

Input data



Instrument Name	Automated 3 Part Cell Counter
Make	Nihon Kohden
Model	MEK-1305K (Celltac Alpha +)
Serial no	897
Calibration date	30.07.2024
Installation place	Vriksh Fertility Centre, Bengaluru



Name : Puttaswamy K Gowda
Designation : Senior Engineer



Calibration Data

Instrument Name : Automated 3 Part Cell Counter
 Make : Nihon Kohden
 MEK-1305K (Celltac Alpha)
 Model : +)
 Serial no : 897
 Calibration date : 30.07.2024
 Installation place : Vriksh Fertility Centre, Bengaluru

CALIBRATION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.4	4.51	13.7	45.1	276
2	9.3	4.62	13.6	45.6	274
3	9.3	4.55	13.7	45.9	275
Mean	9.3	4.61	13.7	45.0	272
CV%	0.5	0.50	0.4	0.20	2.10

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.
Name : Puttaswamy K Gowda
Designation : Senior Engineer



Precision Check Data

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1305K (Celltac Alpha +)
Serial no	:	897
Calibration date	:	30.07.2024
Installation place	:	Vriksh Fertility Centre, Bengaluru

PRECISION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.2	4.55	13.28	45.9	277
2	9.2	4.49	13.21	45.7	273
3	9.1	4.50	13.26	45.3	277
4	9.3	4.59	13.35	45.6	272
5	9.3	4.50	13.18	45.6	265
6	9.2	4.49	13.34	45.9	270
7	9.2	4.55	13.29	45.6	274
8	9.1	4.54	13.21	45.7	276
9	9.2	4.52	13.24	45.4	275
Mean	9.3	4.64	13.59	45.0	272
SD	0.1	0.0	0.1	0.3	3.7
CV%	0.74	1.05	0.86	0.6	1.36

Acceptable CV%	Within 2.0%	Within 1.5%	Within 1.5%	Within 1%	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.

**Name : Puttaswamy K
Gowda**
**Designation : Senior
Engineer**



Certification of Calibration

Instrument Name	: Automated 3 Part Cell Counter
Make	: Nihon Kohden
Model	: MEK-1305K (Celltac Alpha +)
Serial no	: 897
Calibration date	: 30.07.2024
Installation place	: Vriksh Fertility Centre, Bengaluru

This is to certify that the above mentioned instrument has been successfully calibrated on **30th July 2024** with MEK-CAL lot no-**PLUS 247** bearing expiry till **5th August 2024**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High) Lot no-B245** bearing expiry of **5th August 2024**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **29th July 2025**. Validity \pm 30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt.
Ltd.
**Name : Puttaswamy K
Gowda**
Designation : Senior Engineer



Performance Qualification :

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1305K (Celltac Alpha +)
Serial no	:	897

Following are the steps required to validate your instrument and method.

- 1 Run QC samples (Low, Normal and Abnormal) and verifies the values with acceptable range given in the insert of quality control samples

Printouts attached from instrument (Yes/No)

Yes

- 2 Run 10 time patient sample into the system and calculate the %CV. Acceptance limits of %CV ($\leq 5\%$) shall be considered.

Printouts attached from instrument (Yes/No)

Yes

QC RESULTS : PASS/FAIL= PASS
 PRECISION CHECK : PASS/FAIL= PASS

VALIDATION TEAM FROM VENDOR:

Name : Puttaswamy K Gowda
 Designation : Senior Engineer



Signature : _____
 Nihon Kohden India Private Limited

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :
 Designation :
 Signature :
 Date :

CUSTOMER AUTHORIZATION:

Name :
 Designation :
 Signature :
 Date :

