

*Input data*



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Instrument Name	Automated 3 Part Cell Counter
Make	Nihon Kohden
Model	MEK-1301K
Serial no	1009
Calibration date	16th jun 23
Installation place	Promila Diagnostics Center

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Name : Jaswinder Singh  
Designation : R.M.



## Calibration Data

Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-1301K  
 Serial no : 1009  
 Calibration date : 16th jun 23  
 Installation place : Promila Diagnostics Center

CALIBRATION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	8.60	4.69	13.40	39.9	247.0
2	8.70	4.66	13.30	39.8	253.0
3	8.50	4.53	13.10	38.7	262.0
4	8.40	4.54	13.10	38.9	252.0
5	8.60	4.60	13.10	39.5	248.0
6	9.14	4.61	13.20	39.5	250.0
7	8.50	4.63	13.30	39.8	242.0
8	8.50	4.56	12.90	39.0	250.0
9	8.50	4.51	13.00	38.8	243.0
10	8.80	4.64	13.30	39.8	259.0
Mean	8.56	4.41	13.17	39.4	250.6
CV%	1.37	1.30	1.19	1.20	2.50

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 : Jaswinder Singh

Designation : R.M.



## Precision Check Data

Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-1301K  
 Serial no : 1009  
 Calibration date : 29th July 2022  
 Installation place : Promila Diagnostics Center

PRECISION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	7.4	4.49	12.6	39.4	255
2	7.4	4.52	12.6	39.4	254
3	7.2	4.49	12.9	39.3	242
4	7.4	4.49	12.7	39.3	241
5	7.2	4.49	12.9	39.2	243
6	7	4.42	12.7	39.3	230
7	7.3	4.52	12.9	39.2	242
8	7.3	4.52	12.6	39.2	242
9	7.2	4.49	12.7	39.2	234
10	7.3	4.52	12.6	40	240
<b>Mean</b>	7.27	4.495	12.72	39.35	242.3
<b>SD</b>	0.125166556	0.030276504	0.131656118	0.241522946	7.645623294
<b>CV%</b>	<b>1.71</b>	<b>0.67</b>	<b>1.04</b>	<b>0.6</b>	<b>3.16</b>

<b>Acceptable CV%</b>	Within 2.0%	Within 1.5%	Within 1.5%	Within 1%	Within 4%
<b>Result status</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>

\*Precision study performed on the analyzer using a blood samples.

For Nihon Kohden India Pvt. Ltd.

Name : Jaswinder Singh

Designation : R.M.



## Certification of Calibration

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Instrument Name	: Automated 3 Part Cell Counter
Make	: Nihon Kohden
Model	: MEK-1301K
Serial no	: 1009
Calibration date	: 16-Jun-23
Installation place	: Promila Diagnostics Center

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This is to certify that the above mentioned instrument has been successfully calibrated on **16th June 2023** with MEK-CAL lot no-**PLUS 236** bearing expiry till **5th July 2023**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High) Lot no-225** bearing expiry of **5th Aug 2023**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **16th June 2024**. 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.**



## Installation Qualification

## Operation Qualification

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## Performance Qualification

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1301K
Serial no	:	1009

## Validation Report

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1301K
Serial no	:	1009
Supplier Name	:	Nihon Kohden India Pvt. Ltd
Contact Name & Address	:	Promila Diagnostics Center



## Approval of IQ/OQ/PQ Procedure

Both Promila Diagnostics Center and Nihon Kohden India Pvt. Ltd  
jointly responsible for the installation of Automated 3 Part Cell Counter MEK-1301K (1009) in the pathology

VALIDATION TEAM FROM VENDOR:

Name : Jaswinder Singh

Designation : R.M.

Signature : \_\_\_\_\_

Nihon Kohden India Pvt. Ltd



VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :

Designation :

Signature :

Date :

CUSTOMER AUTHORIZATION:

Name :

Designation :

Signature :

Date :

### II. INSTRUCTIONS

- 1 This document is to be completed at the time the instrument is installed at its current location Promila
- 2 An authorized (Company) representative will check the instrument and enter the specific data related
- 3 Employee of Pathology laboratory will verify each result and sign the result.
- 4 All validation from the normal specification to include and problems with installation will be noted

### III. SCOPE

located in pathology.

This protocol defines the documentation that is used to evaluate the instrument installation in accordance with

Successful completion of this protocol verifies that this instrument has been installed, operated in accordance

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

Performance qualification will verify the actual functioning or performance of instrument manufacturer's specifications.

