

exbio

A Brighter Future in Flow

SingleFlowEx Premium Antibodies - Always look on the bright side of Flow

EXBIO has developed a broad portfolio of single-color antibodies for flow cytometry use in Clinical Research and Laboratory Developed Tests, now offered under our trademark SingleFlowEx.

EXBIO Praha, a.s. is the leading manufacturer of monoclonal antibodies and reagents for research and clinical applications with the focus on multi-color flow cytometry analysis of human cellular markers.

Our vision:

A Brighter Future in Flow

Our commitment to the customer's needs, supported by our integrated quality management system compliant with **ISO13485:2016, ISO9001:2015, cGMP (21 CFR part 820)**, allow us to accomplish our mission:

EXBIO strives to exceed the most demanding customer expectations in the field of analytical cytometry by providing a comprehensive portfolio of high quality products and services at affordable prices.

SingleFlowEx reagents are specifically designed for use in multicolor flow cytometry tests in order to examine samples derived from human body.

The versatility of multicolor flow cytometry tests affords outstanding power to be used in

- ❖ every stage of a drug or vaccine development program, from discovery, through to preclinical and into clinical testing (e.g. assess and understanding the immunogenicity and efficacy of a vaccine).
- ❖ development of clinically valid tests to make good healthcare decisions (e.g. diagnosis and follow up of primary immunodeficiencies, leukemias and lymphomas).

Premium Antibodies (GMP)

Contract Research Organizations (CRO)/Pharma Industry and Clinical laboratories/Health Care providers require a high degree of quality assurance for purchased reagents in order to provide clinically valid test results. Therefore, SingleFlowEx reagents are designed and manufactured according to current Good Manufacturing Practices (GMP) in our ISO 13485-certified manufacturing site.

EXBIO Praha, a.s.

Nad Safinou II 341
252 50 Vestec
Czech Republic

Tel. +420 261 090 595

info@exbio.cz
orders@exbio.cz
technical@exbio.cz

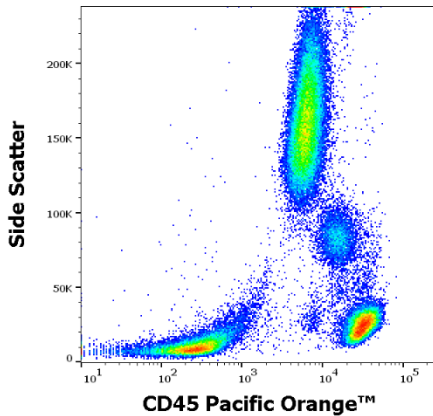
www.exbio.cz

Alexa Fluor®, Pacific Blue™ and Pacific Orange™ are registered trademarks of Life Technologies Corp.
Cy™ and CyDye™ are registered trademarks of GE Healthcare.

exbio

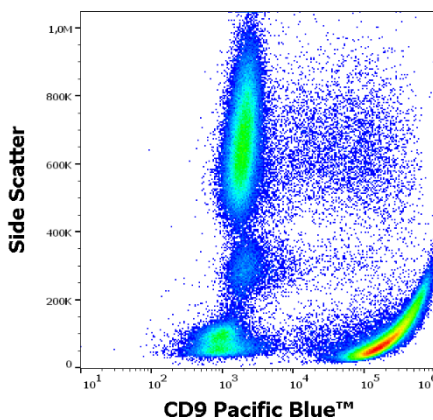
A Brighter Future in Flow

SingleFlowEx CD45 Pacific Orange™



Example of surface staining pattern using SingleFlowEx CD45 Pacific Orange™
Clone: 2D1
Sample: EDTA-anticoagulated human peripheral blood, healthy donor

SingleFlowEx CD9 Pacific Blue™



Example of surface staining pattern using SingleFlowEx CD9 Pacific Blue™
Clone: MEM-61
Sample: EDTA-anticoagulated human peripheral blood, healthy donor

