

exbio

DryFlowEx TBNK 6-color (RUO)

50 tests | Cat. No. ED7789

RUO

Not for use in diagnostic or therapeutic procedures.

Technical Data Sheet (EN)

Version: ED7789_TDS_v2_EN

Date of Issue: 19-09-2025

Symbols used in the product labeling

	Research Use Only		Keep Dry Keep away from rain
	Manufacturer		Caution
	Consult instructions for use		Do not re-use
	Contains sufficient for <n> tests		Contains <n> tubes for single use test
	Catalogue number		Contents
	Batch code		
	Use by date		
	Temperature limit		
	Keep away from sunlight		

Description

The product is For Research Use Only. Diagnostic or therapeutic applications are strictly forbidden.

DryFlowEx TBNK 6-color (RUO) detects and enumerates lymphocyte populations and subsets in human whole blood using flow cytometry.

Specification

TBNK 6-color is used for leukocyte staining.

TBNK 6-color compensation set is used for preparation of compensation tubes to compensate signals of TBNK.

Reagent(s) provided

Contents

The product DryFlowEx TBNK 6-color (RUO) is sufficient for 50 tests and is provided with the following reagents:

TBNK 6-color ED7789-1 (10 pouches). Each pouch consists of 5 capped single-use tubes containing premixed combination of fluorochrome-labeled reagents dried with the stabilizing ingredients as a layer at bottom of the test tubes (12 x 75 mm), see Table 1.

TBNK 6-color Compensation Set ED7789-2 (1 pouch) containing 6 capped single-use tubes, each containing single fluorochrome-labeled reagent (see Table 1) dried with the stabilizing ingredients as a layer at the bottom of the tube (12 x 75 mm).

CAUTION: TBNK 6-color Compensation Set is intended for the compensation setup only. Single fluorochrome-labeled reagents (see Table 1) allow easy and accurate compensation procedure.

Composition

Table 1 Description of the TBNK 6-color active ingredients

Antigen	Fluorochrome	Clone	Isotype
CD3	FITC	UCHT1	IgG1
CD16	PE	3G8	IgG1
CD56	PE	LT56	IgG2a
CD45	PerCP-Cy™5.5	MEM-28	IgG1
CD4	PE-Cy™7	MEM-241	IgG1
CD19	APC	LT19	IgG1
CD8	APC-Cy™7	LT8	IgG1

Materials required but not provided

Erythrocyte lysing solution EXCELLYSE Easy, Cat. No. ED7066

Phosphate buffered saline (1X PBS), pH 7.2 – 7.4

Equipment required

Automatic pipette with disposable tips (20 – 100 µl) for pipetting specimen

Liquid dispenser or pipette with disposable tips (0.5 – 2 ml) for dispensing erythrocyte lysing solution

Liquid dispenser or pipette with disposable tips (0.2 – 0.5 ml) for dispensing PBS

Vortex mixer

Centrifuge with appropriate rotor adaptors for 12 x 75 mm round bottom tubes

Hematology analyzer (for absolute cell counts) capable of white blood cell (WBC) and lymphocyte count per µl of specimen.

Flow cytometer with two laser excitation sources (488 nm and ~635 nm), detectors for scattered light, optical filters and emission detectors appropriate to collect signals from fluorochromes provided in Table 2.

Table 2 Spectral characteristic of fluorochromes use in the product

Flurochrome	Excitation [nm]	Emission [nm]
FITC	488	525
PE	488	576
PerCP-Cy™5.5	488	695
PE-Cy™7	488	780
APC	630 – 640	660
APC-Cy™7	630 - 640	780

NOTICE: The product was tested on flow cytometers BD FACSCanto™ II (BD Biosciences), DxFLEX (Beckman Coulter) and Sysmex XF-1600™ (Sysmex Corporation).

Storage and handling

Store at 20-30 °C.

Avoid prolonged exposure to light.

Keep dry.

CAUTION: Moisture sensitive product. Do not open the foil pouch until the first use.

