Calibration Certificate

Following voltages have been checked and adjusted on Haematology Analyzer CENTUS HA-100 (SLN. A321621070001EH) at Health Care Path Lab Unique Estates, 976/976 Khasra Number 559, Jhajjar Road, Dev Nagar, Bahadurgarh, Jhajjar, Haryana 124507

- System Voltages are in the specified range -Checked by Digital Multimeter are as follows:

S.No.	Module	Observed Value	Acceptable Range
1.	Main Power Supply	221 VAC	220 +/- 5.0 VAC
2.	24 Voltages Supply	24.1 VDC	24.0 +/- 1.0 VDC
3.	12 Voltages Supply	12.1 VDC	12.0 +/- 0.5 VDC
4.	HGB LED Voltages	4.21 VDC	4.25 +/- 0.25 VDC

- Checked the gain and offset of Analog Board and found OK.
- Service program of the instrument was run from the Settings Screen and found Ok.
- Checked the Pumps and Valves and found OK.
- Calibrate the instrument and Run control, Control results were OK.
- Next Calibration will be performed on 24/06/2023.

For T AND D DIAGNOSTICS INDIA PVT LTD.

T AND D DIAGNOSTICS INDIA PVT. LTD. NOIDA

Manish Kumar

Sales & Service Engineer

Date:25/06/2022

INSTALLATION QUALIFICATION

The installation of CENTUS HA-100 Sr no A321621070001EH at Health Care Path Lab Unique Estates, 976/976 Khasra number 559, Jhajjar Road, Dev Nagar, Bahadurgarh, Jhajjar, Haryana 124507.

- Checked all Mechanisms through the software like shear valve movement for different position.
- Checked the system performance for different parameters.
- Calibration and Control for all Assay were satisfactory.
- Carried out the Precision Check for above parameters which was also good.

For T AND D DIAGNOSTICS INDIA PVT LTD.

Manish Kumar

Manish Kumar

Sales & Service Engineer

T AND D DIAGNOSTICS INDIA PVT. LTD. NOIDA

Date: 25/06/2022

PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the system CENTUS HA-100 Sr. no A321621070001EH.

- Run the Normal, Low and High Controls
- Quality Checks for which the performance is OK and the Results are Satisfactory, within the specified range.
- Precision Checks: Carried out the Precision checks for different parameters for which precision was found satisfactory.

For T AND D DIAGNOSTICS INDIA PVT LTD.

Manish Kumar

Sales & Service Engineer

T AND D DIAGNOSTICS INDIA PVT. LTD. NOIDA

Date: 25/06/2022

OPERATIONAL QUALIFICATIONS

For Operational Qualifications carried out the following checks on the CENTUS HA-100 Sr.No. A321621070001EH

- Checked the overall system Mechanism found performance is ok.
- Software Checks: Carried out the check for Calibration, Control, Results, Data and the Performance is OK.
- Checked all the Operational Qualifications and found the functioning is satisfactory.

For T AND D DIAGNOSTICS INDIA PVT LTD.

Manish Kumar

Manish Kumar

Sales and service Engineer

T AND D DIAGNOSTICS INDIA PVT. LTD. NOIDA

Date: 25/06/2022

INSTALLTION CERTIFICATE

This is to certify that the CENTUS HA-100 Haematology Analyzer Instrument serial no. A321621070001EH has been successfully installed and commissioned at Health Care Path Lab Unique Estates, 976/976 Khasra number 559, Jhajjar Road, Dev Nagar, Bahadurgarh, Jhajjar, Haryana 124507 as per the installation procedure and checklist.

For T AND D DIAGNOSTICS INDIA PVT LTD

Name: Manish Kumar

Designation: Sales and Service Engineer

Signature:

Date: 25/06/2022

T AND D DIAGNOSTICS INDIA PVT. LTD. NOIDA

For HEALTH CARE PATH LAB

Name :

Designation:

Signature:

Date:

Quality Control Calibration Records
(3-Reagent System)

★ **Series number**: A3216210700001EH
★**Product software version** V2.0.0
★**Temperature** 27 ℃ **Humidity** 68 %
★**Diluent Batch No.** 220505 **Lyse Batch No.** 220505
★**Quality Control Batch No.** E1164-01-20 (B&E BIO-TECHNOLOGY)

Interface language: ☑ Chinese ☑ English ☑ French ☐ Indonesian ☑ Portuguese ☑ Spanish

