

Certification of Calibration

Instrument Name	: Automated 3 Part Cell Counter
Make	: Nihon Kohden
Model	: MEK 6420 P
Serial no	: 52650
Calibration date	: 11-Mar-24
Installation place	: Arunosha Labs Pvt Ltd. New Delhi

This is to certify that the above mentioned instrument has been successfully calibrated on **11th Mar 2024** with MEK-CAL lot no **PLUS-242** bearing expiry till **05th Apr 2024**. During the calibration of the analyser, all CBC parameters were calibrated.

Run Quality Controls **MEK-3D (Low, Normal, and High)** Lot no-**B242** bearing expiry of **05th May 2024**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **11th Mar 2025**. Validity \pm 30 days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt.
Ltd.

Name : Jaswinder singh
Designation : R M



Calibration Data

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CALIBRATION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	8.90	4.61	13.80	39.4	228
2	9.00	4.59	13.90	39.1	237
3	8.80	4.63	13.90	39.5	235
4	9.10	4.63	13.90	39.5	237
5	9.00	4.66	13.90	39.7	239
6	9.00	4.65	13.90	39.6	233
7	9.10	4.72	14.00	40.3	229
8	9.00	4.63	13.90	39.8	226
9	9.20	4.63	13.90	39.2	237
10	9.00	4.68	13.90	39.7	226
Mean	9.01	4.41	13.90	39.58	232.70
SD	0.11	0.04	0.05	0.34	5
CV%	1.22	0.8	0.34	0.8	2.2

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 Calibrator.*

For Nihon Kohden India
Pvt. Ltd.
Name : Jaswinder singh
Designation : R M



Precision Check Data

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PRECISION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.10	4.59	13.90	39.0	211
2	9.10	4.65	13.90	39.4	237
3	9.00	4.66	13.80	39.6	239
4	9.00	4.69	14.00	39.9	221
5	9.10	4.63	14.00	39.3	215
6	9.00	4.69	13.90	39.8	224
7	9.20	4.66	14.00	39.7	225
8	9.10	4.66	13.90	39.5	223
9	9.10	4.66	13.90	39.7	228
10	9.10	4.64	14.00	39.5	237
Mean	9.08	4.65	13.93	39.54	227.00
SD	0.06	0.0	0.07	0.3	8
CV%	0.70	0.6	0.48	0.7	4

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 Calibrator.

For Nihon Kohden India
 Pvt. Ltd.
 Name : Jaswinder singh
 Designation : R M



Performance Qualification :

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK 6420 P
Serial no	:	52650

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) NO

- 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) NO

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

VALIDATION TEAM FROM VENDOR:

Name : Jaswinder singh
Designation : R M



Signature : _____
Nihon Kohden India Private Limited

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :
Designation :
Signature :
Date :

CUSTOMER AUTHORIZATION:

Name :
Designation :
Signature :
Date :

Input data



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