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

Regd. Office : 308, Tower-A, Spazedge, Sector 47, Sohna Road, Gurgaon-122002, Haryana, India
Tel.: +91-124-4931000, Fax : +91-124-4931029, CIN No : U33110HR2011PTC041863
GSTIN No.: 06AADCN5424H1ZM, Email : info@nihonkohden.in

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

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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: _____

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II. INSTRUCTIONS:

1. This document is to be completed at the time the instrument is installed at its current location ALAKNANDA DIAGONTIC 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.

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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.

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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

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VI. UTILITIES:

No.	Utility	Verified by	Date
1.	Environmental condition as required. (Free from dust, electrical and magnetic interference) **Yes/No** Temperature: 15 – 30 ^{O}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

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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

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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.

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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

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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
3MR.Ramesh

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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 (≤ 5 %) shall be considered.

   Print out attached from instrument = Yes/No=Yes

QC Results : **Pass/ Fail=Pass**

Precision Check : **Pass/ Fail=Pass**

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GSTIN No.: 06AADCN5424H1ZM, Email : info@nihonkohden.in

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: _____

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NIHON KOHDEN

NIHON KOHDEN INDIA PRIVATE LIMITED

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 ± 30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.

RAVINDER SINGH (ENGINEER-CS)

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NIHON KOHDEN

NIHON KOHDEN INDIA PRIVATE LIMITED

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

Sample No.	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.

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NIHON KOHDEN

NIHON KOHDEN INDIA PRIVATE LIMITED

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)

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