
Instrument Name : Automated 3 Part Cell Counter
Make : Nihon Kohden
Model : Mek-6420P
Serial no : 52655
Calibration date : 23rd Aug 21
Installation place : Lotus diagnostic centre

This is to certify that the above mentioned instrument has been successfully calibrated on **23rd Aug 2021** with MEK-CAL lot no-**PLUS 218** bearing expiry till **5th Sept , 2021**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High) Lot no-215** bearing expiry of **5th Nov 2021**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **22nd Aug 2022**. Validity \pm 30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.
Name : Ritesh Pagdhare
Designation : Sr. Engineer CS





Instrument Name : Automated 3 Part Cell Counter
 Make : Nihon Kohden
 Model : Mek-6420P
 Serial no : 52655
 Calibration date : 23rd Aug 21
 Installation place : Lotus diagnostic centre

PRECISION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	7.6	5.44	14.60	43.3	294
2	7.8	5.57	14.80	44.4	296
3	7.8	5.50	14.80	43.7	276
4	7.7	5.58	14.90	44.3	291
5	7.9	5.56	15.00	44.3	278
6	7.6	5.55	14.90	44.4	277
7	8.0	5.52	14.90	43.9	279
8	7.9	5.58	14.90	44.5	283
9	7.8	5.54	14.90	44.2	283
10	8.0	5.56	15.10	44.1	278
Mean	7.8	4.73	14.88	44.1	284
SD	0.1	0.0	0.13	0.4	7
CV%	1.9	0.9	0.88	0.9	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 blood samples.

For Nihon Kohden India Pvt. Ltd.
 Name : Ritesh Pagdhare
 Designation : Sr. Engineer CS



Instrument Name : Automated 3 Part Cell Counter
 Make : Nihon Kohden
 Model : Mek-6420P
 Serial no : 52655
 Calibration date : 23rd Aug 21
 Installation place : Lotus diagnostic centre

CALIBRATION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	8.8	4.54	14.00	40.8	245
2	8.6	4.61	14.10	41.4	241
3	8.6	4.65	14.10	41.9	255
4	8.5	4.67	14.30	42	239
5	8.7	4.59	14.10	41.1	244
6	8.7	4.68	14.10	42.1	249
7	8.6	4.68	14.20	42.1	240
8	8.6	4.63	14.10	41.7	249
9	8.6	4.65	14.10	41.8	227
10	8.6	4.70	14.20	42.3	242
Mean	8.6	4.64	14.13	41.70	243
CV%	0.8	1.10	0.6	1.2	3.1

Acceptable CV%	Within 2.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4%
Result status	PASS	PASS	FAIL	PASS	PASS

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

For Nihon Kohden India Pvt. Ltd.
 Name : Ritesh Pagdhare
 Designation : Sr. Engineer CS



Open	08/23	08/23
DATE	08/23	08/23
TIME	08:11:04	08:11:04
WBC	1052	1052
RBC	1089	1082
HGB	993	993
HCT	1131	1131
PLT	1223	1223
LY%	923	923
MO%	1007	1007
RDW	1165	1165
MPV	1242	1242

LAB HISTORY

en

Parameter	08/23 Celltac	08/23 Celltac
WBC	1052	1052
RBC	1089	1082
HGB	993	993
HCT	1131	1131
PLT	1223	1223
LY%	923	923
MO%	1007	1007
RDW	1165	1165
MPV	1242	1242

Total data: 11
 Page: 4 / 4

River
 Performed by.

