

Input data



| | |
|--------------------|------------------------------|
| Instrument Name | Automated 3Part Cell Counter |
| Make | Nihon Kohden |
| Model | MEK-6510K |
| Serial no | 5515 |
| Calibration date | 23-May-24 |
| Installation place | PAYAS PATHOLOGY LABORATORY |



Rajesh Kasar



Name : RAJESH KASAR
Designation : Territory Manager-CS

Calibration Data

Instrument Name : Automated 3Part Cell Counter
 Make : Nihon Kohden
 MEK-
 Model : 6510K
 Serial no : 5515
 Calibration date : 23-MAY-24
 Installation place : PAYAS PATHOLOGY LABORATORY

| CALIBRATION RUN DATA | | | | | |
|----------------------|-----|------|------|------|------|
| Sample No. | WBC | RBC | HGB | HCT | PLT |
| 1 | 9.0 | 4.67 | 14.1 | 40.4 | 238 |
| 2 | 9.1 | 4.70 | 14.2 | 40.5 | 234 |
| 3 | 8.9 | 4.63 | 14.1 | 40.1 | 238 |
| 4 | 9.0 | 4.59 | 14.1 | 39.7 | 244 |
| 5 | 9.0 | 4.60 | 14.1 | 39.9 | 249 |
| 6 | 9.2 | 4.61 | 14.1 | 40.1 | 255 |
| 7 | 9.2 | 4.68 | 14.1 | 40.2 | 245 |
| 8 | 9.2 | 4.61 | 14.2 | 39.9 | 246 |
| 9 | 9.3 | 4.65 | 14.2 | 40.1 | 244 |
| 10 | 9.2 | 4.67 | 14.2 | 40.4 | 233 |
| Mean | 9.1 | 4.64 | 14.1 | 40.1 | 243 |
| SD | 0.1 | 0.03 | 0.0 | 0.2 | 2 |
| CV% | 0.9 | 0.62 | 0.33 | 0.42 | 0.78 |

| | | | | | |
|-----------------------|----------------|----------------|----------------|----------------|--------------|
| 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 : RAJESH KASAR

Designation : Territory Manager- CS



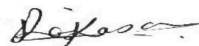
Precision Check Data

| | | |
|--------------------|---|------------------------------|
| Instrument Name | : | Automated 3Part Cell Counter |
| Make | : | Nihon Kohden |
| Model | : | MEK-6510K |
| Serial no | : | 5515 |
| Calibration date | : | 23-May-24 |
| Installation place | : | PAYAS PATHOLOGY LABORATORY |

| PRECISION RUN DATA | | | | | |
|--------------------|-------------|-------------|-------------|-------------|-------------|
| Sample No. | WBC | RBC | HGB | HCT | PLT |
| 1 | 5.80 | 5.19 | 12.60 | 37.70 | 327 |
| 2 | 5.80 | 5.01 | 12.50 | 36.40 | 307 |
| 3 | 5.70 | 5.10 | 12.70 | 36.90 | 302 |
| 4 | 5.80 | 5.10 | 12.60 | 37.00 | 299 |
| 5 | 5.70 | 5.15 | 12.50 | 37.20 | 294 |
| 6 | 5.70 | 5.18 | 12.60 | 37.50 | 304 |
| 7 | 5.70 | 5.12 | 12.60 | 37.00 | 286 |
| 8 | 5.60 | 5.17 | 12.70 | 37.40 | 305 |
| 9 | 5.70 | 5.14 | 12.70 | 37.30 | 305 |
| 10 | 5.70 | 5.14 | 12.60 | 37.20 | 307 |
| Mean | 8.69 | 3.94 | 12.61 | 37.16 | 304 |
| SD | 0.06 | 0.05 | 0.07 | 0.34 | 10 |
| CV% | 0.69 | 1.26 | 0.56 | 0.93 | 3.29 |

| | | | | | |
|-----------------------|-------------|-------------|-------------|-------------|-------------|
| 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 : RAJESH KASAR

Designation : Territory Manager-CS



Certification of Calibration

| | |
|--------------------|--------------------------------|
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| Make | : Nihon Kohden |
| Model | : MEK-6510K |
| Serial no | : 5515 |
| Calibration date | : 23-May-24 |
| Installation place | : PAYAS PATHOLOGY LABORATORY |

This is to certify that the above mentioned instrument has been successfully calibrated on **23May2024** with MEK-CAL lot no-**PLUS 245** bearing expiry till **5thJune2024**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High) Lot no-245** bearing expiry of **5Aug2024**, Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **22May2025**. Validity \pm 30days. Or depends on QC performance/subject to replacement or change in hardware.



For Nihon Kohden India Pvt. Ltd.
Name : RAJESH KASAR
Designation : Territory Manager- CS



Performance Qualification :

| | | |
|------------------------|---|------------------------------|
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| Model | : | MEK-6510K |
| Serial no | : | 5515 |

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 : RAJESH KASAR

Designation : Territory Manager-CS




SIGNATURE

NIHON KOHDEN INDIA PVT LTD

VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :

Designation :

Signature :

Date :

CUSTOMER AUTHORIZATION:

Name :

Designation :

Signature :

Date :