

Certificate of Calibration

Instrument : Automated 3Part Cell Counter
Make : Nihon Kohden
Model : MEK -6510K
Serial No : 4225
Date Calibration : 18-11-2020
Installation place : ALAKNANDA DIAGNOSTICS LAB-NEW DELHI

This is to certify that the above mentioned instrument has been successfully calibrated on **18th NOV 2020** with MEK-CAL lot no-PLUS 20Y bearing expiry till **5th Dec, 2020**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High) Lot no- 20Y** bearing expiry of **5th FEB 2021**. Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **17th NOV 2021**. Validity \pm 30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.

RAVINDER SINGH (ENGINEER-CS)



Calibration Data

Instrument: Automated 3 Part Cell Counter

Make: Nihon Kohden

Model: MEK-6510K

Serial No: 4225

Date Calibration: 18-11-2020

Installation place: ALAKNANDA DIAGNOSTICS LAB-NEW DELHI

<i>Sample No.</i>	WBC	RBC	HGB	HCT	PLT
1	9.2	4.66	14.2	42.0	247
2	9.0	4.64	14.3	42.0	245
3	9.0	4.67	14.3	42.2	231
4	8.9	4.71	14.2	42.2	248
5	9.0	4.66	14.2	42.2	236
Mean	9.0	4.67	14.2	42.1	241
CV%	1.2	0.6	0.4	0.2	3.1

Nihon Kohden India Pvt. Ltd.

RAVINDER SINGH (ENGINEER -CS)



PRECISION CHECK CERTIFICATE

Instrument : Automated 3Part Cell Counter
Make : Nihon Kohden
Model : MEK-6510K
Serial No : 4225
Date of Calibration: 18-11-2020
Installation place: ALAKNANDA DIAGNOSTICS LAB-NEW DELHI

PRECISION CHECK DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	12.1	5.48	15.80	48.3	312
2	12.1	5.49	16.00	48.6	314
3	12.1	5.50	15.70	48.6	307
4	12.1	5.47	15.90	48.4	330
5	12.2	5.51	16.00	48.6	311
6	12.1	5.50	15.90	48.7	328
7	12.1	5.48	16.00	48.4	318
8	12.1	5.47	15.90	49.4	329
9	12.0	5.53	16.00	49.2	332
10	12.2	5.54	16.10	48.9	315
Mean	12.1	4.73	15.93	48.7	320
SD	0.1	0.02	0.11	0.3	8.8
CV%	0.4	0.5	0.7	0.7	2.7

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.

RAVINDER SINGH (ENGINEER-CS)



Open

Time	14:19	14:20	14:22	MEAN
WBC	9.2	9.0	9.0	9.0
RBC	4.66	4.64	4.67	4.67
HGB	14.2	14.3	14.3	14.2
HCT	42.0	42.0	42.2	42.1
MCV	90.1	90.5	90.4	90.2
MCH	30.5	30.8	30.6	30.5
MCHC	33.8	34.0	33.9	33.8
PLT	247	245	231	241
LY%	5.5	4.8	5.2	4.6
MO%	0.1	0.1	0.2	0.1
GR%	94.4	95.1	94.6	95.3
RDW-CV	15.3	15.7	15.6	15.5
PCT	0.21	0.20	0.19	0.20
MPV	8.3	8.1	8.3	8.3
PDW	17.9	17.7	17.2	17.6

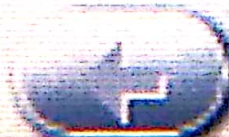
DELETE

Total data: 5

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OK

CV



CAL DATA LIST



18 NOV '20 14:37

Open

Time	14:24	14:27	MEAN
WBC	8.9	9.0	9.0
RBC	4.71	4.66	4.67
HGB	14.2	14.2	14.2
HCT	42.2	42.1	42.1
MCV	89.6	90.3	90.2
MCH	30.1	30.5	30.5
MCHC	33.6	33.7	33.8
PLT	248	236	241
LY%	4.2	3.1	4.6
MO%	0.0F:	0.3	0.1
GR%	95.8F:	96.6	95.3
RDW-CV	15.6	15.2	15.5
PCT	0.21	0.20	0.20
MPV	8.5	8.3	8.3
PDW	17.9	17.2	17.6