Jarvis
 APPROVED BY

ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.6 $10^3/uL$
 RBC 5.44H $10^9/uL$
 HGB 14.6 g/dL
 HCT 43.3 %
 MCV 79.6L fL
 MCH 26.8L pg
 MCHC 33.7 g/dL
 PLT 294 $10^3/uL$
 LY 2.0 [26.6 %]
 MO 0.3 [3.8 %]
 GR 5.3 [69.6 %]
 RDW 13.9 %
 PCT 0.24 %
 MPV 8.1 fL
 PDW 16.8 %

21/08/23 13:59
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.8 $10^3/uL$
 RBC 5.57H $10^9/uL$
 HGB 14.8 g/dL
 HCT 44.4 %
 MCV 79.7L fL
 MCH 26.6L pg
 MCHC 33.3 g/dL
 PLT 296 $10^3/uL$
 LY 1.8 [22.7 %]
 MO 0.3 [4.2 %]
 GR 5.7 [73.1 %]
 RDW 13.7 %
 PCT 0.24 %
 MPV 8.0 fL
 PDW 16.9 %

21/08/23 14:06
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 8.0 $10^3/uL$
 RBC 5.52H $10^9/uL$
 HGB 14.9 g/dL
 HCT 43.9 %
 MCV 79.5L fL
 MCH 27.0 pg
 MCHC 33.9 g/dL
 PLT 279 $10^3/uL$
 LY 2.0 [25.2 %]
 MO 0.4 [4.8 %]
 GR 5.6 [70.0 %]
 RDW 13.8 %
 PCT 0.24 %
 MPV 8.5 fL
 PDW 16.9 %

ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.8 $10^3/uL$
 RBC 5.54H $10^9/uL$
 HGB 14.9 g/dL
 HCT 44.2 %
 MCV 79.8L fL
 MCH 26.9L pg
 MCHC 33.7 g/dL
 PLT 283 $10^3/uL$
 LY 2.1 [27.2 %]
 MO 0.4 [4.5 %]
 GR 5.3 [68.3 %]
 RDW 13.7 %
 PCT 0.24 %
 PV 8.5 fL
 DW 16.9 %

21/08/23 14:02
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.7 $10^3/uL$
 RBC 5.58H $10^9/uL$
 HGB 14.9 g/dL
 HCT 44.3 %
 MCV 79.4L fL
 MCH 26.7L pg
 MCHC 33.6 g/dL
 PLT 291 $10^3/uL$
 LY 1.8 [22.9 %]
 MO 0.4 [4.9 %]
 GR 5.5 [72.2 %]
 RDW 13.7 %
 PCT 0.24 %
 MPV 8.3 fL
 PDW 16.3 %

PRECISION RUN DATA

Siten

Performed by.

Jambin

APPROVED BY

ID 285
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 8.0 10³/uL
 RBC 5.56H 10⁶/uL
 HGB 15.1 g/dL
 HCT 44.1 %
 MCV 79.3L fL
 MCH 27.2 pg
 MCHC 34.2 g/dL
 PLT 278 10³/uL
 LY 2.0 [24.8 %]
 MO 0.3 [4.3 %]
 GR 5.7 [70.9 %]
 RDW 13.7 %
 PCT 0.23 %
 MPV 8.4 fL
 PDW 16.9 %

21/08/23 14:00
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.9 10³/uL
 RBC 5.58H 10⁶/uL
 HGB 14.9 g/dL
 HCT 44.5 %
 MCV 79.7L fL
 MCH 26.7L pg
 MCHC 33.5 g/dL
 PLT 283 10³/uL
 LY 2.0 [24.6 %]
 MO 0.4 [4.6 %]
 GR 5.5 [70.8 %]
 RDW 13.5 %
 PCT 0.24 %
 MPV 8.4 fL
 PDW 16.9 %

21/08/23 14:00
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.8 10³/uL
 RBC 5.50H 10⁶/uL
 HGB 14.8 g/dL
 HCT 43.7 %
 MCV 79.5L fL
 MCH 26.9L pg
 MCHC 33.9 g/dL
 PLT 276 10³/uL
 LY 1.9 [23.8 %]
 MO 0.4 [5.0 %]
 GR 5.5 [71.2 %]
 RDW 13.8 %
 PCT 0.23 %
 MPV 8.5 fL
 PDW 17.6 %

