

Certificate of Calibration

Instrument : Automated 3Part Cell Counter
Make : Nihon Kohden
Model : MEK -6510K
Serial No : 4489
Date Calibration : 18-01-2022
Installation place :SYNERGEN DIAGNOSTICS - PUNE

This is to certify that the above-mentioned instrument has been successfully calibrated on 18th JAN 2022 with MEK-CAL lot no-PLUS 21 bearing expiries till 5th FEB, 2022. During the calibration of the analyzer, all CBC parameters were calibrated.

Ran Quality Controls MEK-3D (Low, Normal, and High) Lot no-B21Y bearing expiry of 5th MAY, 2022, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on 17th JAN 2023. Validity \pm 30 days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.


RAJESH KASAR (SR.ENGINEER-CS)



This is computer generated Calibration Certificate therefore no signature required

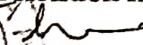
Calibration Data

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CALIBRATION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.5	4.62	14.3	41.5	243
2	9.8	4.65	14.4	41.4	240
3	9.4	4.63	14.5	41.7	246
Mean	9.7	4.62	14.3	41.60	238
SD	0.1	0.030	0.02	0.2	2.7
CV%	1.8	0.50	0.8	0.5	3.3

Acceptable CV%	Within 2.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4%
Result status	PASS	PASS	PASS	PASS	PASS

**Precision study performed on the analyzer using a blood samples.*

For Nihon Kohden India Pvt. Ltd.

Rajesh Kasar (Sr.Engineer-CS)

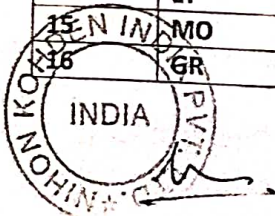
Control Data

Instrument: Automated 3 Part Cell Counter
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Control Data run on MEK 6510K Machine.

Normal Control B21YN

Sr. No	Parameters	Acceptable Range	Target Value	Reading On MEK 6510K
1	WBC	+/- 0.8	7.6	7.1
2	RBC	+/- 0.20	4.65	4.55
3	HGB	+/- 0.5	13.6	13.4
4	HCT	+/- 3.0	40.0	38.8
5	MCV	+/- 7.0	86.1	85.4
6	MCH	+/- 2.4	29.2	29.0
7	MCHC	+/- 3.0	34.0	33.7
8	PLT	+/- 50	267	260
9	MPV	+/- 2.0	8.7	8.5
10	RDW	+/- 3.0	16.7	16.4
11	LY%	+/- 10.0	29.9	28.7
12	MO%	+/- 5.0	3.9	2.8
13	GR%	+/- 10.0	66.2	68.5
14	LY	+/- 1.0	2.3	2.1
15	MO	+/- 0.4	0.3	0.2
16	GR	+/- 1.0	5.0	4.0



Low Control B21YL

Sr. No	Parameters	Acceptable Range	Target Value	Reading On MEK 6510K
1	WBC	+/- 0.6	2.0	1.9
2	RBC	+/- 0.15	2.40	2.35
3	HGB	+/- 0.4	6.0	5.8
4	HCT	+/- 2.0	18.1	71.8
5	MCV	+/- 9.0	75.5	73.4
6	MCH	+/- 2.4	25.0	24.7
7	MCHC	+/- 3.0	33.1	32.6
8	PLT	+/- 30	68	62
9	MPV	+/- 3.0	8.8	8.1
10	RDW	+/- 3.0	17.5	17.1
11	LY%	+/- 10.0	52.3	51.3
12	MO%	+/- 5.0	10.8	8.9
13	GR%	+/- 10.0	36.9	39.8
14	LY	+/- 0.5	1.0	0.9
15	MO	+/- 0.2	0.2	0.1
16	GR	+/- 0.5	0.8	1.0