DELETE

Total data: 5

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OK

CV





	MEAN	CV
WBC	9.0	1.2
RBC	4.67	0.6
HGB	14.2	0.4
HCT	42.1	0.2
MCV	90.2	0.4
MCH	30.5	0.8
MCHC	33.8	0.5
PLT	241	3.1
LY%	4.6	20.8
MO%	0.1	82.0
GR%	95.3	1.0
RDW-CV	15.5	1.4
PCT	0.20	4.1
MPV	8.3	1.7
PDW	17.6	2.0

Total data:

5

OK



WBC	1.9	$10^3/\mu\text{L}$
RBC	2.50	$10^6/\mu\text{L}$
HGB	6.1	g/dL
HCT	17.9	%
MCV	71.6	fL
MCH	24.4	pg
MCHC	34.1	g/dL
PLT	65	$10^3/\mu\text{L}$
LY	1.0	[55.0 %]
MO	0.2	[9.3 %]
GR	0.7	[35.7 %]
RDW-CV	18.3	%
PCT	0.05	%
MPV	8.1	fL
PDW	18.2	%

DETAILS

OK

HISTORY

GRAPH

L&J (NORMAL)



18 NOV '20 14:48

WBC	7.2	$10^3/\mu\text{L}$
RBC	4.76	$10^6/\mu\text{L}$
HGB	13.9	g/dL
HCT	40.9	%
MCV	85.9	fL
MCH	29.2	pg
MCHC	34.0	g/dL
PLT	237	$10^3/\mu\text{L}$
LY	2.4	[32.9 %]
MO	0.4	[5.2 %]
GR	4.4	[61.9 %]
RDW-CV	16.3	%
PCT	0.19	%
MPV	7.9	fL
PDW	17.6	%

DETAILS

OK

HISTORY

GRAPH

L&J (HIGH)



18 NOV '20 14:49

WBC	19.3		$10^3/\mu\text{L}$
RBC	5.84		$10^6/\mu\text{L}$
HGB	19.1		g/dL
HCT	54.7		%
MCV	93.7		fL
MCH	32.7		Pg
MCHC	34.9		g/dL
PLT	501		$10^3/\mu\text{L}$
LY	3.8	[19.7 %]
MO	0.4	[1.8 %]
GR	15.1	[78.5 %]
RDW-CV	15.6		%
PCT	0.41		%
MPV	8.1		fL
PDW	17.7		%

DETAILS

OK

HISTORY

GRAPH

ID	*HEK3DL 11181st	*HEK3DH 11181st	*P 0001	*P 0002
Date	18 NOV	18 NOV	18 NOV	18 NOV
Time	14:44	14:46	15:16	15:19
SEQ#	0003689	0003690	0003693	0003694
WBC	1.9	19.3	12.1H	12.1H
RBC	2.50	5.84	5.48	5.49
HGB	6.1	19.1	15.8	16.0
HCT	17.9	54.7	48.3H	48.5H
MCV	71.6	93.7	88.1	88.5
MCH	24.4	32.7	28.8	29.1
MCHC	34.1	34.9	32.7	32.9
PLT	65	501	312	314
LY%	55.0	19.7	16.0L	15.3L
MO%	9.3	1.8	2.4	2.7
GR%	35.7	78.5	81.5H	82.0H

PRINT

SEND

DELETE

Total data:

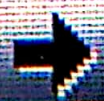
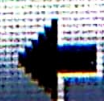
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SEARCH



*P	0003	*P	0004	*P	0005	*P	0006
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ID

Date

Time

SEQ#

18 NOV	18 NOV	18 NOV	18 NOV
15:21	15:22	15:24	15:25
0003695	0003696	0003697	0003698

WBC

RBC

HGB

HCT

MCV

MCH

MCHC

PLT

12.1H	12.0H	12.2H	12.1H
5.50	5.47	5.51	5.50
15.7	15.9	16.0	15.9
48.3H	48.4H	48.6H	48.7H
88.4	88.5	88.2	88.5
28.5	29.1	29.0	28.9
32.3	32.9	32.9	32.6
307	330	311	328

LY%

MO%

GR%

15.5L	12.2L	12.9L	14.0L
2.6	3.3	2.9	3.6
81.3H	84.5H	83.2H	81.8H

PRINT

SEND

DELETE

Total data:

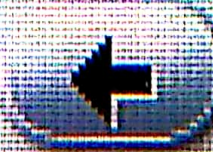
400

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MENU

SEARCH



ID	*P 0007	*P 0008	*P 0009	*P 0010
Date	18 NOV	18 NOV	18 NOV	18 NOV
Time	15:28	15:29	15:30	15:33
SEQ#	0003699	0003700	0003701	0003702
WBC	12.1H	12.1H	12.0H	12.2H
RBC	5.48	5.47	5.53	5.54
HGB	16.0	15.9	16.0	16.1
HCT	48.4H	48.4H	49.2H	48.9H
MCV	88.3	88.5	89.0	88.3
MCH	29.2	29.1	28.9	29.1
MCHC	33.1	32.9	32.5	32.9
PLT	318	329	332	315
LY%	14.3L	16.3L	16.3L	17.4L
MO%	3.9	2.9	3.2	3.5
GR%	81.8H	80.8H	80.5H	79.1H

PRINT

SEND

DELETE

Total data:

400

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MENU

SEARCH



**INSTALLATION QUALIFICATION,
OPERATIONAL QUALIFICATION
&
PERFORMANCE QUALIFICATION**

Name of Instrument:	Fully Automated 3 Part differential blood Cell counter
Make:	NIHON KOHDEN
Model:	MEK-6510
Serial number	4225



VALIDATION REPORT

INSTRUMENT NAME	:	FULLY AUTOMATED 3 PART DIFFERENTIAL BLOOD CELL COUNTER
INSTRUMENT MAKE	:	NIHON KOHDEN
INSTRUMENT MODEL No.	:	MEK-6510
INSTRUMENT SERIAL No.	:	4225
SUPPLIER	:	NIHON KOHDEN INDIA PVT LTD
CONTACT NAME & ADDRESS	:	ALAKNANDA DIAGNOSTICS LAB, NEW DELHI



APPROVAL OF THE IQ/OQ/PQ PROCEDURE

Both **ALAKNANDA DIAGNOSTICS LAB, NEW DELHI** and Nihon Kohden jointly responsible for the installation of fully automated **3** part blood cell counter **MEK-6510(SERIAL NUMBER-4225)** in the pathology laboratory.

VALIDATION TEAM FROM (VENDOR):

Name: Ravinder Singh

Designation: ENGINEER (C.S)

Signature: _____

Company: NIHON KOHDEN INDIA PVT. LTD



VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name: _____

Designation: _____

Signature: _____

Date: _____

CUSTOMER AUTHORIZATION:

Name: _____

Designation: Pathologist

Signature: _____

Date: _____

II. INSTRUCTIONS:

1. This document is to be completed at the time the instrument is installed at its current location **ALAKNANDA DIAGNOSTIC LAB, NEW DELHI** and setup for operation.
2. An authorized (Company) representative will check the instrument and enter the specific data related to installation, operational and performance qualification.
3. Employee of Pathology laboratory will verify each result and sign the result. Validation team will carry this out.
4. All validation from the normal specification to include and problems with installation will be noted under COMMENTS.



III. SCOPE:

This installation qualification protocol is performed on the fully automated 3 part blood cell counter **MEK-6510, SERIAL NUMBER-4225** located in pathology laboratory.

This protocol defines the documentation that is used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended usage.

Successful completion of this protocol verifies that this instrument has been installed, operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connection and utilities.

Operational qualification will evaluate the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument.



IV. CERTIFICATE OF PURCHASE ORDER COMPLIANCE:

I certify to the best of my knowledge, the instrument fully automated 3 part blood cell counter **MEK-6510, SERIAL NUMBER-4225** has been installed in pathology is in compliance with the specification of the agreement order.

V. INSTRUMENT DESCRIPTION:

No.	Instrument Identification	Verified by	Date
1.	Instrument name (Fully automated 3 part blood cell counter)	Yes	02-08-2019
2.	Manufacturer: Nihon Kohden Corporation	Yes	02-08-2019
3.	Model: MEK-6510	Yes	02-08-2019
4.	Instrument ID: NA	Yes	02-08-2019
5	Serial No. 4225	Yes	02-08-2019
6.	Size: As per specifications given	Yes	02-08-2019
7.	Power: As per specifications given	Yes	02-08-2019