21/08/23 14:03
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.9 10³/uL
 RBC 5.58H 10⁶/uL
 HGB 15.0 g/dL
 HCT 44.3 %
 MCV 79.7L fL
 MCH 27.0 pg
 MCHC 33.9 g/dL
 PLT 278 10³/uL
 LY 2.2 [28.1 %]
 MO 0.4 [4.7 %]
 GR 5.3 [67.2 %]
 RDW 13.7 %
 PCT 0.23 %
 MPV 8.4 fL
 PDW 16.9 %

21/08/23 14:05
 ID 2851
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 7.6 10³/uL
 RBC 5.55H 10⁶/uL
 HGB 14.9 g/dL
 HCT 44.4 %
 MCV 80.0 fL
 MCH 28.8L pg
 MCHC 33.6 g/dL
 PLT 277 10³/uL
 LY 1.9 [24.5 %]
 MO 0.4 [4.9 %]
 GR 5.3 [70.6 %]
 RDW 13.3 %
 PCT 0.23 %
 MPV 8.4 fL
 PDW 16.4 %

PRECISION RUN DATA

Ritesh

Performed by.

Saurin

APPROVED BY

Calibration

21/08/23 12:36
CALIBRATION - OPEN

WBC	8.5	10 ³ /uL
RBC	4.54	10 ⁶ /uL
HGB	14.0	g/dL
HCT	40.8	%
MCV	89.9	fL
MCH	30.8	pg
MCHC	34.3	g/dL
PLT	245	10 ³ /uL
LY	0.3	[2.9 %]
MO	0.0	[0.1 %]
GR	8.2	[97.0 %]
RDW	15.8	%
PCT	0.21	%
MPV	8.4	fL
PDW	18.1	%

21/08/23 12:38
CALIBRATION - OPEN

WBC	8.6	10 ³ /uL
RBC	4.61	10 ⁶ /uL
HGB	14.1	g/dL
HCT	41.4	%
MCV	89.8	fL
MCH	30.6	pg
MCHC	34.1	g/dL
PLT	241	10 ³ /uL
LY	0.1	[1.6 %]
MO	0.0	[0.0 %]
GR	8.5	[98.4 %]
RDW	16.0	%
PCT	0.20	%
MPV	8.3	fL
PDW	18.1	%

21/08/23 12:39
CALIBRATION - OPEN

WBC	8.6	10 ³ /uL
RBC	4.65	10 ⁶ /uL
HGB	14.1	g/dL
HCT	41.9	%
MCV	90.1	fL
MCH	30.3	pg
MCHC	33.7	g/dL
PLT	255	10 ³ /uL
LY	0.1	[1.4 %]
MO	0.0	[0.0 %]
GR	8.5	[98.6 %]
RDW	16.1	%
PCT	0.20	%
MPV	8.0	fL
PDW	17.4	%

21/08/23 12:41
CALIBRATION - OPEN

WBC	8.5	10 ³ /uL
RBC	4.87	10 ⁶ /uL
HGB	14.3	g/dL
HCT	42.0	%
MCV	89.9	fL
MCH	30.6	pg
MCHC	34.0	g/dL
PLT	239	10 ³ /uL
LY	0.1	[1.6 %]
MO	0.0	[0.0 %]
GR	8.4	[98.4 %]
RDW	16.1	%
PCT	0.20	%
MPV	8.4	fL
PDW	18.1	%

21/08/23 12:43
CALIBRATION - OPEN

WBC	8.7	10 ³ /uL
RBC	4.59	10 ⁶ /uL
HGB	14.1	g/dL
HCT	41.1	%
MCV	89.5	fL
MCH	30.7	pg
MCHC	34.3	g/dL
PLT	244	10 ³ /uL
LY	0.3	[3.0 %]
MO	0.0	[0.0 %]
GR	8.4	[97.0 %]
RDW	15.8	%
PCT	0.20	%
MPV	8.3	fL
PDW	18.1	%

CALIBRATION RUN DATA

Rishi
Performed by.

