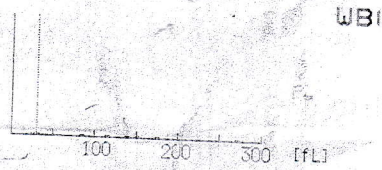


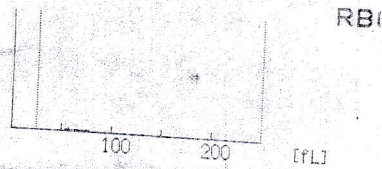
# Background

No. 0  
Date 04/07/22 17:10  
Mode WB

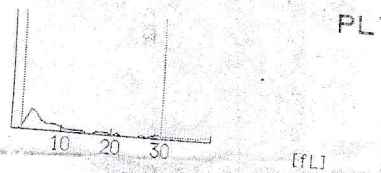
WBC 0.0 × 10<sup>9</sup> / μl  
RBC 0.01 × 10<sup>6</sup> / μl  
HGB 0.0 g / dL  
HCT 0.1 %  
MCV ---- fL  
MCH ---- fL  
MCHC ---- g / dL  
PLT 1 × 10<sup>3</sup> / μl



LYM% ---- %  
MXD% ---- %  
NEUT% ---- %  
LYM# ---- × 10<sup>3</sup> / μl  
MXD# ---- × 10<sup>3</sup> / μl  
NEUT# ---- × 10<sup>3</sup> / μl



RDW ---- %



PDW ---- fL  
MPV ---- fL  
P-LCR ---- %

# Calibrator Datasheet

No. 2-1	No. 2-2	No. 2-3
Date 04/07/22 18:37	Date 04/07/22 18:39	Date 04/07/22 18:42
Mode WB	Mode WB	Mode WB
WBC 8.8x10 <sup>9</sup> /μL	WBC 8.8x10 <sup>9</sup> /μL	WBC 8.7x10 <sup>9</sup> /μL
RBC 4.48x10 <sup>6</sup> /μL	RBC 4.47x10 <sup>6</sup> /μL	RBC 4.50x10 <sup>6</sup> /μL
HGB 13.4g/dL	HGB 13.4g/dL	HGB 13.4g/dL
HCT 37.0%	HCT 36.6%	HCT 36.9%
MCV - 82.6fL	MCV - 81.9fL	MCV - 82.0fL
MCH 29.9pg	MCH 30.0pg	MCH 29.8pg
MCHC 36.2g/dL	MCHC 36.6g/dL	MCHC 36.3g/dL
PLT 254x10 <sup>3</sup> /μL	PLT 249x10 <sup>3</sup> /μL	PLT 245x10 <sup>3</sup> /μL
LYM% - 2.2%	LYM% - 1.7%	LYM% - 1.6%
MXD% 1.9%	MXD% 1.5%	MXD% 1.8%
NEUT% + 95.9%	NEUT% + 96.8%	NEUT% + 96.6%
LYM# 0.2x10 <sup>9</sup> /μL	LYM# 0.1x10 <sup>9</sup> /μL	LYM# 0.1x10 <sup>9</sup> /μL
MXD# 0.2x10 <sup>9</sup> /μL	MXD# 0.1x10 <sup>9</sup> /μL	MXD# 0.2x10 <sup>9</sup> /μL
NEUT# 8.4x10 <sup>9</sup> /μL	NEUT# 8.6x10 <sup>9</sup> /μL	NEUT# 8.4x10 <sup>9</sup> /μL
RDW - 8.9%	RDW - 8.9%	RDW - 8.8%
PDW 13.7fL	PDW 13.8fL	PDW 13.3fL
MPV 10.3fL	MPV 10.3fL	MPV 10.1fL
P-LCR 28.1%	P-LCR 27.4%	P-LCR 27.2%