Data List Details



28/09/2024 16:10

Sample ID

B245N

Patient ID

Date

15/08/2024 15:16

Mode

Normal

ESR

8

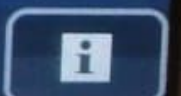
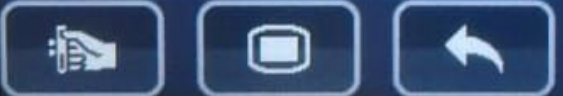
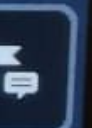
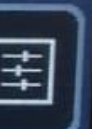
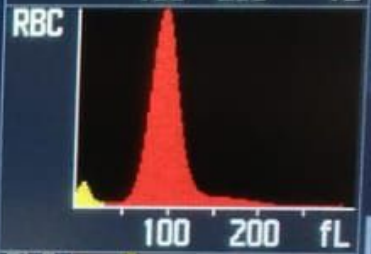
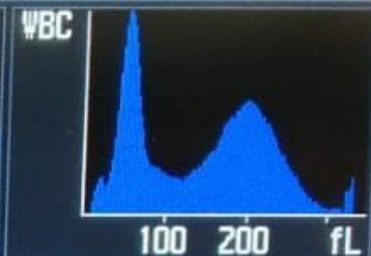
mm

5



15

WBC	7.90	$10^3/\mu\text{L}$
LY	2.63	[33.32 %]
MO	0.29	[3.61 %]
GR	4.98	[63.07 %]
RBC	4.75	$10^6/\mu\text{L}$
HGB	14.20	g/dL
HCT	46.3	%
MCV	97.5	fL
MCH	29.9	pg
MCHC	30.7	g/dL
RDW-CV	17.1	%
RDW-SD	66.7	fL
PLT	268.7	$10^3/\mu\text{L}$
PCT	0.23	%
MPV	8.5	fL
PDW	18.9	%
P-LCR	37.6	%





Sample ID

B245L

Patient ID

Date

17/08/2024 10:31

Mode

Normal

ESR

52

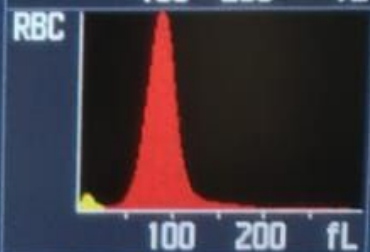
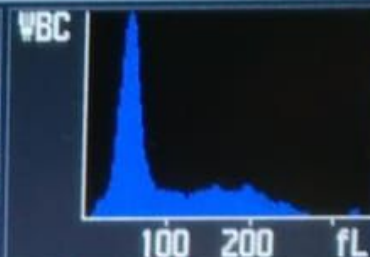
mm

31



65

WBC	2.27	10 ⁹ /μL
LY	1.39	[61.07 %]
MO	0.09	[4.10 %]
GR	0.79	[34.83 %]
RBC	2.32	10 ⁶ /μL
HGB	6.23	g/dL
HCT	20.7	%
MCV	89.2	fL
MCH	26.9	pg
MCHC	30.1	g/dL
RDW-CV	16.8	%
RDW-SD	59.9	fL
PLT	78.8	10 ⁹ /μL
PCT	0.07	%
MPV	8.4	fL
PDW	18.1	%
P-LCR	37.2	%



Navigation icons: Up arrow, Down arrow, Checkmark, Histogram, Settings, Home

Bottom navigation icons: Hand, Tablet, Back arrow

Bottom navigation buttons: Edit, Print, Delete, Send

Bottom navigation icon: Information

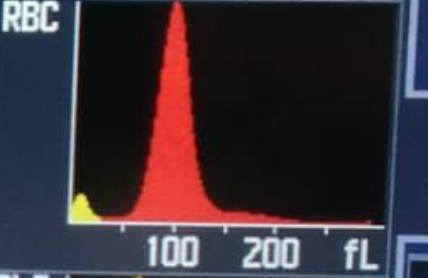
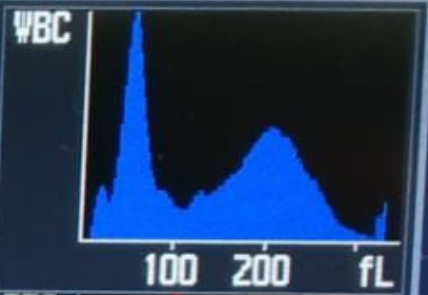
Data List Details