See Section Procedure (Preparation of reagent(s) provided) for information about the storage conditions and stability of working solutions (where applicable).

Warnings, precautions and limitations of use

GHS Hazard Classification

Consult Safety Data Sheet (SDS) available on the product page at www.exbio.cz for the full information on the risks posed by chemical substances and mixtures contained in the Product and how they should be handled and disposed.

Biological Hazard

Human biological samples and blood specimens and any materials coming into contact with them are always considered as infectious materials.

Use personal protective and safety equipment to avoid contact with skin, eyes and mucous membranes.

Follow all applicable laws, regulations and procedures for handling and disposing of infectious materials.

Evidence of deterioration

Normal appearance of the reagent provided is a transparent dried layer at the bottom of the tube. Do not use the reagent if you observe any change in appearance, for example presence of moisture inside the tube.

Limitation of use

Do not use after the expiry date stated on the product labels.

Do not re-use test tubes.

Specimen

Use venous peripheral blood collected in specimen receptacle classified as a medical product, with the anticoagulant EDTA.

NOTICE: Determine WBC absolute cell count and lymphocyte count in the collected blood specimen by a hematology analyzer. The DryFlowEx TBNK 6-color (RUO) alone does not provide enumeration of absolute cell counts.

Blood specimen with WBC count exceeding 40×10^3 cells/ μ l will require dilution with 1X PBS before sample processing.

Process the blood specimen no later than 24 hours after collection. Store the specimen at laboratory temperature (20 – 25°C). Do not refrigerate the specimen.

Procedure

Preparation of reagent(s) provided

TBNK 6-color

No reagent preparation is necessary, supplied in test tubes for single use only.

CAUTION: Moisture sensitive product. Do not open the foil pouch until the first use.



Each pouch consists of 5 capped single-use TBNK 6-color tubes. After each opening, thoroughly reseal the foil pouch with the zip-lock for storage of the remaining unused tubes. After the first opening, use remaining TBNK 6-color tubes within 30 days.

Preparation of materials required but not provided

Dilute concentrated erythrocyte lysing solution with deionized water according to the manufacturer's instructions. Diluted (1X) erythrocyte lysing solution is stable for 1 month when stored in a liquid dispenser or closed container at room temperature.

Compensation setup

Acquire Compensation Set tubes using the same flow cytometer set-up, prior to the analysis of TBNK 6-color stained tubes.

CAUTION: TBNK 6-color and TBNK 6-color Compensation Set require the same type of specimen.

TBNK 6-color compensation tubes

1. Pipette 50 μ l of well-mixed blood specimen into the bottom of each single-color compensation tube.
2. Vortex vigorously for 7-10 seconds and incubate for 20 minutes at room temperature in the dark.
3. Add 1 ml of diluted (1X) erythrocyte lysing solution to each compensation tube.
4. Vortex and incubate for 10 minutes at room temperature in the dark.
5. Centrifuge for 5 minutes at 300 \times g, discard supernatant and resuspend the cell pellet in 0.2 ml of 1X PBS.
6. Set voltages on fluorescence detectors of interest prior to stained specimen analysis. Voltage on a PMT detector should be set high enough, so that minimum of negatively stained events interfere with 0th channel on the fluorescence axis. Also, PMT detector voltage should not exceed values at

which positive events are pressed to the right axis.

7. Acquire the stained sample immediately using flow cytometer.

Compensate fluorescence signals between detectors prior to or after data acquisition. Data may be incorrectly interpreted if fluorescence signals are compensated improperly or if gates are positioned inaccurately.

Set the gates for positive and negative populations for each compensation tube according to the Figure 1.

Calculate compensation matrix either in cytometer software developed by manufacturer or software dedicated for offline cytometry data analysis. Use this compensation matrix for all test tubes of this lot of TBNK 6-color.

CAUTION: Once set for the specific TBNK 6-color lot, do not change fluorescent detectors settings in order to retain the same compensation matrix acquisition settings and compensation results.

Specimen staining

1. Label TBNK 6-color tube with the appropriate sample identification.
2. Pipette 50 μ l of well-mixed blood specimen into the bottom of the TBNK 6-color tube.