No. 2-4	No. 2-5	No. 2-6
Date 04/07/22 18:44	Date 04/07/22 18:45	Date 04/07/22 18:46
Mode WB	Mode WB	Mode WB
WBC 8.9x10 <sup>9</sup> /μL	WBC 8.9x10 <sup>9</sup> /μL	WBC 8.9x10 <sup>9</sup> /μL
RBC 4.44x10 <sup>6</sup> /μL	RBC 4.46x10 <sup>6</sup> /μL	RBC 4.47x10 <sup>6</sup> /μL
HGB 13.4g/dL	HGB 13.4g/dL	HGB 13.4g/dL
HCT 36.5%	HCT 36.6%	HCT 36.7%
MCV - 82.2fL	MCV - 82.1fL	MCV - 82.1fL
MCH 30.2pg	MCH 30.0pg	MCH 30.0pg
MCHC 36.7g/dL	MCHC 36.6g/dL	MCHC 36.5g/dL
PLT 250x10 <sup>3</sup> /μL	PLT 263x10 <sup>3</sup> /μL	PLT 249x10 <sup>3</sup> /μL
LYM% - 1.7%	LYM% - 2.0%	LYM% - 1.4%
MXD% 2.4%	MXD% 1.7%	MXD% 1.7%
NEUT% + 95.9%	NEUT% + 96.3%	NEUT% + 96.9%
LYM# 0.2x10 <sup>9</sup> /μL	LYM# 0.2x10 <sup>9</sup> /μL	LYM# 0.1x10 <sup>9</sup> /μL
MXD# 0.2x10 <sup>9</sup> /μL	MXD# 0.2x10 <sup>9</sup> /μL	MXD# 0.2x10 <sup>9</sup> /μL
NEUT# 8.5x10 <sup>9</sup> /μL	NEUT# 8.5x10 <sup>9</sup> /μL	NEUT# 8.6x10 <sup>9</sup> /μL
RDW - 9.2%	RDW - 9.0%	RDW - 8.9%
PDW 13.4fL	PDW 13.7fL	PDW 13.6fL
MPV 10.1fL	MPV 10.3fL	MPV 10.3fL
P-LCR 26.8%	P-LCR 27.2%	P-LCR 28.4%



# NEK-CAL

## HEMATOLOGY CALIBRATOR

### CALIBRATOR

LOT NK0722



2022-08-05

### Calibration Values for Manual Mode

Parameter	Sysmex® XT-4000i	Acceptable Range	Sysmex XE-2100™ XE-2100D	Acceptable Range	Sysmex KX-21 KX-21N	Acceptable Range
WBC 10 <sup>3</sup> /μL	9.1	± 0.2	9.3	± 0.2	8.9	± 0.2
RBC 10 <sup>6</sup> /μL	4.50	± 0.10	4.52	± 0.10	4.47	± 0.10
HGB g/dL	13.4	± 0.2	13.5	± 0.2	13.5	± 0.2
HCT %	38.7	± 1.0	38.9	± 1.0	36.7	± 1.0
MCV fL	86.0	± 2.0	86.0	± 2.0	82.0	± 2.0
PLT 10 <sup>3</sup> /μL	245	± 12	233	± 12	257	± 12

Note: The instrument manufacturer states that a Sysmex Field Service Representative is solely responsible for calibration of WBC, RBC, and PLT. The operator is responsible for calibration of HGB and HCT.

#### INTENDED USE

NEK-CAL is designed for use in the calibration of Sysmex hematology analyzers. Please refer to the assay table for specific instrument models.

#### SUMMARY AND PRINCIPLE

Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of select hematology instruments.

Calibrator values for NEK-CAL are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

#### REAGENTS

NEK-CAL is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.



#### PRECAUTION

NEK-CAL is intended for *in vitro* diagnostic use only by trained personnel.



#### WARNING:

**POTENTIAL BIOHAZARDOUS MATERIAL.** For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.



#### STABILITY AND STORAGE

Store NEK-CAL upright at 2 - 8° C (35-46° F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 5 days, provided they are handled properly.

#### INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**

# Control

No. 3-1  
Date 04/07/22 18:52  
Mode WB

WBC		$8.2 \times 10^9 / \mu\text{L}$
RBC		$1.08 \times 10^{12} / \mu\text{L}$
HGB		12.3 g/dL
HCT		33.1%
MCV	-	81.1 fL
MCH		30.1 pg
MCHC	+	37.2 g/dL
PLT		$204 \times 10^9 / \mu\text{L}$

LYM%		31.4%
MXD%		16.4%
NEUT%		52.2%
LYM#		$2.6 \times 10^9 / \mu\text{L}$
MXD#		$1.3 \times 10^9 / \mu\text{L}$
NEUT#		$4.3 \times 10^9 / \mu\text{L}$
RDW	-	9.7%
PDW		12.0 fL
MPV		9.9 fL
P-LCR		25.1%