VI. UTILITIES:

No.	Utility	Verified by	Date
1.	Environmental condition as required. (Free from dust, electrical and magnetic interference) Yes/No Temperature: 15 – 30 °C Humidity: 30 to 85 % non condensing	Yes	02-08-2019
2.	Adequate space for installation: (As per the specification given) Yes/No	yes	02-08-2019
3.	Electrical Outlets: Actual voltage on site (228 VAC) Yes/No	yes	02-08-2019
4.	Grounded Yes/No	yes	02-08-2019
5.	Connected through UPS Yes/No	yes	02-08-2019
6.	Waste Liquid Yes/No	yes	02-08-2019

VII. THE INSTRUMENT HAS BEEN CHECKED FOR THE FOLLOWING:

No.	Verification	Verified by	Date
1.	Instrument is identified Yes/No	yes	02-08-2019
2.	Manufacturer's specification are included Yes/No	yes	02-08-2019
3.	Accessories /consumables are listed Yes/No	yes	02-08-2019
4.	Equipment manual from the manufacturer Yes/No	yes	02-08-2019



ACCESSORIES / CONSUMABLES:

The following accessories were supplied with the instrument

No.	Description	Quantity	Verified by	Date
01	Accessories box	01	yes	02-08-2019

VIII. LIST OF MANUALS AND CERTIFICATES

Supplier provided the following with the instrument

1	Operating Manual	Available-	Yes/No	yes	Date
2	Invoice	Available-	Yes/No	yes	02-08-2019
3	Safety instruction (Equipment manual)	Available-	Yes/No	yes	02-08-2019
4	Training records	Available-	Yes/No	yes	02-08-2019
5	If any other	Available-	Yes/No	No	02-08-2019



IX. MAINTENANCE:

The instrument listed within this document will be placed under the control of **ALAKNANDA DIAGNOSTIC LAB, NEW DELHI** Pathology laboratory institution with respect to proper maintenance procedure as detailed in the operator's manual.

A trained analyst using the manual provided with the instrumentation can perform basic and operation maintenance. Upon expiration of the warranty period vendor will offer

Several levels of maintenance agreement and performance testing service to assist you in maintaining compliance. Contacting your local representative and requesting the additional service agreement can supply additional information.

X. INSTALLATION PROCEDURE:

1. Installation of Hardware and Software

Follow the instruction mentioned in the installation guide.

2. Installation of printer

Follow the instruction mentioned in the installation guide.



OPERATIONAL QUALIFICATION:

Name of Instrument:	Fully Automated 3 Part differential blood Cell counter
Make:	NIHON KOHDEN
Model:	MEK-6510
Serial number	4225

XI. OPERATIONAL QUALIFICATION:

Following features/ functions are available in the instrument as per manufacturer's specification and verified e.g. Start-up, Calibration, quality control, maintenance checks.

Sr. No.	Test Name	Test Procedure	Verified by	Date
1	Start-up	Retest Testing	Yes	02-08-2019
2	Calibration feature	Calibration performance	yes	02-08-2019
3	Quality Control	Control Running	yes	02-08-2019
4	Maintenance	Operation Maintenance	yes	02-08-2019

Printouts of the above features / tests attached-

Yes/ No=yes



CERTIFICATE OF TRAINING:

1. Operator and Maintenance Training

This certifies that the technicians listed below have received basic user training for the system described.

Sr. No.	Training Program	Signature	Date
1.	Instrument Set-up		02-08-2019
2.	System Operation	yes	02-08-2019
3.	Basic Troubleshooting	yes	02-08-2019

Training Given By: Ravinder Singh
Designation: Engineer (C.S)

Training Attended By:

- 1) DR. Rohini Kalhan
- 2) MS. Jaya
- 3) MR. Ramesh



PERFROMANCE QUALIFICATION:

Name of Instrument:	Fully Automated 3 Part differential blood cell counter
Make:	NIHON KOHDEN
Model:	MEK-6510
Serial number	4225

- **PPERFROMANCE QUALIFICATION:**

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.

Print out 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.

Print out attached from instrument = Yes/No=Yes

QC Results : Pass/ Fail=Pass
Precision Check : Pass/ Fail=Pass



VALIDATION TEAM FROM (VENDOR):

Name: Ravinder Singh

Designation: **ENGINEER (C.S)**

Signature: _____

Company: NIHON KOHDEN INDIA PVT. LTD



VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name: _____

Designation: _____

Signature: _____

Date: _____

CUSTOMER AUTHORIZATION:

Name: _____

Designation: _____

Signature: _____

Date: _____