**IV. CERTIFICATE OF PURCHASE ORDER COMPLIANCE:**

I certify to the best of my knowledge, the instrument Automated 3 Part Cell Counter MEK-1301K (1009) has

**V. INSTRUMENT DESCRIPTION:**

S.no.	Instrument identification	Verified	Date
1	Automated 3 Part Cell Counter	Yes	16-Jun-23
2	Nihon Kohden	Yes	16-Jun-23
3	Model: MEK-1301K	Yes	16-Jun-23
4	Instrument ID	Yes	16-Jun-23
5	Serial no.1009	Yes	16-Jun-23
6	Size : As per specification given	Yes	16-Jun-23
7	Power : As per specification given	Yes	16-Jun-23

**VI. UTILITIES :**

S.no.	Instrument identification	Yes/No	Date
1	Environmental condition as required. (Free from dust, electrical and magnetic interference) Temperature: 15 – 30 OC Humidity: 30 to 85 % non condensing	Yes	16-Jun-23
2	Adequate space for installation: (As per the specification given)	Yes	16-Jun-23
3	Electrical Outlets: Actual voltage on site (228 VAC)	Yes	16-Jun-23
4	Grounded	Yes	16-Jun-23
5	Connected through UPS	Yes	16-Jun-23
6	Waste Liquid	Yes	16-Jun-23


**VII. THE INSTRUMENT HAS BEEN CHECKED FOR THE FOLLOWING :**

S.no.	Instrument identification	Yes/No	Date
1	Instrument is identified	Yes	16-Jun-23



2	Manufacturer's specification are included	Yes	
3	Accessories / Consumables are listed	Yes	16-Jun-23
4	Equipment manual from the manufacturer	Yes	16-Jun-23

**ACCESSORIES / CONSUMABLES:**

The following accessories were supplied with the instrument

S.no.	Description	Qty	Verified by	Date
1	Accessories box	1	Yes	16-Jun-23

**VIII. LIST OF MANUALS AND CERTIFICATES**

Supplier provided the following with the instrument

S.no.	Particulars	Available or not	Date
1	Operating Manual	Yes	16-Jun-23
2	Invoice	Yes	16-Jun-23
3	Safety instruction (equipment manual)	Yes	16-Jun-23
4	Training records	Yes	16-Jun-23
5	if any other	NO	16-Jun-23

**IX. MAINTENANCE:**

The instrument listed within this document will be placed under the control of Promila Diagnostics Center

A trained analyst using the manual provided with the instrumentation can perform basic and operation

Several levels of maintenance agreement and performance testing service to assist you in maintaining

**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.





# Operation Qualification:

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1301K
Serial no	:	1009

## XI. OPERATIONAL QUALIFICATION:

Following features/ functions are available in the instrument as per manufacturer's specification and verified

S.no.	Test Name	Y/N	Test Procedure	Date
1	Start up	Yes	Retest Testing	16-Jun-23
2	Calibration Feature	Yes	Calibration Performance	16-Jun-23
3	Quality Control	Yes	Control Running	16-Jun-23
4	Maintenance	Yes	Operation Maintenance	16-Jun-23

Printouts of the above features / tests attached (Yes/No)

Yes



# CERTIFICATE OF TRAINING: NIHON KOHDEN

NIHON KOHDEN INDIA PRIVATE LIMITED

**1. Operator and Maintenance Training**

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

S.no.	Training Program	Signature	Date
1	Instrument Set-up	Yes	16-Jun-23
2	System Operation	Yes	16-Jun-23
3	Basic troubleshooting	Yes	16-Jun-23

Traning given by : Name : Jaswinder Singh

Designation : R.M.

Training attended by :

lab staff

## Performance Qualification :

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1301K
Serial no	:	1009

Following are the steps required to validate your instrument and method.

- Run QC samples (Low, Normal and Abnormal) and verifies the values with acceptable range given in the insert

**Printouts attached from instrument (Yes/No) Yes**

- Run 10 time patient sample into the system and calculate the %CV. Acceptance limits of %CV ( $\leq 5\%$ ) shall be

**Printouts attached from instrument (Yes/No) Yes**

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

VALIDATION TEAM FROM VENDOR:

Name : Jaswinder Singh

Designation : R.M.

Signature : \_\_\_\_\_  
 Nihon Kohden India Pvt. Ltd



VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :

Designation :

Signature :

Date :

CUSTOMER AUTHORIZATION:

Name :

Designation :

Signature :

Date :