CAUTION: Avoid pipetting blood on the side of the test tube. If blood smear or droplet remains on the side of the tube, it may not be stained with the reagent or erythrocytes may not be lysed and the test result may not be valid.

3. Vortex vigorously for 7 – 10 seconds and incubate the test tube for 20 minutes at room temperature in the dark.

CAUTION: Shortening the vortex time may affect the test results.

4. Add 1 ml of diluted (1X) erythrocyte lysing solution to TBNK 6-color tube.
5. Vortex and incubate for 10 minutes at room temperature in the dark.
6. Centrifuge the TBNK 6-color tube for 5 minutes at 300 \times g.
7. Discard supernatant without disturbing the cell pellet and add 0.2 ml of 1X PBS to the test tube.
8. Vortex shortly to resuspend the cell pellet.
9. Acquire the stained sample using flow cytometer. If the stained sample will not be acquired immediately, store at 2-8 °C in the dark and analyze within 24 hours.

CAUTION: Vortex the stained sample immediately before acquisition on the flow cytometer to avoid aggregates.

Flow cytometry analysis

The flow cytometer selected for use with the product DryFlowEx TBNK 6-color (RUO) shall be calibrated on a routine basis using fluorescent microbeads to ensure stable sensitivity of detectors according to the cytometer manufacturers instructions.

If not maintained properly the flow cytometer may produce false results.

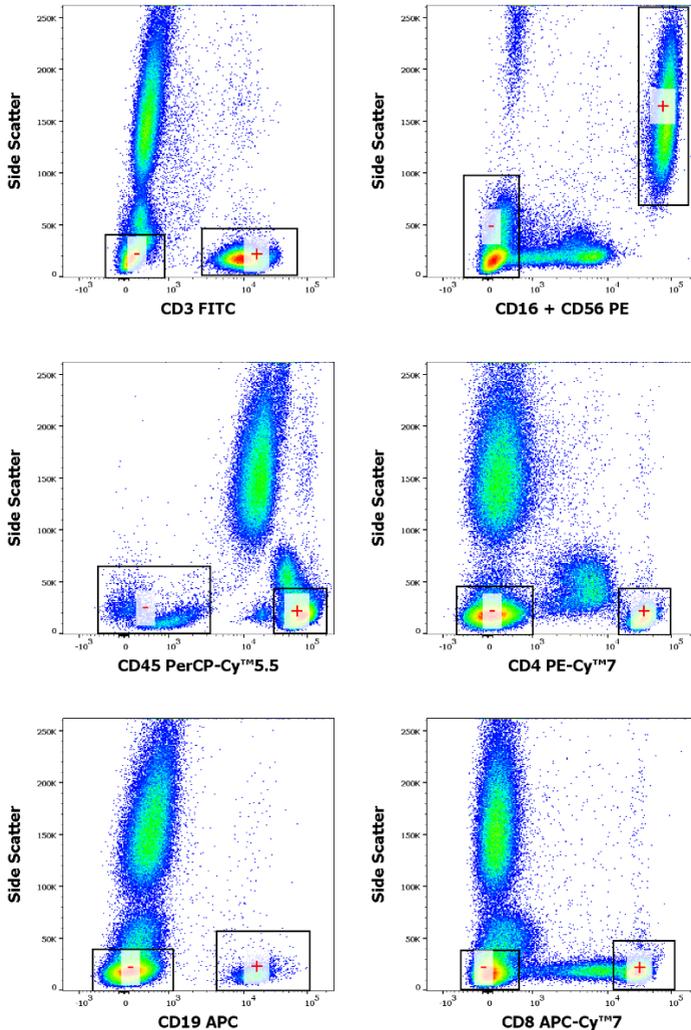
Refer to the manufacturer's cytometer specifications for lasers and fluorescence detectors according to the excitation and emission characteristics of the fluorochromes in Section Equipment required.