High Control B21YH

Sr. No	Parameters	Acceptable Range	Target Value	Reading On MEK 6510K
1	WBC	+/- 2.2	20.5	21.5
2	RBC	+/- 0.25	5.79	5.71
3	HGB	+/- 0.7	18.8	18.5
4	HCT	+/- 4.0	54.1	54.3
5	MCV	+/- 7.0	93.5	93.2
6	MCH	+/- 2.8	32.5	32.4
7	MCHC	+/- 3.0	34.8	34.6
8	PLT	+/- 70	566	545
9	MPV	+/- 3.0	8.6	8.3
10	RDW	+/- 3.0	15.7	15.2
11	LY%	+/- 10.0	15.1	14.8
12	MO%	+/- 5.0	3.1	2.9
13	GR%	+/- 10.0	81.8	82.3
14	LY	+/- 1.8	3.1	3.0
15	MO	+/- 0.7	0.6	0.4
16	GR	+/- 2.0	16.8	17.8



For Nihon Kohden India Pvt. Ltd.

Rajesh Kasar (Sr. Engineer-CS)

NIHON KOHDEN

MEK-3DN HEMATOLOGY CONTROLS 2.0mL

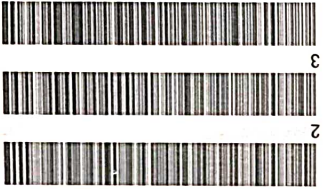
NORMAL ASSAY SHEET

LOT No.	B21YN
EXP. DATE	05 Feb 2022
OPEN VIAL STABILITY	14 DAYS

PARAMETER	RANGE	HEMOLYSING REAGENT				DILUENT	
		MEK-6400 -6410 -6420	MEK-6500 -6510	MEK-6450	MEK-6550	ISOTONAC-3 VALUES	ISOTONAC-4 VALUES
WBC	10 ³ /μL	±0.8	7.6	7.6	7.6	7.6	7.54
RBC	10 ⁶ /μL	±0.20	4.65	4.65	4.65	4.65	4.65
HGB	g/dL	±0.5	13.5	13.6	13.5	13.6	13.65
HCT	%	±3.0	40.0	40.0	40.0	40.0	45.2
MCV	fL	±7.0	86.1	86.1	86.1	86.1	97.3
MCH	pg	±2.4	29.0	29.2	29.0	29.2	29.4
MCHC	g/dL	±3.0	33.8	34.0	33.8	34.0	30.2
PLT	10 ³ /μL	±50	267	267	267	267	286.0
MPV	fL	±2.0	6.6	8.7	6.6	8.7	9.1
RDW*	%	±3.0	16.7	16.7	16.7	16.7	16.9
LY%	%	±10.0	29.9	29.9	29.9	29.9	31.58
MO%	%	±5.0	3.9	3.9	3.9	3.9	2.61
GR%	%	±10.0	66.2	66.2	66.2	66.2	65.81
LY	10 ³ /μL	±1.0	2.3	2.3	2.3	2.3	2.38
MO	10 ³ /μL	±0.4	0.3	0.3	0.3	0.3	0.20
GR	10 ⁷ /μL	±1.0	5.0	5.0	5.0	5.0	4.96

MEK-1301
-1302
-1305
QC ESR *3
11±5 mm

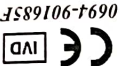
MEK-1301,1302,1305 Barcode Entry *2



NIHON KOHDEN CORPORATION
1-31-4 NISHIOCHIAI, SHINJUKU-KU
TOKYO 161-8560 JAPAN

NOTE :
*1 RDW is displayed as RDW-CV on MEK-6500,6510,6550/1301,1302,1305.
*2 Read the three barcodes that are printed below "Barcode Entry" on the assay sheet of the Nihon Kohden genuine control with the barcode reader.
The barcodes may be read in any order.
When all the barcodes are read, the control target value and the control limit value are automatically entered.

*3 The value is not an actual erythrocyte sedimentation rate. The value was calculated specifically for quality control of a Nihon Kohden analyzer based on the optical density, HCT and MCV of the hematology control.
* Please note that the assay value ranges are reviewed lot by lot and are subject to change.