28/09/2024 16:09

Sample ID
 Patient ID BZ45N
 Date 20/08/2024 19:18
 Mode Normal
 ESR 8 mm
 5 15

WBC	7.61	$10^3/\mu\text{L}$
LY	2.59	[34.06 %]
MO	0.24	[3.15 %]
GR	4.78	[62.79 %]
RBC	4.70	$10^6/\mu\text{L}$
HGB	14.42	g/dL
HCT	46.9	%
MCV	99.8	fL
MCH	30.7	pg
MCHC	30.7	g/dL
RDW-CV	17.1	%
RDW-SD	68.3	fL
PLT	276.9	$10^3/\mu\text{L}$
PCT	0.23	%
MPV	8.3	fL
PDW	17.8	%
P-LCR	37.1	%



Navigation icons: Up arrow, Down arrow, Checkmark, Histogram, List, Flag, Info.

Bottom navigation bar: Hand icon, Tablet icon, Back arrow, Edit, Print, Delete, Send, Info icon.

Data List Details



28/09/2024 16:06

Sample ID
B248N

Patient ID

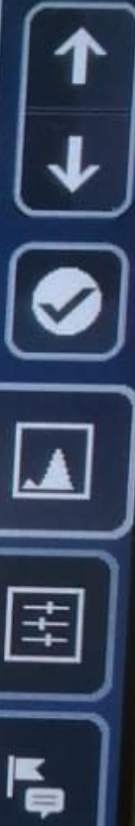
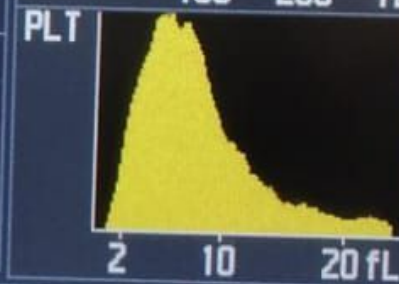
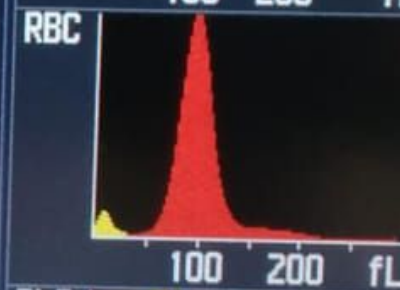
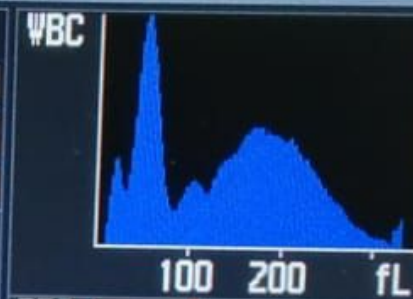
Date
23/09/2024 18:35

Mode
Normal

ESR 7 mm

3 ————— 13

WBC	7.76	$10^3/\mu\text{L}$
LY	2.18	[28.06 %]
MO	0.14	[1.83 %]
GR	5.44	[70.11 %]
RBC	4.77	$10^6/\mu\text{L}$
HGB	14.59	g/dL
HCT	47.2	%
MCV	99.0	fL
MCH	30.6	Pg
MCHC	30.9	g/dL
RDW-CV	17.0	%
RDW-SD	67.3	fL
PLT	256.5	$10^3/\mu\text{L}$
PCT	0.22	%
MPV	8.7	fL
PDW	17.6	%
P-LCR	39.6	%



