

Input data



Instrument Name	Automated 3 Part Cell Counter
Make	Nihon Kohden
Model	MEK 6510K
Serial no	7468
Calibration date	20-Apr-24
Installation place	Delhi Health Lab New Delhi



Name : Jaswinder singh
Designation : R M



Calibration Data

Instrument Name : Automated 3 Part Cell Counter
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CALIBRATION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.00	4.52	13.80	39.7	237
2	9.00	4.62	13.90	40.7	244
3	9.30	4.61	14.00	40.4	232
4	9.20	4.55	13.80	39.9	234
5	9.10	4.50	13.90	39.6	224
6	9.30	4.57	14.00	40.3	239
7	9.30	4.61	14.00	40.4	218
8	9.10	4.54	13.90	39.9	223
9	9.30	4.60	14.00	40.3	224
10	9.50	4.66	14.10	40.7	227
Mean	9.21	4.41	13.94	40.19	230.20
SD	0.16	0.05	0.10	0.39	8
CV%	1.73	1.1	0.69	1.0	3.6

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

Instrument Name : Automated 3 Part Cell Counter
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 Model : MEK 6510K
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 Calibration date : 20-Apr-24

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PRECISION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.70	4.37	12.80	37.5	257
2	9.30	4.49	12.80	38.4	262
3	9.30	4.40	12.80	37.6	252
4	9.40	4.45	12.80	38.0	247
5	9.30	4.46	12.90	38.1	261
6	9.40	4.45	12.80	37.8	251
7	9.50	4.43	12.80	37.9	257
8	9.30	4.47	12.90	38.2	258
9	9.30	4.46	12.90	38.0	253
10	9.20	4.43	12.90	37.8	272
Mean	9.37	4.44	12.84	37.93	257.00
SD	0.14	0.0	0.05	0.3	7
CV%	1.51	0.8	0.40	0.7	3

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



Certification of Calibration

Instrument Name	: Automated 3 Part Cell Counter
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Model	: MEK 6510K
Serial no	: 7468
Calibration date	: 20-Apr-24
Installation place	: Delhi Health Lab. New Delhi

This is to certify that the above mentioned instrument has been successfully calibrated on **20th Apr 2024** with MEK-CAL lot no-**PLUS-244** bearing expiry till **05th May 2024**. During the calibration of the analyser, all CBC parameters were calibrated.

Run Quality Controls **MEK-3D (Low, Normal, and High) Lot no-B-242** 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 **19th Apr 2025**. Validity \pm 30days. Or depends on QC performance/subject to replacement or change in hardware.

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 6510K
Serial no	:	7468

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 :