

Input data



Instrument Name	Automated 5Part Cell Counter
Make	Nihon Kohden
Model	MEK-7300K
Serial no	1360
Calibration date	24-May-24
Installation place	Deep Clinical Laboratory



Name : Nileshtelng
Designation :Territory Manager-
CS



Calibration Data

Instrument Name	:	Automated 5Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-7300K
Serial no	:	1360
Calibration date	:	24-May-24
Installation place	:	Deep Clinical Laboratory

CALIBRATION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.1	4.45	13.3	40.8	230
2	8.9	4.52	13.1	41.7	244
3	9.0	4.44	13.1	41.1	233
4	9.0	4.40	13.3	40.6	230
5	8.9	4.44	13.3	40.9	229
Mean	9.0	4.45	13.2	41.0	233
SD	0.1	0.04	0.1	0.4	6
CV%	0.9	0.80	0.71	0.91	2.58

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 : Nilesch Telang
Designation : Territory
Manager-CS



Precision Check Data

Instrument Name	:	Automated 5Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-7300K
Serial no	:	1360
Calibration date	:	24-May-24
Installation place	:	Deep Clinical Laboratory

PRECISION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	6.20	4.62	14.30	44.40	309
2	6.20	4.55	14.20	44.00	310
3	6.20	4.60	14.20	43.90	314
4	6.20	4.52	14.20	43.40	302
5	6.20	4.54	14.20	43.60	314
6	6.10	4.52	14.10	43.40	298
7	6.40	4.54	14.20	43.50	311
8	6.30	4.51	14.40	43.30	298
9	6.20	4.54	14.40	43.50	289
10	6.20	4.61	14.30	44.30	329
Mean	8.69	3.94	14.25	43.73	307
SD	0.07	0.04	0.09	0.37	11
CV%	0.86	0.96	0.65	0.86	3.44

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 : Nilesh Telang
Designation : Territory Manager-CS



Certification of Calibration

Instrument Name	: Automated 5Part Cell Counter
Make	: Nihon Kohden
Model	: MEK-7300K
Serial no	: 1360
Calibration date	: 24-May-24
Installation place	: Deep Clinical Laboratory

This is to certify that the above mentioned instrument has been successfully calibrated on **24May2024** with MEK-CAL lot no-**PLUS 245** bearing expiry till **5thJune2024**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-5D (Low, Normal, and High) Lot no-245** bearing expiry of **5Aug2024**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **23May2025**. Validity \pm 30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.
Name : Nilesh Telang
**Designation : Territory Manager-
CS**



Performance Qualification :

Instrument Name	:	Automated 5Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-7300K
Serial no	:	1360

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 : Nilesh Telang
 Designation :Territory Manager-CS



SIGNATURE
NIHON KOHDEN INDIA PVT LTD

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :
 Designation :
 Signature :
 Date :

CUSTOMER AUTHORIZATION:

Name :
 Designation :
 Signature :
 Date :