Edit

Print

Delete

Send



Data List Details



28/09/2024 16:06

Sample ID
B248H

Patient ID

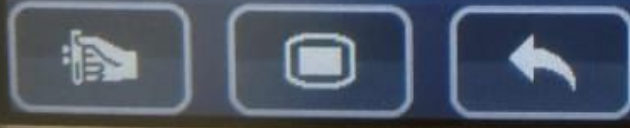
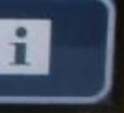
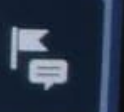
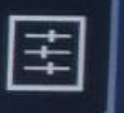
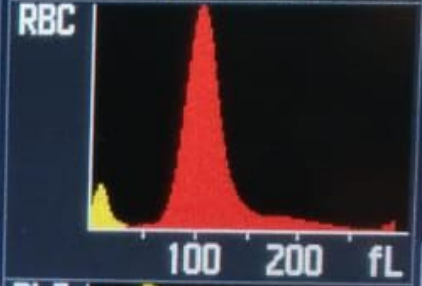
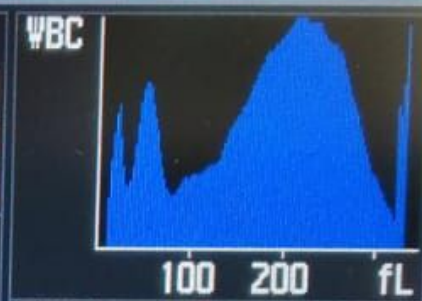
Date
25/09/2024 12:47

Mode
Normal

ESR
0 mm



WBC	20.57	10 ³ /μL
LY	2.54	[12.33 %]
MO	0.53	[2.56 %]
GR	17.50	[85.11 %]
RBC	5.98	10 ⁶ /μL
HGB	20.05	g/dL
HCT	65.3	%
MCV	109.2	fL
MCH	33.5	Pg
MCHC	30.7	g/dL
RDW-CV	19.2	%
RDW-SD	83.9	fL
PLT	539.6	10 ³ /μL
PCT	0.46	%
MPV	8.6	fL
PDW	18.4	%
P-LCR	39.1	%



Data List Details



28/09/2024 16:05

Sample ID
B248N

Patient ID

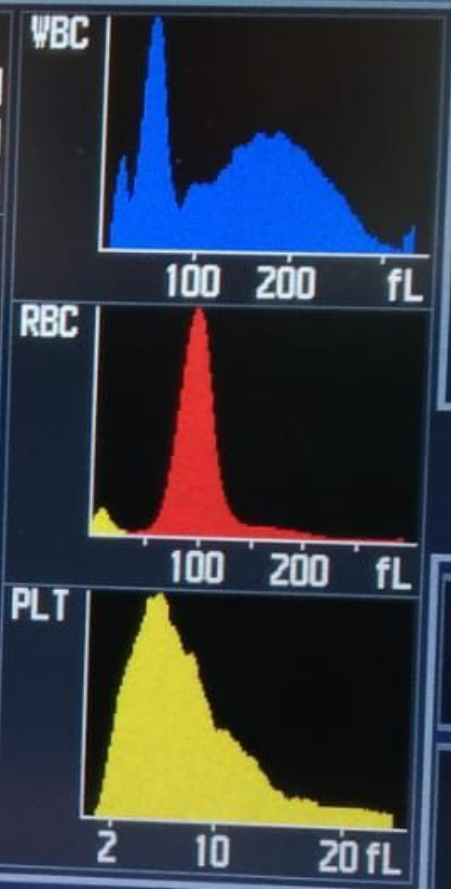
Date
27/09/2024 15:34

Mode
Normal

ESR
6 mm

3 13

WBC	7.85	$10^3/\mu\text{L}$
LY	2.20	[28.03 %]
MO	0.27	[3.48 %]
GR	5.38	[68.49 %]
RBC	4.81	$10^6/\mu\text{L}$
HGB	14.83	H g/dL
HCT	47.3	%
MCV	98.3	fL
MCH	30.8	pg
MCHC	31.4	g/dL
RDW-CV	17.3	%
RDW-SD	68.0	fL
PLT	260.4	$10^3/\mu\text{L}$
PCT	0.23	%
MPV	8.7	fL
PDW	18.7	%
P-LCR	40.0	%



Navigation icons: Up arrow, Down arrow, Checkmark, Histogram, List, Flag, Info.