<table>
<tr><th>No</th><th>Items</th><th colspan="8">Requirements</th><th>Results Determination</th></tr>
<tr><td>1</td><td>Appearance of the structure</td><td colspan="8">a. Text and logo should be clearly visible, the surface should be of uniform color, no dent, scratch and other defects. Fastener connection should be firm and reliable, not loose.
b. After the device is powered on, ensure that the indicator, screen, keyboard and mouse work properly, the time and date display is correct, and the heat dissipation fan runs smoothly and properly.</td><td>☑ Pass
☐ Fail</td></tr>
<tr><td rowspan="5">2</td><td rowspan="5">Blank Count</td><td colspan="8">After the cleaning procedure is performed, dilute solution is used as a sample for three consecutive tests on the analyzer, and the maximum value of the three test results should meet the requirements in below table.</td><td rowspan="5">☑ Pass
☐ Fail</td></tr>
<tr><td></td><td>Requirements</td><td colspan="2">Reading 1</td><td colspan="2">Reading 2</td><td colspan="2">Reading 3</td></tr>
<tr><td>WBC</td><td>≤0.2×10⁹/L</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">0</td></tr>
<tr><td>RBC</td><td>≤0.02×10¹²/L</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">0</td></tr>
<tr><td>HGB</td><td>≤1g/L</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">0</td></tr>
<tr><td>PLT</td><td>≤10×10⁹/L</td><td colspan="2">0</td><td colspan="2">0</td><td colspan="2">0</td></tr>
<tr><td rowspan="6">★3</td><td rowspan="6">Carry contamination rate inspection</td><td rowspan="2"></td><td rowspan="2">Requirments</td><td colspan="3">High value quality control product determination value</td><td colspan="3">Diluent determination value</td><td>Results</td><td rowspan="6">☑ Pass
☐ Fail</td></tr>
<tr><td>1</td><td>2</td><td>3</td><td>1</td><td>2</td><td>3</td><td></td></tr>
<tr><td>WBC</td><td>≤0.5%</td><td>20.4</td><td>20.4</td><td>20.5</td><td>0</td><td>0</td><td>0</td><td>0%</td></tr>
<tr><td>RBC</td><td>≤0.5%</td><td>5.45</td><td>5.49</td><td>5.49</td><td>0</td><td>0</td><td>0</td><td>0%</td></tr>
<tr><td>HGB</td><td>≤0.5%</td><td>185</td><td>186</td><td>186</td><td>0</td><td>0</td><td>0</td><td>0%</td></tr>
<tr><td>PLT</td><td>≤1.0%</td><td>485</td><td>485</td><td>491</td><td>0</td><td>0</td><td>0</td><td>0%</td></tr>
<tr><td>★4</td><td colspan="2">Repeatability of measurement</td><td>WBC</td><td colspan="3">≤2.0%</td><td colspan="3">0.98%</td><td>☑ Pass</td></tr>
</table>

T&D Diagnostics Canada Pvt. Ltd.

219 WAVERLEY ROAD, SUITE 201 DARTMOUTH, NS, B2X 2C3, Canada.

Toll Free: 1-800-853-7255; **Email:** info@td-diagnostics.ca

Quality Control Calibration Records
(3-Reagent System)

		RBC	≤1.5%	0.24%	☐Fail
		HGB	≤1.5%	0.90%	
		MCV	≤0.4%	0.06%	
		PLT	≤4.0%	1.00%	
★5	**Comparability**	WBC	±5%	-1.45%	☑ Pass
		RBC	±2.5%	-1.14%	
		HGB	±2.5%	-1.93%	☐Fail
		MCV	±3%	0.13%	
		PLT	±8%	-0.20%	
6	**Lack of paper alarm and print function test of recorder**	a. "Lack of paper" alarm function is normal b. The printed characters and graphics of the recorder shall be correct and clear and the operation of the mechanism shall be smooth and sound without paper jam, alarm information and alarm sound. It can print the quantitative analysis results of 21 measurement parameters and 3 histograms.			☑ Pass ☐Fail
7	**Communication function check**	The PC connected to the instrument should be able to receive complete and correct data when sending sample test data on the review interface.			☑ Pass ☐Fail

Conclusion:

☑ Pass ☐Fail

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Quality Control Calibration Records
(3-Reagent System)

Inspected By : Jacob	**Audit By:** Thomas	**Date :** 2022.05.05
Remark : WBC Circuit Gain / WBC: 225	**RBC Circuit Gain / RBC:** 195	

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