

Product fact sheet

Sysmex TBNK test system

Version 1.2

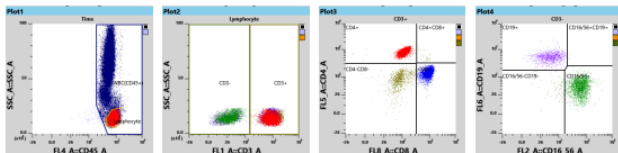
Results

Item	%	Count#/(μ L)
CD3+	74.46	1223
CD3+CD4+CD8-	40.17	660
CD3+CD4-CD8+	25.87	425
CD3-CD16/56+CD19-	17.32	285
CD3-CD16/56-CD19+	7.58	124

Research Parameters

Item	Value	Judge
T-Sum	8.14	Pass
Lymphsum	99.36	Pass
CD4/8 ratio	1.55	Pass

Item	%	Count#/(μ L)
WBC(CD45+)		6557
Lymphocyte		1642
CD3-	25.54	419
CD3+CD4+CD8+	0.28	5



Product names and manufacturer information

The Sysmex TBNK test system consists of the following products:

Product	Manufacturer	Regulatory status
XF-1600	Sysmex Corporation www.sysmex-europe.com	IVD
XF-1600 TBNK SW	Sysmex Corporation	IVD
CyLyse FX	Sysmex Partec GmbH	IVD
KOMBITEST TBNK 6-color	EXBIO Praha, a.s. Nad Safinou II 341 252 50 Vestec Czech Republic www.exbio.cz	IVD

Summary

The Sysmex TBNK test system consists of an IVD SW of the Sysmex Flow Cytometer XF-1600 that performs auto-gating and establishes absolute counts when used in combination with the KOMBITEST TBNK 6-color cocktail (consisting of CD3 FITC/CD4 PE-Cy7/CD8 APC-Cy7/CD16 and 56 PE/CD19 APC and CD45 PerCP-Cy5.5) and CyLyse FX lysing solution.

Within the pre-defined template, XF-1600 TBNK SW supports the gating of the TBNK analysis, then calculates the results for the identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD3-CD19+ and CD3-CD56+CD16+ lymphocyte percentages and absolute counts in peripheral whole blood.

Due to the volumetric count function of the XF-1600 flow cytometer, the XF-1600 TBNK SW delivers absolute counts without the use of count beads.

For the use of XF-1600, CyLyse FX and KOMBITEST TBNK 6-color please refer to the Instruction for Use of the respective products.

Productivity values

- Auto-gating on all parameters
- Automated calculation of results within the panel
- Absolute count results for the parameters listed below
- Does not require the use of count beads
- Gains and parameter QC are monitored by radar and Levey Jennings plots
- Report that can be saved or printed
- Easy lyse/no-wash staining procedure
- Automated sample acquisition on an XF-1600 flow cytometer

Parameters

Items	Measurement items	
	Item name	Statistics
CD3-positive cells	CD3+	Absolute count (*) %(**)
CD3-positive, CD4-positive and CD8-negative cells	CD3+CD4+CD8-	Absolute count (*) %(**)
CD3-positive, CD4-negative and CD8-positive cells	CD3+CD4-CD8+	Absolute count (*) %(**)
CD3-negative, CD16-positive or CD56-positive, and CD19-negative cells	CD3- CD16/56+CD19-	Absolute count (*) %(**)
CD3-negative, CD16-negative and CD56-negative, and CD19-positive cells	CD3-CD16/56- CD19+	Absolute count (*) %(**)

*Number of cells per μ L

**Ratio to lymphocyte (based on a lymphocyte gate)

Research Parameters

Absolute counts* of:

- WBC (CD45+)
- Lymphocytes

Absolute counts* and Percentages (%)**

- CD3- (CD45 & CD3-)
- CD3+CD4+CD8+

Sums and ratios

- T-Sum
- Lymphsum
- CD4/8 ratio

*Number of cells per μ L

**Ratio to lymphocyte (based on a lymphocyte gate)

Channel and parameters

Channel	Channel name	Parameter		
		Height	Area	Width
FCS	n/a	√	√	-
SSC	n/a	√	√	-
FL1	CD3	√	√	-
FL2	CD16_56	√	√	-
FL4	CD45	√	√	-
FL5	CD4	√	√	-
FL6	CD19	√	√	-
FL8	CD8	√	√	-

Panel/ subpanel name

Panel/Subset panel	Name
Panel	[SP_TBKNK]
Subset panel	[TBNK 6Color]

Measurement conditions

Item	Condition
[Required volume select]	250 µL
[Flow Rate]	High (90 µL/min)
[Stop Time]	100 seconds

Sysmex TBNK test system hardware and software

Since the XF-1600 TBNK SW functionality is part of the main XF-1600 instrument software from V 06 onwards please refer to the XF-1600 IFU for hardware and software specifications.

Ordering information

Product code	Item	Description	Qty
ZE004373	XF-1600 TBNK SW	TBKNK Software licence key*	1
ED7733	KOMBITEST TBNK 6-color	Pre-mixed reagent cocktail (CD3 FITC/CD4 PE-Cy7/CD8 APC-Cy7/CD16 and 56 PE/CD19 APC and CD45 PerCP-Cy5.5	1
BD303500	CyLyse FX (IVD)	Lyse/Fix Reagent	1

*the XF-1600 TBNK SW functionality is part of the main XF-1600 instrument software from v 06 onwards, and must be opened with a license key

The required product code for the TBNK software for registration is the CB493081.

Please Note: The products listed may not be available for sale in all countries. Please contact your Sysmex representative for availability.

Required (not provided by SEU)

Item	Description
Appropriate blood QC material	Blood QC material is required as a process control, as described in the IFU of KOMBITEST TBNK 6c

For further information please refer to the IFUs of the XF-1600, XF-1600 TBNK SW and KOMBITEST TBNK 6c

For Instrument specifications of the XF-1600 please refer to chapter 7 in the XF-1600 Instruction for use.

Each of the individual components of the system described here is conform with the applicable requirements of CE IVD. The use of the Sysmex TBNK test system must be validated by each user to ensure that it meets their individual requirements.