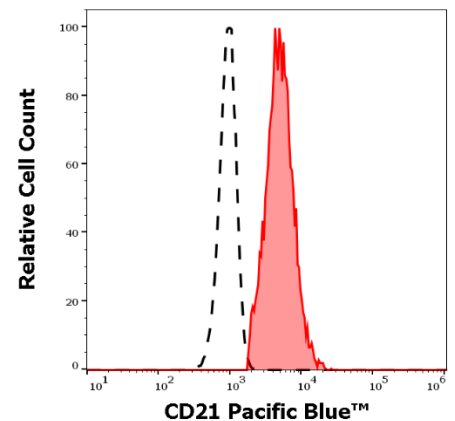
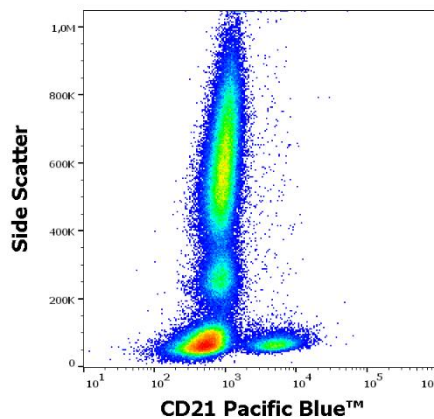
Product Design

The design and development of SingleFlowEx reagents is conducted in defined steps. The integral part of the product design phase is the validation of each SingleFlowEx reagent in clinical laboratories directly by users, ensuring suitability to be used in robust and consistent flow cytometry tests developed in-house, also called Laboratory Developed Tests (LDTs).

Lot-to-Lot Consistency and Reproducibility in performance

In order to produce accurate and reproducible results, laboratories require reagents that maintain their performance characteristics with minimum lot-to-lot variability and stable fluorescence intensity over a time. It is known that monoclonal antibody conjugates are susceptible to variability that contributes to inconsistent results in assays using antibodies. We developed detailed working instructions and protocols that allow for the manufacture of SingleFlowEx reagents with excellent lot-to-lot consistency. Each new lot must pass stringent quality control specifications for physicochemical properties (absorption and emission spectra, homogeneity analysis by HPLC) and performance characteristics (specificity staining patterns, MFI intensities and stain index by flow cytometry). New lots are always tested against previous (reference) lots to control for degree of variability.

SingleFlowEx CD21 Pacific Blue™



Example of surface staining pattern / separation of positive (red-filled) and negative (black-dashed) event using SingleFlowEx CD21 Pacific Blue™

Clone: LT21

Sample: EDTA-anticoagulated human peripheral blood, healthy donor

exbio

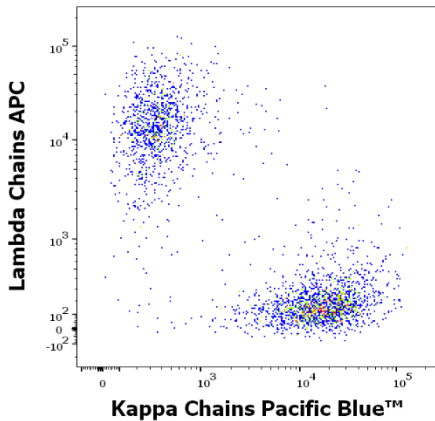
A Brighter Future in Flow

Difference between Premium antibodies (GMP) and traditional research-use versions

Customers using our traditional research use only (RUO) reagents for their flow cytometry assays often ask what is so different with the SingleFlowEx reagents and what are the reasons to use preferentially the SingleFlowEx reagents for building their multicolor panels. Indeed, hybridoma cell line, fluorochrome material, and the basic working instructions/ manufacturing procedures for Premium antibodies (GMP) and traditional RUO reagents are the similar, as well as their application in flow cytometry.

It is the **GMP regulation** which makes the difference. Compared to traditional RUO products, SingleFlowEx reagents come with extensive documentation for traceability as well as stringent quality control testing. Full quality assurance (QA) review of the complete batch record (including bottling and labeling records) is performed prior to product release to the market. SingleFlowEx reagents therefore meet the essential safety and performance requirements to facilitate use in laboratory developed tests by accredited healthcare institutions in accordance with EU regulation (2017/746) on in-vitro medical devices (IVDR).