# CBC-ST Plus


## HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

QCP DATA MONTHS: JUNE, JULY, AUGUST

LOT

 ST0622  
 2022-09-05

Instrument	Parameter	Low	Normal	High
		<div style="border: 1px solid black; padding: 1px;">LOT</div> ST0622L	<div style="border: 1px solid black; padding: 1px;">LOT</div> ST0622N	<div style="border: 1px solid black; padding: 1px;">LOT</div> ST0622H
SYSMEX™ KX-21/KX-21N	WBC × 10 <sup>3</sup> /μL	2.8 ± 0.4	8.0 ± 0.8	20.1 ± 2.4
	RBC × 10 <sup>6</sup> /μL	2.45 ± 0.16	4.10 ± 0.22	5.79 ± 0.28
	HGB g/dL	5.3 ± 0.4	12.1 ± 0.5	18.4 ± 0.7
	HGB g/L	53 ± 4	121 ± 5	184 ± 7
	HGB mmol/L	3.9 ± 0.2	7.5 ± 0.3	11.4 ± 0.5
	HCT %	18.3 ± 1.8	33.2 ± 2.4	51.2 ± 3.0
	HCT L/L	0.183 ± 0.018	0.332 ± 0.024	0.512 ± 0.030
	MCV fL	74.5 ± 5.0	81.0 ± 5.0	88.5 ± 5.0
	MCH pg	25.7 ± 2.8	29.5 ± 2.0	31.8 ± 2.0
	MCH fmoI	1.59 ± 0.18	1.83 ± 0.16	1.97 ± 0.16
	MCHC g/dL	34.5 ± 3.6	36.4 ± 2.8	35.9 ± 2.8
	MCHC g/L	345 ± 36	364 ± 28	359 ± 28
	MCHC mmol/L	21.4 ± 2.3	22.6 ± 1.8	22.3 ± 1.8
	RDW-SD fL	38.0 ± 8.0	37.0 ± 8.0	39.5 ± 8.0
	RDW-CV %	12.5 ± 5.0	11.0 ± 5.0	10.5 ± 5.0
	PLT × 10 <sup>3</sup> /μL	62 ± 18	204 ± 30	390 ± 60
	MPV fL	9.1 ± 3.0	9.0 ± 3.0	9.3 ± 3.0
	W-SCR (LYMPH) %	12.0 ± 4.0	31.0 ± 4.0	61.5 ± 7.0
	W-MCR (MXD) %	18.5 ± 5.0	16.5 ± 4.0	13.5 ± 4.0
	W-LCR (NEUT) %	69.5 ± 7.0	52.5 ± 5.0	25.0 ± 5.0
	W-SCC (LYMPH) × 10 <sup>3</sup> /μL	0.3 ± 0.2	2.5 ± 0.6	12.4 ± 3.0
	W-MCC (MXD) × 10 <sup>3</sup> /μL	0.5 ± 0.3	1.3 ± 0.5	2.7 ± 1.2
	W-LCC (NEUT) × 10 <sup>3</sup> /μL	1.9 ± 0.5	4.2 ± 0.9	5.0 ± 1.8

Before using, refer to the instruction sheet for mixing directions.

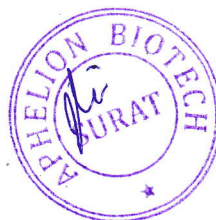
For technical assistance in the USA and Canada call Technical Service at (800) 523-3395.

• All brands and products are trademarks or registered trademarks of their respective companies.

R&D Systems, Inc.  
 614 McKinley Place NE  
 Minneapolis, MN 55413 USA  
 AS066-018 Rev. 11/17

## PRECISION DATA

SAMPLE ID	WBC	RBC	HGB	HCT	PLT
1-1	3.5	4.43	14.4	42.1	162
1-2	3.7	4.36	14.3	41.6	163
1-3	3.7	4.35	14.4	41.4	158
1-4	3.7	4.41	14.5	42	159
1-5	3.6	4.36	14.3	41.4	158
1-6	3.7	4.38	14.4	41.6	166
1-7	3.6	4.35	14.3	41.3	156
1-8	3.8	4.4	14.3	41.6	160
1-9	3.7	4.35	14.4	41.1	158
1-10	3.7	4.4	14.5	41.6	162
MEAN	3.7	4.38	14.4	41.6	160
S.D	0.08	0.03	0.08	0.32	3.19
C.V.%	2.24	0.67	0.54	0.77	1.99
ACCEPTABLE C.V.%	<=3.5%	<=2.0%	<=1.5	<=2.0	<=6.0
RESULT	PASS	PASS	PASS	PASS	PASS