For measured data analysis, it is possible to use cytometer software developed by the manufacturer, or software dedicated for offline cytometry data analysis (for example FlowJo™, VenturiOne®, Infinicyt™).

Analysis of the compensation tubes

Visualize non-compensated data for each compensation tube in a side-scatter (SSC) versus “fluorochrome to be compensated” dot-plot. Set the gates for positive (+) and negative (-) populations as shown in Figure 1.

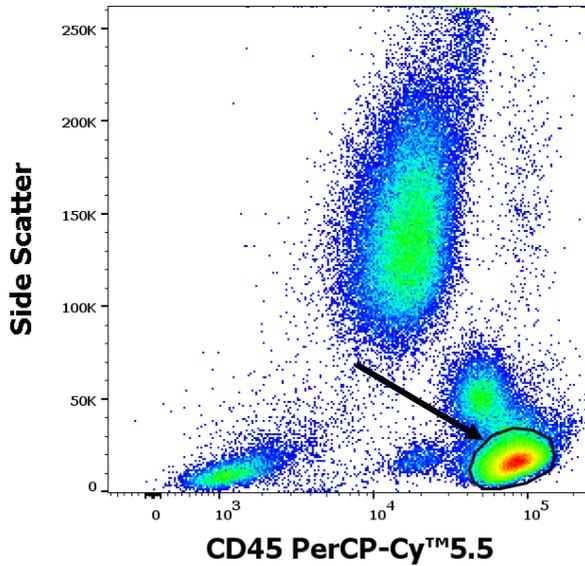
Figure 1 Identification of positive (+) and negative (-) events in compensation tubes (data acquired on BD FACSCanto™ II)



Analysis of the TBNK 6-color stained specimen

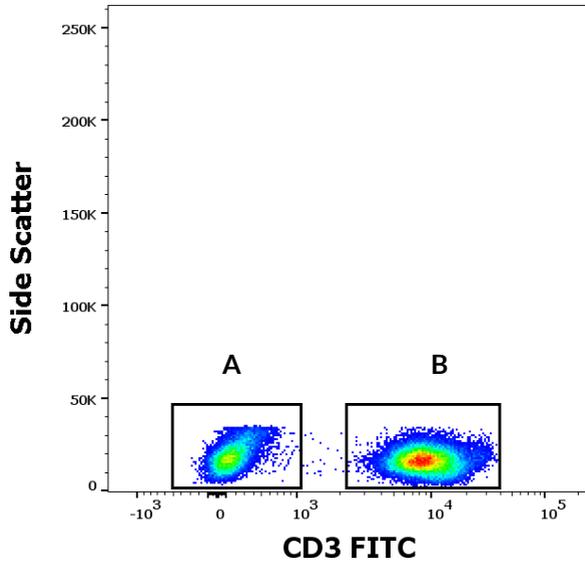
Visualize compensated data in a side-scatter (SSC) versus CD45 PerCP-CyTM5.5 plot. Set the gate for CD45+ lymphocyte population as shown in Figure 2.

Figure 2 Delineation of CD45+ lymphocyte population
(data acquired on BD FACSCantoTM II)



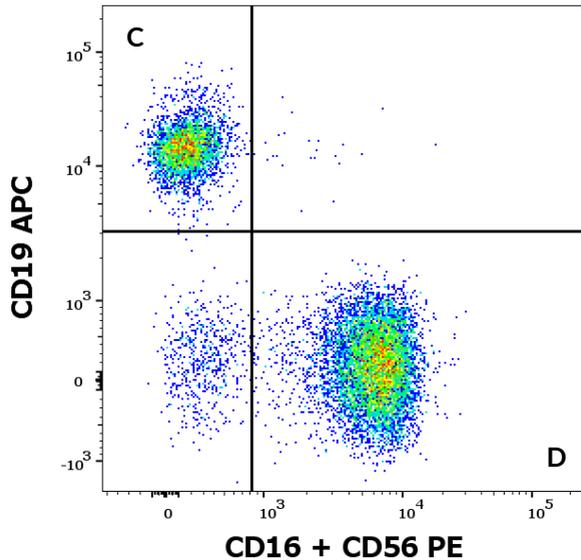
Plot the gated CD45+ lymphocytes in a side-scatter (SSC) versus CD3 FITC plot as shown in Figure 3. Separate CD3+ and CD3- lymphocytes using appropriate gates. Calculate the percentage of T cells (CD3+; region B on the Figure 3) from all lymphocytes.