Bottom toolbar: Hand icon, Tablet icon, Back arrow, Edit, Print, Delete, Send, Info.

Data List Details



28/09/2024 16:02

Sample ID
B248H

Patient ID

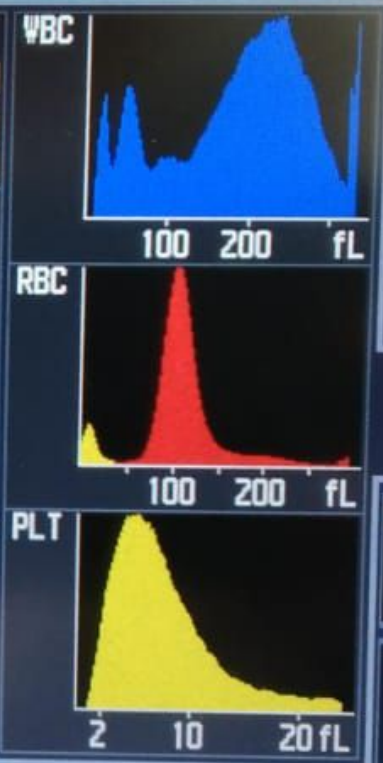
Date
28/09/2024 10:58

Mode
Normal

ESR
0 mm

Progress bar

WBC	20.88	10 ⁹ /μL
LY	2.26	[10.81 %]
MO	0.72	[3.46 %]
GR	17.90	[85.73 %]
RBC	5.92	10 ⁶ /μL
HGB	19.90	g/dL
HCT	64.8	%
MCV	109.5	fL
MCH	33.6	pg
MCHC	30.7	g/dL
RDW-CV	19.0	%
RDW-SD	83.2	fL
PLT	538.6	10 ⁹ /μL
PCT	0.47	%
MPV	8.7	fL
PDW	19.2	%
P-LCR	38.7	%



Navigation icons: Up, Down, Checkmark, Home, List, Flag, Info

Bottom toolbar: Hand, Home, Back, Edit, Print, Delete, Send, Info

Data List Details



28/09/2024 16:07

Sample ID

B248H

Patient ID

Date

22/09/2024 18:52

Mode

Normal

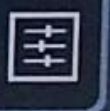
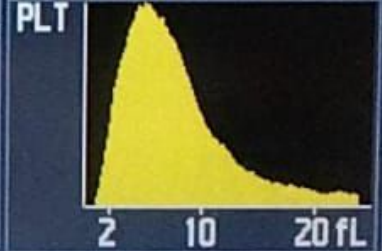
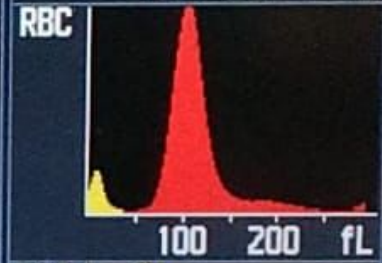
ESR

0

mm



WBC	20.65	$10^3/\mu\text{L}$
LY	2.49	[12.04 %]
MO	0.64	[3.11 %]
GR	17.52	[84.85 %]
RBC	5.82	$10^6/\mu\text{L}$
HGB	20.03	g/dL
HCT	63.2	%
MCV	108.6	fL
MCH	34.4	Pg
MCHC	31.7	g/dL
RDW-CV	19.0	%
RDW-SD	82.5	fL
PLT	543.4	$10^3/\mu\text{L}$
PCT	0.47	%
MPV	8.7	fL
PDW	18.4	%
P-LCR	38.7	%



