

**Input data**



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Instrument Name	Automated 3 Part Cell Counter
Make	Nihon Kohden
Model	MEK-1305
Serial no	16 -
Calibration date	18-Oct-23
Installation place	Velys diagnostics & pathology center private limited

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Name : ANKIT DAVE  
Designation : CS



## Calibration Data

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Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-1305  
 Serial no : 16  
 Calibration date : 18-Oct-23  
 Velys diagnostics & pathology center private  
 Installation place : limited

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### CALIBRATION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	9.08	4.56	13.67	44.8	240
2	8.96	4.57	13.70	44.9	243
3	8.91	4.55	13.67	44.7	242
4	8.79	4.60	13.64	45.2	233
5	9.09	4.46	13.67	43.9	232
6	8.99	4.56	13.69	44.8	253
7	8.98	4.58	13.69	44.9	233
8	8.82	4.49	13.65	44.1	236
9	8.95	4.47	13.65	43.9	240
10	8.95	4.54	13.67	44.6	238
<b>Mean</b>	8.95	4.54	13.67	44.58	239.00
SD	0.10	0.05	0.02	0.45	6
CV%	1.07	1.1	0.14	1.0	2.7

Acceptable CV%	Within 2.0%	Within 1.5%	Within 1.5%	Within 1.5%	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 : ANKIT DAVE

Designation : CS




## Precision Check Data

Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-1305  
 Serial no : 16  
 Calibration date : 18-Oct-23  
 Installation place : Velys diagnostics & pathology center private limited

### PRECISION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	6.19	5.85	15.81	48.6	237
2	6.50	5.85	15.98	48.4	230
3	6.30	5.85	15.91	48.4	237
4	6.41	5.80	15.99	48.0	222
5	6.50	5.80	15.93	48.0	231
6	6.29	5.85	15.93	48.5	226
7	6.42	5.81	15.93	48.1	221
8	6.30	5.81	15.96	48.0	239
9	6.44	5.89	15.98	48.7	235
10	6.23	5.82	15.98	48.1	230
<b>Mean</b>	6.36	5.83	15.94	48.28	230.77
<b>SD</b>	0.11	0.0	0.05	0.3	6
<b>CV%</b>	<b>1.74</b>	<b>0.5</b>	<b>0.34</b>	<b>0.6</b>	<b>3</b>

Acceptable CV%	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 : ANKIT DAVE  
Designation : CS




## Certification of Calibration

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Instrument Name	: Automated 3 Part Cell Counter
Make	: Nihon Kohden
Model	: MEK-1305
Serial no	: 16
Calibration date	: 18-Oct-23
Installation place	: Velys diagnostics & pathology center private limited

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This is to certify that the above mentioned instrument has been successfully calibrated on **17th Oct 2023** with MEK-CAL lot no-**PLUS-23X** bearing expiry till **05th Nov 2023**. During the calibration of the analyser, all CBC parameters were calibrated.

Run Quality Controls **MEK-3D (Low, Normal, and High) Lot no-B238** bearing expiry of **05th Nov 2023**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **17th Oct 2024**. Validity  $\pm$  30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt.  
Ltd.

**Name : ANKIT DAVE**

**Designation : CS**





## Approval of IQ/OQ/PQ Procedure

Both Velys diagnostics & pathology center private limited and Nihon Kohden India Private Limited jointly responsible for the installation of Automated 3 Part Cell Counter MEK-1305 (17) in the pathology laboratory

VALIDATION TEAM FROM VENDOR:

Name : ANKIT DAVE

Designation : CS

Signature : 

Nihon Kohden India Private Limited



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 Velys diagnostics & pathology center private limited and set up 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 Automated 3 Part Cell Counter MEK-1305 (16) located in pathology.

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 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-1305 (16) has been installed in pathology is in compliance with the specification of the agreement order

**V. INSTRUMENT DESCRIPTION:**

S.no.	Instrument identification	Verified	Date
1	Automated 3 Part Cell Counter	Yes	25-May-21
2	Nihon Kohden	Yes	25-May-21
3	Model:MEK-1305	Yes	25-May-21
4	Instrument ID	Yes	25-May-21
5	Serial no.16	Yes	25-May-21
6	Size : As per speciifcation given	Yes	25-May-21
7	Power : As per speciifcation given	Yes	25-May-21

**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	25-May-21
2	Adequate space for installation: (As per the specification given)	Yes	25-May-21
3	Electrical Outlets: Actual voltage on site (228 VAC)	Yes	25-May-21
4	Grounded	Yes	25-May-21
5	Connected through UPS	Yes	25-May-21
6	Waste Liquid	Yes	25-May-21

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

S.no.	Instrument identification	Yes/No	Date
1	Instrument is identified	Yes	25-May-21
2	Manufacturer's specification are included	Yes	25-May-21
3	Accessories / Consumables are listed	Yes	25-May-21
4	Equipment manual from the manufacturer	Yes	25-May-21

**ACCESSORIES / CONSUMABLES:**

The following accessories were supplied with the instrument

S.no.	Description	Qty	Verified by	Date
1	Accessories box	1	Yes	25-May-21

**VIII. LIST OF MANUALS AND CERTIFICATES**

Supplier provided the following with the instrument

S.no.	Particulars	Available or not	Date
1	Operating Manual	Yes	25-May-21
2	Invoice	Yes	25-May-21
3	Safety instruction (equipment manual)	Yes	25-May-21
4	Training records	Yes	25-May-21
5	if any other	NO	25-May-21

**IX. MAINTENANCE:**

The instrument listed within this document will be placed under the control of Velys diagnostics & pathology center private limited 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.

## Operation Qualification:

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1305
Serial no	:	16

**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.

S.no.	Test Name	Y/N	Test Procedure	Date
1	Start up	Yes	Retest Testing	25-May-21
2	Calibration Feature	Yes	Calibration Performance	25-May-21
3	Quality Control	Yes	Control Running	25-May-21
4	Maintenance	Yes	Operation Maintenance	25-May-21

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.

S.no.	Training Program	Signature	Date
1	Instrument Set-up	Yes	25-May-21
2	System Operation	Yes	25-May-21
3	Basic troubleshooting	Yes	25-May-21

Traning given by : Name : ANKIT DAVE

Designation : CS.



Training attended by :

## Performance Qualification :

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-1305
Serial no	:	16

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 : ANKIT DAVE**  
**Designation : CS**

**Signature :**   
**Nihon Kohden India Private Limited**

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :  
 Designation :  
 Signature :  
 Date :

CUSTOMER AUTHORIZATION:

Name :