Figure 3 Separation of CD3+ and CD3- lymphocytes
(data acquired on BD FACSCanto™ II)



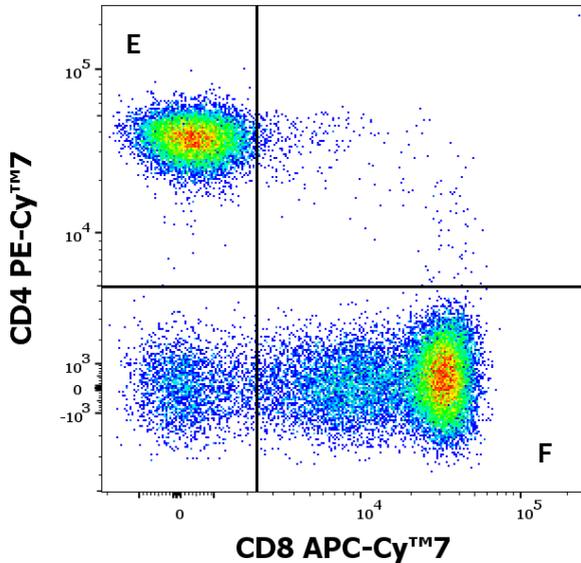
Plot the gated CD3- lymphocytes (region A on the Figure 3) as CD19 APC versus CD16+CD56 PE as shown in Figure 4. Set appropriate gates and calculate the percentage of B cells (CD16-CD56-CD19+; region C on the Figure 4) and natural killer (NK) cells (CD16+CD56+CD19-; region D on the Figure 4) from all lymphocytes.

Figure 4 CD3- lymphocytes in a dot-plot CD19 APC vs. CD16+CD56 PE (data acquired on BD FACSCanto™ II)



Plot the gated T cells (CD3+; region B on the Figure 3) as CD4 PE-CyTM7 versus CD8 APC-CyTM7 as shown in Figure 5. Set appropriate gates and calculate the percentage of helper/inducer T cells (CD4+CD8-; region E on the Figure 5) and suppressor/cytotoxic T cells (CD4-CD8+; region F on the Figure 5) from all lymphocytes.

Figure 5 CD3+ lymphocytes in a dot-plot CD4 PE-CyTM7 vs. CD8 APC-CyTM7 (data acquired on BD FACSCantoTM II)



Calculation and interpretation of analytical results

To have absolute counts, use the absolute lymphocyte count as determined by a hematology analyzer. Refer to hematology analyzer manufacturer’s instructions. Use the equations below for absolute count enumeration of required lymphocyte subset.

$$A \times \frac{B (\%)}{100 (\%)} = \text{Absolute count of required lymphocyte subset}$$

A = absolute lymphocyte count (data from hematology analyzer; cells / μl)

B = relative percentages of required lymphocyte subset from all lymphocytes (data from flow cytometer; %)

References

N/A

Trademarks

BD FACSCanto™ II and FlowJo™ are registered trademarks of Becton, Dickinson and Company; DxFLEX is registered trademark of Beckman Coulter; Cy™ is registered trademark of Cytiva; Sysmex XF-1600™ is registered trademark of Sysmex Corporation; VenturiOne® is registered trademark of Applied Cytometry; Infinicyt™ is registered trademark of Cytognos S.L..

Revision History

Version 2, ED7789_TDS_v2

- 1) Removal of Process control cells from section Materials required but not provided.
- 2) Revision of References and Trademarks.
- 3) Removal of Quality control, Analytical performance, Interfering substances and limitations sections.

Manufacturer

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NOTICE: Any serious incident that has occurred in relation to the product shall be reported to the manufacturer and the local competent authority.