# Sample Precision Data

No. 1-6	No. 1-7	No. 1-8
Date 04/07/22 18:29	Date 04/07/22 18:29	Date 04/07/22 18:30
Mode WB	Mode WB	Mode WB
WBC 3.7×10 <sup>3</sup> /μL	WBC 3.6×10 <sup>3</sup> /μL	WBC 3.8×10 <sup>3</sup> /μL
RBC 4.38×10 <sup>6</sup> /μL	RBC 4.35×10 <sup>6</sup> /μL	RBC 4.40×10 <sup>6</sup> /μL
HGB 14.4g/dL	HGB 14.3g/dL	HGB 14.3g/dL
HCT 41.6%	HCT 41.3%	HCT 41.6%
MCV 95.0fL	MCV 94.9fL	MCV 94.5fL
MCH 32.9pg	MCH 32.9pg	MCH 32.5pg
MCHC 34.6g/dL	MCHC 34.6g/dL	MCHC 34.4g/dL
PLT 166×10 <sup>3</sup> /μL	PLT 156×10 <sup>3</sup> /μL	PLT 160×10 <sup>3</sup> /μL
LYM% + 55.3%	LYM% 54.5%	LYM% 54.1%
MXD% 15.9%	MXD% 19.9%	MXD% + 23.5%
NEUT% - 28.8%	NEUT% - 25.6%	NEUT% - 22.4%
LYM# 2.0×10 <sup>3</sup> /μL	LYM# 2.0×10 <sup>3</sup> /μL	LYM# 2.1×10 <sup>3</sup> /μL
MXD# 0.6×10 <sup>3</sup> /μL	MXD# 0.7×10 <sup>3</sup> /μL	MXD# 0.9×10 <sup>3</sup> /μL
NEUT# 1.1×10 <sup>3</sup> /μL	NEUT# 0.9×10 <sup>3</sup> /μL	NEUT# 0.8×10 <sup>3</sup> /μL
RDW 14.2%	RDW 14.4%	RDW 14.2%
PDW 10.4fL	PDW 9.8fL	PDW 9.7fL
MPV 8.7fL	MPV 8.8fL	MPV 8.9fL
P-LCR 15.6%	P-LCR 16.2%	P-LCR 16.3%

No. 1-9	No. 1-10
Date 04/07/22 18:31	Date 04/07/22 18:32
Mode WB	Mode WB
WBC 3.7×10 <sup>3</sup> /μL	WBC 3.7×10 <sup>3</sup> /μL
RBC 4.35×10 <sup>6</sup> /μL	RBC 4.40×10 <sup>6</sup> /μL
HGB 14.4g/dL	HGB 14.5g/dL
HCT 41.1%	HCT 41.6%
MCV 94.5fL	MCV 94.5fL
MCH 33.1pg	MCH 33.0pg
MCHC 35.0g/dL	MCHC 34.9g/dL
PLT 158×10 <sup>3</sup> /μL	PLT 162×10 <sup>3</sup> /μL
LYM% + 55.9%	LYM% 54.5%
MXD% 14.5%	MXD% 15.9%
NEUT% - 29.6%	NEUT% - 29.6%
LYM# 2.1×10 <sup>3</sup> /μL	LYM# 2.0×10 <sup>3</sup> /μL
MXD# 0.5×10 <sup>3</sup> /μL	MXD# 0.6×10 <sup>3</sup> /μL
NEUT# 1.1×10 <sup>3</sup> /μL	NEUT# 1.1×10 <sup>3</sup> /μL
RDW 14.5%	RDW 14.0%
PDW 10.1fL	PDW 9.7fL
MPV 8.7fL	MPV 8.9fL
P-LCR 15.6%	P-LCR 16.2%

# Sample Precision Data

No. 1-1  
 Date 04/07/22 18:1  
 Mode WB

WBC  $3.5 \times 10^3 / \mu\text{L}$   
 RBC  $4.43 \times 10^6 / \mu\text{L}$   
 HGB 14.4g/dL  
 HCT 42.1%  
 MCV 95.0fL  
 MCH 32.5Pg  
 MCHC 34.2g/dL  
 PLT  $162 \times 10^3 / \mu\text{L}$

LYM% 53.6%  
 MXD% + 24.1%  
 NEUT% - 22.3%  
 LYM#  $1.9 \times 10^3 / \mu\text{L}$   
 MXD#  $0.8 \times 10^3 / \mu\text{L}$   
 NEUT#  $0.8 \times 10^3 / \mu\text{L}$   
 RDW 14.1%  
 PDW 10.1fL  
 MPV - 8.8fL  
 P-LCR 16.5%

No. 1-2  
 Date 04/07/22 18:2  
 Mode WB

WBC  $3.7 \times 10^3 / \mu\text{L}$   
 RBC  $4.36 \times 10^6 / \mu\text{L}$   
 HGB 14.3g/dL  
 HCT 41.6%  
 MCV 95.4fL  
 MCH 32.8Pg  
 MCHC 34.4g/dL  
 PLT  $163 \times 10^3 / \mu\text{L}$