SingleFlowEx Kappa Chains Pacific Blue™

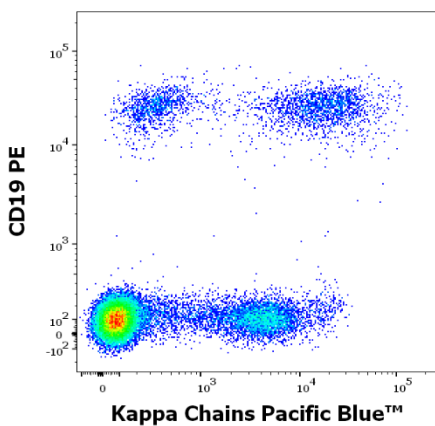


Example of surface staining pattern using SingleFlowEx Kappa Chains Pacific Blue™
Clone: TB28-2

Sample: pre-washed EDTA-anticoagulated human peripheral blood, healthy donor
Staining protocol: 10 µl reagent / 100 µl blood sample; Lyse and Wash
Erythrocyte lysis: EXCELLYSE Easy (ED7066)

Graphic display: gated CD45 positive CD19 positive lymphocytes displayed as SingleFlowEx Kappa Chains Pacific Blue™ versus Lambda Chains APC

List of EXBIO SingleFlowEx reagents available on our web site www.exbio.cz



Example of surface staining pattern using SingleFlowEx Kappa Chains Pacific Blue™
Clone: TB28-2

Sample: pre-washed EDTA-anticoagulated human peripheral blood, healthy donor
Graphic display: gated CD45 positive lymphocytes displayed as SingleFlowEx Kappa Chains Pacific Blue™ versus CD19 PE

exbio		CLINICAL PRODUCTS	RESEARCH PRODUCTS	CUSTOM PRODUCTS	ABOUT EXBIO	Search
EXBIO - CLINICAL PRODUCTS - PREMIUM ANTIBODIES (GMP)						
Premium antibodies (GMP)						
Results: 246						
<ul style="list-style-type: none">REGULATORY STATUSPRODUCT TYPEANTIGENCLONEFORMATAPPLICATIONSREACTIVITYEXCITATION LASERISOTYPE						
Catalog #	Product name	Clone	Reg. status	Application	Quantity	
ED7677	SingleFlowEx CD62L Pacific Blue™	DREG56	RUO (GMP)	FC	1 ml	
ED7201	SingleFlowEx CD99 FITC	3B2/T48	RUO (GMP)	FC	1 ml	
ED7739	SingleFlowEx CD45R0 PerCP-Cy™5.5	UCHL1	RUO (GMP)	FC	1 ml	
ED7738	SingleFlowEx CD11b Pacific Blue™	ICRF44	RUO (GMP)	FC	1 ml	
ED7729	SingleFlowEx CD193 PE	5E8	RUO (GMP)	FC	1 ml	
ED7564	SingleFlowEx CD45 PE-DyLight® 594	2D1	RUO (GMP)	FC	1 ml	
ED7730	SingleFlowEx CD38 Alexa Fluor® 700	HIT2	RUO (GMP)	FC	1 ml	
ED7710	SingleFlowEx CD81 APC	M38	RUO (GMP)	FC	1 ml	
ED7712	SingleFlowEx CD22 Alexa Fluor® 700	S-HCL-1	RUO (GMP)	FC	1 ml	
ED7676	SingleFlowEx CD62L PE-Cy™7	DREG56	RUO (GMP)	FC	1 ml	
ED7197	SingleFlowEx CD61 APC	VIPL2	RUO (GMP)	FC	1 ml	
ED7727	SingleFlowEx CD38 PE-Cy™7	HIT2	RUO (GMP)	FC	1 ml	
ED7246	SingleFlowEx CD123 APC	6H6	RUO (GMP)	FC	1 ml	
ED7660	SingleFlowEx CD71 APC	MEM-75	RUO (GMP)	FC	1 ml	
ED7114	SingleFlowEx CD25 Pacific Blue™	MEM-181	RUO (GMP)	FC	1 ml	
ED7252	SingleFlowEx CD235a FITC	JC159	RUO (GMP)	FC	1 ml	