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Biomedical LLP

Date:05/12/2020

EffectiveDate:05/12/2020

## Certificate of Calibration

**CustomerName: Dhiraj General Hospital**

**Model: Automated Hematology Analyzer Sysmex Kx-21**

**SerialNo.: B7507**

**Calibration Done Date: 05/12/2020**

**Next Calibration Due Date On or Before: 05/12/2021**

**Lab In-charge: Dr. Jasmin Jasani**

*This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, HCT and PLT) according to the standard procedures provided by Sysmex Corporation, Japan.*

*The reference instruments used for value-assignment are managed by the traceability system in Sysmex Corporation and these are traceable to the International Standards, such as ICSH.*

Calibration at site performed by  
BRIJESH PATEL  
SR. SERVICE ENGINEER  
Pathohub Biomedical LLP  
Ahmedabad



Encl:

1. Certificate of Inspection
2. Assay Sheet of Calibrator NEK-CAL
3. Printouts



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## Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex kx21

2. Serial No.: B-7507

3. Calibration Date: 05/12/2020

4. Material used: NEK-CAL (Lot No. NK1220, Expiry date: 05-01-2021)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC5 parameters using the measurement standard material (NEK-CAL) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.



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## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.1	$0.3 \times 10^3/\mu\text{L}$
RBC	0.00	$0.02 \times 10^6/\mu\text{L}$
HGB	0.0	0.1 g/dL
PLT	0	$10 \times 10^3/\mu\text{L}$



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6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE  
(ORIGINALS ATTACHED)

SMPNO	WBC	RBC	HGB	HCT	PLT
2	7.8	4.74	14.7	43.5	252
3	7.6	4.76	14.7	43.8	256
4	7.8	4.72	14.8	43.4	243
5	7.7	4.73	14.8	43.6	250
6	7.9	4.74	14.7	43.5	253
7	7.6	4.75	14.7	43.8	256
8	7.8	4.74	14.7	43.7	260
9	7.8	4.71	14.7	43.4	247
10	7.8	4.71	14.7	43.4	256
11	7.7	4.73	14.7	43.4	265
Mean	7.75	4.73	14.72	43.55	253.80
SD	0.097	0.018	0.042	0.165	6.321
CV%	1.254	0.373	0.286	0.379	2.491
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS



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### 7. CALIBRATION DATA

SMPNO/TIME	WBC	RBC	HGB	HCT	PLT
12202	8.8	4.60	13.9	37.7	269
12203	8.8	4.59	14.0	37.8	270
12204	9.0	4.57	13.9	37.3	264
12205	8.8	4.54	14.0	37.3	265
12206	8.8	4.62	14.0	37.9	258
<b>MEAN</b>	<b>8.9</b>	<b>4.53</b>	<b>13.96</b>	<b>37.6</b>	<b>266</b>
Acceptable Limits	8.6-9.0	4.39-4.59	13.8-14.2	37.2-39.2	248-272
<b>Result</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>



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