LYM% + 56.4%  
 MXD% 17.9%  
 NEUT% - 25.7%  
 LYM#  $2.1 \times 10^3 / \mu\text{L}$   
 MXD#  $0.7 \times 10^3 / \mu\text{L}$   
 NEUT#  $0.9 \times 10^3 / \mu\text{L}$   
 RDW 14.2%  
 PDW 10.0fL  
 MPV - 8.7fL  
 P-LCR 15.8%

No. 1-3  
 Date 04/07/22 18:2  
 Mode WB

WBC  $3.7 \times 10^3 / \mu\text{L}$   
 RBC  $4.35 \times 10^6 / \mu\text{L}$   
 HGB 14.4g/dL  
 HCT 41.4%  
 MCV 95.2fL  
 MCH 33.1Pg  
 MCHC 34.8g/dL  
 PLT  $158 \times 10^3 / \mu\text{L}$

LYM% 53.9%  
 MXD% + 20.1%  
 NEUT% - 26.0%  
 LYM#  $2.0 \times 10^3 / \mu\text{L}$   
 MXD#  $0.7 \times 10^3 / \mu\text{L}$   
 NEUT#  $1.0 \times 10^3 / \mu\text{L}$   
 RDW 14.3%  
 PDW 9.7fL  
 MPV - 8.8fL  
 P-LCR 16.6%

No. 1-5  
 Date 04/07/22 18:2  
 Mode WB

WBC  $3.7 \times 10^3 / \mu\text{L}$   
 RBC  $4.41 \times 10^6 / \mu\text{L}$   
 HGB 14.5g/dL  
 HCT 42.0%  
 MCV 95.2fL  
 MCH 32.9Pg  
 MCHC 34.5g/dL  
 PLT  $159 \times 10^3 / \mu\text{L}$

LYM% + 56.4%  
 MXD% T2 ---, -%  
 NEUT% T2 ---, -%  
 LYM#  $2.1 \times 10^3 / \mu\text{L}$   
 MXD# T2 ---,  $- \times 10^3 / \mu\text{L}$   
 NEUT# T2 ---,  $- \times 10^3 / \mu\text{L}$   
 RDW 14.2%  
 PDW 9.9fL  
 MPV - 8.5fL  
 P-LCR 14.5%

No. 1-4  
 Date 04/07/22 18:2  
 Mode WB

WBC  $3.6 \times 10^3 / \mu\text{L}$   
 RBC  $4.36 \times 10^6 / \mu\text{L}$   
 HGB 14.3g/dL  
 HCT 41.4%  
 MCV 95.0fL  
 MCH 32.8Pg  
 MCHC 34.5g/dL  
 PLT  $158 \times 10^3 / \mu\text{L}$

LYM% 54.6%  
 MXD% + 20.7%  
 NEUT% - 24.7%  
 LYM#  $2.0 \times 10^3 / \mu\text{L}$   
 MXD#  $0.7 \times 10^3 / \mu\text{L}$   
 NEUT#  $0.9 \times 10^3 / \mu\text{L}$   
 RDW 14.2%  
 PDW 9.2fL  
 MPV - 8.5fL  
 P-LCR 13.6%





REF. NO.AB/TSC/CC/001

## Caibration Certificate

Customer Name	ADVANCE MALAVIYA PATHALOGY LABORATORY
Model	Fully Automated 3-Parts Celcounter SYSMEX KX-21
Serial no.	B8349
Calibration Date	04/07/2022
Next Calibration Due Date	03/07/2023

This is to certify that the above mentioned product has been calibrated by calibrator CBC NEK CAL R & D SYSTEM USA LOT NO. NK0722 EXP.05/08/2022 for 5 parameters (WBC,RBC,HGB,MCV and PLT) according to standard procedure provided by Manufacturer. Also varify by Normal control CBC ST PLUSLOT No ST0622N EXP. 05/09/2022 and results are in range provided by R & D system USA.

The refernce instruments used for value assignment are managed by R & D system and these are traceable to the International Standards, such as ICSH.

Calibration performed by,



Service Engineer,

Apheion Biotech

Surat.

Attachment

1. Certificate of Inspection(TSR).
2. Assay Sheet of Calibrator
3. Printouts

## APHELION BIOTECH

BLOCK NO-317, PLOT NO-113, SAHYOG INDUSTRIAL ESTATE, DASTAN-KARELI ROAD,MOJE-KARELI, TA- PALSANA, DIST.-SURAT - 394310,  
M. 90990 18292 / 9898202300 E-mail: apheionbiotech@gmail.com