Edit



Print



Delete



Send



Data List Details



28/09/2024 16:06

Sample ID
B248N

Patient ID

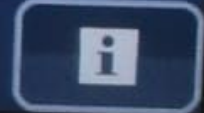
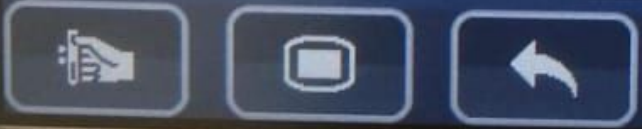
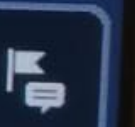
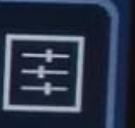
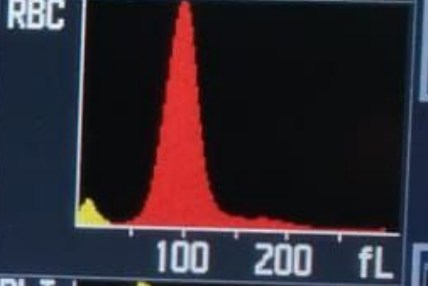
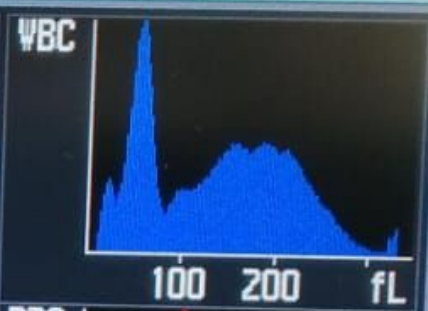
Date
22/09/2024 18:57

Mode
Normal

ESR
7 mm

3 13

WBC	7.84	$10^3/\mu\text{L}$
LY	2.23	[28.47 %]
MO	0.29	[3.75 %]
GR	5.32	[67.78 %]
RBC	4.79	$10^6/\mu\text{L}$
HGB	14.59	g/dL
HCT	47.2	%
MCV	98.5	fL
MCH	30.5	Pg
MCHC	30.9	g/dL
RDW-CV	17.1	%
RDW-SD	67.4	fL
PLT	264.0	$10^3/\mu\text{L}$
PCT	0.23	%
MPV	8.7	fL
PDW	18.4	%
P-LCR	40.3	%



Data List Details



28/09/2024 16:02

Sample ID
B248H

Patient ID

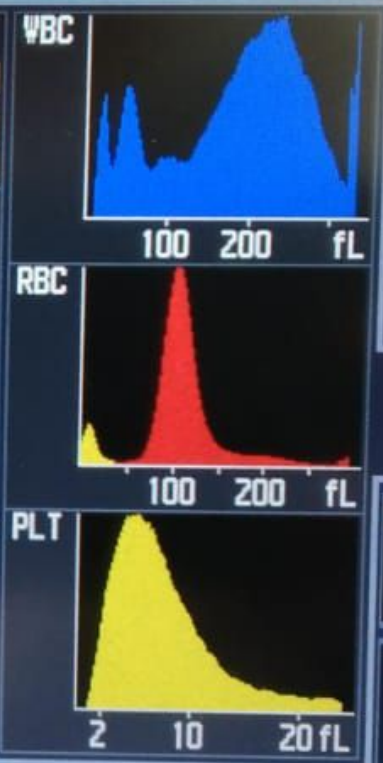
Date
28/09/2024 10:58

Mode
Normal

ESR
0 mm

Progress bar

WBC	20.88	10 ⁹ /μL
LY	2.26	[10.81 %]
MO	0.72	[3.46 %]
GR	17.90	[85.73 %]
RBC	5.92	10 ⁶ /μL
HGB	19.90	g/dL
HCT	64.8	%
MCV	109.5	fL
MCH	33.6	pg
MCHC	30.7	g/dL
RDW-CV	19.0	%
RDW-SD	83.2	fL
PLT	538.6	10 ⁹ /μL
PCT	0.47	%
MPV	8.7	fL
PDW	19.2	%
P-LCR	38.7	%



Navigation icons: Up, Down, Checkmark, Home, List, Flag, Info

Bottom toolbar: Hand, Home, Back, Edit, Print, Delete, Send, Info