0694-901685F

LOT No.	B21YH
EXP. DATE	05 Feb 2022
OPEN VIAL STABILITY	14 DAYS

PARAMETER	RANGE	HEMOLYSING REAGENT			
		ISOTONAC-3		ISOTONAC-4	
WBC	10 ³ /µL ±2.2	20.5	20.5	20.5	20.5
RBC	10 ⁶ /µL ±0.25	5.79	5.79	5.79	5.79
HGB	g/dL ±0.7	18.9	18.8	18.9	18.8
HCT	% ±4.0	54.1	54.1	54.1	54.1
MCV	fL ±7.0	93.5	93.5	93.5	93.5
MCH	pg ±2.8	32.6	32.5	32.6	32.5
MCHC	g/dL ±3.0	34.9	34.8	34.9	34.8
PLT	10 ³ /µL ±7.0	566	566	566	566
MPV	fL ±3.0	6.4	8.6	6.4	8.6
RDW*	% ±3.0	15.7	15.7	15.7	15.7
LY%	% ±10.0	15.1	15.1	15.1	15.1
MO%	% ±5.0	3.1	3.1	3.1	3.1
GR%	% ±10.0	81.8	81.8	81.8	81.8
LY	10 ³ /µL ±1.8	3.1	3.1	3.1	3.1
MO	10 ³ /µL ±0.7	0.6	0.6	0.6	0.6
GR	10 ³ /µL ±2.0	16.8	16.8	16.8	16.8

HEMOLYSING REAGENT	ISOTONAC-3	ISOTONAC-4	HEMOLYNAC-3N	HEMOLYNAC-310
ISOTONAC-3	17.13	16.8	16.8	16.8
ISOTONAC-4	0.57	0.6	0.6	0.6

1	MEK-1301,1302,1305 Barcode Entry *2
2	
3	

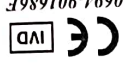
NOTE:

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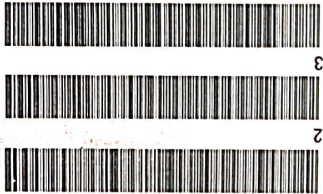
0694-901686F

LOT No.	B21YL
EXP. DATE	05 Feb 2022
OPEN VIAL STABILITY	14 DAYS

MEK-1305
QC ESR *3
46±17 mm

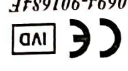
PARAMETER	RANGE	HEMOLYSING REAGENT				
		ISOTONAC-3		ISOTONAC-4		ISOTONAC-3
WBC	10 ³ /µL ±0.6	2.0	2.0	2.0	2.0	2.0
RBC	10 ⁶ /µL ±0.15	2.40	2.40	2.40	2.40	2.35
HGB	g/dL ±0.4	5.8	5.8	6.0	6.0	6.08
HCT	% ±2.0	18.1	18.1	18.1	18.1	20.1
MCV	fL ±9.0	75.5	75.5	75.5	75.5	85.4
MCH	pg ±2.4	24.2	24.2	25.0	25.0	25.9
MCHC	g/dL ±3.0	32.0	33.1	33.1	33.1	30.2
PLT	10 ³ /µL ±30	68	68	68	68	75.4
MPV	fL ±3.0	6.8	6.8	6.8	6.8	9.0
RDW*	% ±3.0	17.5	17.5	17.5	17.5	16.6
LY%	% ±10.0	52.3	52.3	52.3	52.3	53.85
MO%	% ±5.0	10.8	10.8	10.8	10.8	7.50
GR%	% ±10.0	36.9	36.9	36.9	36.9	38.65
LY	10 ³ /µL ±0.5	1.0	1.0	1.0	1.0	1.10
MO	10 ³ /µL ±0.2	0.2	0.2	0.2	0.2	0.15
GR	10 ³ /µL ±0.5	0.8	0.8	0.8	0.8	0.79

MEK-1301, 1302, 1305 Barcode Entry *2



NOTE :
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