Tanvir
APPROVED BY

1/08/23 12:45
 CALIBRATION - OPEN
 WBC 8.7 10³/uL
 RBC 4.66 10⁶/uL
 HGB 14.2 g/dL
 HCT 42.1 %
 MCV 90.0 fL
 MCH 30.3 pg
 MCHC 33.7 g/dL
 PLT 249 10³/uL
 LY 0.2 [2.0 %]
 MO 0.0 [0.0 %]
 GR 8.5 [98.0 %]
 RDW 16.0 %
 PCT 0.20 %
 MPV 8.1 fL
 PDW 17.4 %

21/08/23 12:46
 CALIBRATION - OPEN
 WBC 8.6 10³/uL
 RBC 4.68 10⁶/uL
 HGB 14.2 g/dL
 HCT 42.1 %
 MCV 90.0 fL
 MCH 30.3 pg
 MCHC 33.7 g/dL
 PLT 240 10³/uL
 LY 0.2 [1.9 %]
 MO 0.0 [0.0 %]
 GR 8.4 [98.1 %]
 RDW 16.1 %
 PCT 0.20 %
 MPV 8.2 fL
 PDW 18.1 %

21/08/23 12:51
 CALIBRATION - OPEN
 WBC 8.6 10³/uL
 RBC 4.63 10⁶/uL
 HGB 14.1 g/dL
 HCT 41.7 %
 MCV 90.1 fL
 MCH 30.5 pg
 MCHC 33.8 g/dL
 PLT 249 10³/uL
 LY 0.2 [1.9 %]
 MO 0.0 [0.0 %]
 GR 8.4 [98.1 %]
 RDW 16.3 %
 PCT 0.21 %
 MPV 8.6 fL
 PDW 17.6 %

21/08/23 12:52
 CALIBRATION - OPEN
 WBC 8.6 10³/uL
 RBC 4.65 10⁶/uL
 HGB 14.1 g/dL
 HCT 41.8 %
 MCV 89.9 fL
 MCH 30.3 pg
 MCHC 33.7 g/dL
 PLT 227 10³/uL
 LY 0.2 [2.4 %]
 MO 0.0 [0.0 %]
 GR 8.4 [97.6 %]
 RDW 15.9 %
 PCT 0.19 %
 MPV 8.4 fL
 PDW 18.1 %

21/08/23 12:53
 CALIBRATION - OPEN
 WBC 8.6 10³/uL
 RBC 4.70 10⁶/uL
 HGB 14.2 g/dL
 HCT 42.3 %
 MCV 90.0 fL
 MCH 30.2 pg
 MCHC 33.6 g/dL
 PLT 242 10³/uL
 LY 0.2 [2.4 %]
 MO 0.0 [0.0 %]
 GR 8.4 [97.6 %]
 RDW 16.0 %
 PCT 0.20 %
 MPV 8.3 fL
 PDW 18.1 %

CALIBRATION RUN DATA

Reds
 Performed by.

Tanvir
 APPROVED BY

21/08/23 12:33

Blank

ID 0000
 MODE (OPEN)
 SAMPLE TYPE : Normal
 WBC 0.1L 10³/uL
 RBC 0.00L 10⁹/uL
 HGB 0.0L g/dL
 HCT 0.0L %
 MCV fL
 MCH pG
 MCHC g/dL
 PLT 2L 10³/uL

 LY [%]
 MO [%]
 GR [%]

 RDW %
 PCT %
 MPV fL
 PDW %

21/08/23 13:20

L&J(NORMAL)

WBC 7.8 10³/uL
 RBC 4.84 10⁹/uL
 HGB 13.9 g/dL
 HCT 39.3 %
 MCV 84.7 fL
 MCH 30.0 pG
 MCHC 35.4 g/dL
 PLT 262 10³/uL

 LY 2.5 [31.9 %]
 MO 0.2 [3.0 %]
 GR 5.1 [65.1 %]

 RDW 16.0 %
 PCT 0.22 %
 MPV 8.3 fL
 PDW 16.9 %

21/08/23 13:27

L&J(LOW)

WBC 2.2 10³/uL
 RBC 2.39 10⁹/uL
 HGB 6.0 g/dL
 HCT 17.8 %
 MCV 74.5 fL
 MCH 25.1 pG
 MCHC 33.7 g/dL
 PLT 88 10³/uL

