and provides a complete statistical analysis of your instrument's performance as compared with instruments used by a global peer group.

The IQAP report also provides QC at-a-glance with an Instrument Performance Matrix (a graphical representation of accuracy and precision in a single point).

To enroll in the IQAP program for all your instruments from Beckman Coulter Life Sciences visit the eIQAP website at www.beckmancoulter.com/qap/index.jsp

For complete details, visit beckman.com and enter IQAP into the Search window, which will enable you to download the IQAP Procedure Manual. This manual presents information on the IQAP program, enrollment, registration to the Beckman Coulter website, data entry and submission, quality control concepts, the IQAP report, troubleshooting, answers to the most commonly asked questions, and the glossary.

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Ordering Information

Part Number	Description
B96805	ClearLLab 10C B Cell Tube
B96806	ClearLLab 10C T Cell Tube
B96807	ClearLLab 10C M1 Cell Tube
B96808	ClearLLab 10C M2 Cell Tube
B74074	ClearLLab Compensation Kit
B99883	ClearLLab Compensation Beads
B90002	ClearLLab Control Cells Normal
B90003	ClearLLab Control Cells Abnormal
C10574	Kaluza C Analysis Software Perpetual, 1-User (Single)
C10575	Kaluza C Analysis Software 1 Year, 1-User (Single)
C10576	Kaluza C Analysis Software, 10-User (Network)
C10577	Kaluza C Analysis Software, 5-User (Network)
C10578	Kaluza C Analysis Software Educational Perpetual, 1-User (Single)
C10579	Kaluza C Analysis Software Educational 1 Year, 1-User (Single)
C10580	Kaluza C Analysis Software Educational, 10-User (Network)
C10581	Kaluza C Analysis Software Educational, 5-User (Network)

THE CLEARLLAB 10C SYSTEM IS A SIMPLE AND POWERFUL WAY TO EXPEDITE AND STANDARDIZE COMPLIANT L&L IMMUNOPHENOTYPING

"As a lab manager I need to provide accurate patient results for L&L analysis in a compliant laboratory setting. Currently, there's no CE-IVD solution available that covers both lymphoid and myeloid cell immunophenotyping, and therefore I'm forced to perform extensive validation, preparation and QC.

Implementing the ClearLLab 10C system provides me with a comprehensive assessment of lymphoid and myeloid linages."

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