 LY 1.3 [57.5 %]
 MO 0.2 [8.1 %]
 GR 0.7 [34.4 %]

 RDW 17.4 %
 PCT 0.06 %
 MPV 8.9 fL
 PDW 17.0 %

21/08/23 13:38

L&J(HIGH)

WBC 20.3 10³/uL
 RBC 5.86 10⁹/uL
 HGB 19.4 g/dL
 HCT 54.7 %
 MCV 93.3 fL
 MCH 33.1 pG
 MCHC 35.5 g/dL
 PLT 518 10³/uL

 LY 3.4 [16.5 %]
 MO 0.2 [1.0 %]
 GR 16.7 [82.5 %]

 RDW 14.9 %
 PCT 0.42 %
 MPV 8.1 fL
 PDW 17.4 %

BACKGROUND CHECK

QC RUN DATA

Peter
 Performed by.

Tanvir
 APPROVED BY

Installation Qualification

Operation Qualification

&

Performance Qualification

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-6420P
Serial no	:	52655



Validation Report

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-6420P
Serial no	:	52655
Supplier Name	:	Nihon Kohden India Private Limited
Contact Name & Address	:	Lotus Diagnostic -Mumbai



Approval of IQ/OQ/PQ Procedure

Both Lotus Diagnostic -Mumbai and Nihon Kohden India Private Limited jointly responsible for the installation of Automated 3 Part Cell Counter MEK-6420P (S2655) in the pathology laboratory

VALIDATION TEAM FROM VENDOR:

Name : Ritesh Pagdhare
Designation : Sr. Engineer CS
Signature : Ritesh
Nihon Kohden India Private Limited

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name : Dr. Jankhi Ahuja
Designation : Laboratory Director
Signature : Jankhi
Date : 23-8-2021

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 Lotus Diagnostic -Mumbai 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-6420P (52655) located in pathology.

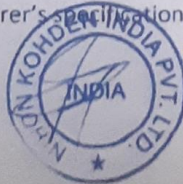
This protocol defines the documentation that is used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended usage.

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-6420P (52655) 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	23-8-2021
2	Nihon Kohden	Yes	23-8-2021
3	Model:MEK-6420P	Yes	23-8-2021
4	Instrument ID	Yes	23-8-2021
5	Serial no.52655	Yes	23-8-2021
6	Size : As per specification given	Yes	23-8-2021
7	Power : As per specification given	Yes	23-8-2021

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	23-8-2021
2	Adequate space for installation: (As per the specification given)	Yes	23-8-2021
3	Electrical Outlets: Actual voltage on site (228 VAC)	Yes	23-8-2021
4	Grounded	Yes	23-8-2021
5	Connected through UPS	Yes	23-8-2021
6	Waste Liquid	Yes	23-8-2021



VII. THE INSTRUMENT HAS BEEN CHECKED FOR THE FOLLOWING :

S.no.	Instrument Identification	Yes/No	Date
1	Instrument is identified	Yes	23-Aug-21
2	Manufacturer's specification are included	Yes	23-Aug-21
3	Accessories / Consumables are listed	Yes	23-Aug-21
4	Equipment manual from the manufacturer	Yes	23-Aug-21

ACCESSORIES / CONSUMABLES:

The following accessories were supplied with the instrument

S.no.	Description	Qty	Verified by	Date
1	Accessories box	1	Yes	23-Aug-21
				23-Aug-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	23-Aug-21
2	Invoice	Yes	23-Aug-21
3	Safety instruction (equipment manual)	Yes	23-Aug-21
4	Training records	Yes	23-Aug-21
5	if any other	NO	23-Aug-21

IX. MAINTENANCE:

The instrument listed within this document will be placed under the control of Lotus Diagnostic -Mumbai 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-6420P
Serial no	:	52655

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	23-Aug-21
2	Calibration Feature	Yes	Calibration Performance	23-Aug-21
3	Quality Control	Yes	Control Running	23-Aug-21
4	Maintenance	Yes	Operation Maintenance	23-Aug-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	23-Aug-21
2	System Operation	Yes	23-Aug-21
3	Basic troubleshooting	Yes	23-Aug-21

Traning given by : Name : Ritesh Pagdhare
Designation : Sr. Engineer CS

Training attended by :

1. Dr Janhvi Ahuja
2. Mrs Arti Gurav
3. Mr Yogesh Ade
4. Mrs Hetal Gandhi
5. Mrs Pooja Jadhav.



Performance Qualification :

Instrument Name	:	Automated 3 Part Cell Counter
Make	:	Nihon Kohden
Model	:	MEK-6420P
Serial no	:	52655

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) Yes

- 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) Yes

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

VALIDATION TEAM FROM VENDOR:

Name : Ritesh Pagdhare
Designation : Sr. Engineer CS

Signature : Ritesh
Nihon Kohden India Private Limited

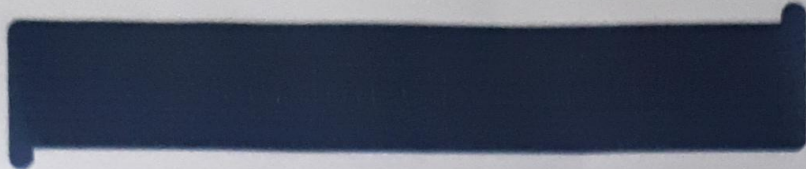
VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name : Dr. Jankvi Ahuja
Designation : Laboratory Director
Signature : Jankvi
Date : 23/8/2021

CUSTOMER AUTHORIZATION:

Name :
Designation :
Signature :
Date :





Instrument Name : Automated 3 Part Cell Counter
 Make : Nihon Kohden
 Model : Mek-6420P
 Serial no : 52655
 Calibration date : 23rd Aug 21
 Installation place : Lotus diagnostic centre

PRECISION RUN DATA

Sample No.	WBC	RBC	HGB	HCT	PLT
1	7.6	5.44	14.60	43.3	294
2	7.8	5.57	14.80	44.4	296
3	7.8	5.50	14.80	43.7	276
4	7.7	5.58	14.90	44.3	291
5	7.9	5.56	15.00	44.3	278
6	7.6	5.55	14.90	44.4	277
7	8.0	5.52	14.90	43.9	279
8	7.9	5.58	14.90	44.5	283
9	7.8	5.54	14.90	44.2	283
10	8.0	5.56	15.10	44.1	278
Mean	7.8	4.73	14.88	44.1	284
SD	0.1	0.0	0.13	0.4	7
CV%	1.9	0.9	0.88	0.9	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 blood samples.

For Nihon Kohden India Pvt. Ltd.
 Name : Ritesh Pagdhare
 Designation : Sr. Engineer CS



Instrument Name : Automated 3 Part Cell Counter
 Make : Nihon Kohden
 Model : Mek-6420P
 Serial no : 52655
 Calibration date : 23rd Aug 21
 Installation place : Lotus diagnostic centre

CALIBRATION RUN DATA					
Sample No.	WBC	RBC	HGB	HCT	PLT
1	8.8	4.54	14.00	40.8	245
2	8.6	4.61	14.10	41.4	241
3	8.6	4.65	14.10	41.9	255
4	8.5	4.67	14.30	42	239
5	8.7	4.59	14.10	41.1	244
6	8.7	4.68	14.10	42.1	249
7	8.6	4.68	14.20	42.1	240
8	8.6	4.63	14.10	41.7	249
9	8.6	4.65	14.10	41.8	227
10	8.6	4.70	14.20	42.3	242
Mean	8.6	4.64	14.13	41.70	243
CV%	0.8	1.10	0.6	1.2	3.1

Acceptable CV%	Within 2.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4%
Result status	PASS	PASS	FAIL	PASS	PASS

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

For Nihon Kohden India Pvt. Ltd.
 Name : Ritesh Pagdhare
 Designation : Sr. Engineer CS

