

CALIBRATION CERTIFICATE

This is to certify that the System Calibration (Preventive Maintenance) was performed on **25th April 2024** for the machine Vitros 250 Analyzer (S/N- 27004442) installed at **LU-PIN HEALTHCARE LTD BEHRAMPORE**.

The system's calibration includes checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer. The next System's calibration (Preventive Maintenance) is due on **October 2024**.

Thanking you,

Regards,



KAUSHIK DAS,
Service Engineer,
KOLKATA.



TOSOH INDIA PVT.LTD.

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 Bhiwandi, Thane -421 302, India, Tel.: +91-25 222 84100
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HLC-723 Report of Calibration Date YY: 21 MM: 09 DD: 12

Laboratory <u>Lupin Diagnostic Limited</u> Address <u>29, K.P. Chattarajan Road,</u> <u>Gurabazar, Mimtala, Borhampore</u> Department <u>-712101</u>	Signature <u>Subrata Murmu</u>	No.							
	Service Engineer Name <u>Engineering SUBRATA MURMU</u> Division <u>Engineering</u>								

Sign of Check ok: V replace: X adjustment: A repair R cleaning :C grease up: L

Machine Information	Measurement Conditions
Instrument <u>HLC 723 GX</u> Instrument S/N <u>(12743703)</u> Sample Loader S/N () Needle type <input checked="" type="checkbox"/> standard <input type="checkbox"/> side-hole AUTO SAVE <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO Bar-code <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	SYSTEM Ver. No. _____ Sample <input checked="" type="checkbox"/> whole blood <input type="checkbox"/> centrifuged <input type="checkbox"/> mixed FLOW <u>1.02</u> Z1-SMP <u>3025</u> Y1-SMP <u>3640</u> Y1-STAT _____ SYS-IN1 <u>1319</u> _____ SYL-IN3 _____
1. Alarm setting <input checked="" type="checkbox"/> paper-end, condition of printing <input type="checkbox"/> Column oven temperature	4. Pump <input checked="" type="checkbox"/> Check if the pump cam is not dirty <input type="checkbox"/> Leak from plunger-seal <input type="checkbox"/> Check if the diaphragm and plunger are not worn <input checked="" type="checkbox"/> Actions & leak of check-valves (Uptake & Purge) <input checked="" type="checkbox"/> Leak from drain-valve <input checked="" type="checkbox"/> Suction & line filters clogging <input checked="" type="checkbox"/> Pressure (MPa) w/o column <u>0.35</u> w/ column <u>7.86</u> <input checked="" type="checkbox"/> Vacuum condition <input checked="" type="checkbox"/> Drain flush <input checked="" type="checkbox"/> Valves actions FLOW FACTOR <u>1.02</u> Measured flow <u>1.02</u> ml/min
2. Sampling unit <input type="checkbox"/> Rotor-seal (Injection valve) <input type="checkbox"/> Stator-face (Injection valve) <input checked="" type="checkbox"/> Arm (Injection valve, check if loosened or not) <input checked="" type="checkbox"/> Sample-loop (Injection valve) <input checked="" type="checkbox"/> Rotor-seal (Rotary valve) <input checked="" type="checkbox"/> Round head screws at the coupling (Rotary valve) <input checked="" type="checkbox"/> Packing, check leak and worn or not (Syringe-S) <input checked="" type="checkbox"/> Packing, check leak and worn or not (Syringe-L) <input type="checkbox"/> Dilution port & Needle wash block, clean or not <input checked="" type="checkbox"/> Leak from O-ring (P/N:017092) <input checked="" type="checkbox"/> Barcode reader, readable without error <input checked="" type="checkbox"/> End-marker, detection sensitivity <input checked="" type="checkbox"/> Positions of rack-holder, tube-holder & sample sensor <input checked="" type="checkbox"/> Actions of Z1 & Y1 axes and SY-S & SY-L <input checked="" type="checkbox"/> Actions of X1, X2, Y2 and Y3 axes, no loosened screw <input checked="" type="checkbox"/> Position of X1 pitch-sensor <input checked="" type="checkbox"/> Positions between the main body and loader <input checked="" type="checkbox"/> Needle positions (at sampling, at dilution, at STAT) <input checked="" type="checkbox"/> Sample suction positions Whole blood sample Aspiration check: <u>3.0</u> uL Diluted blood sample Aspiration check: <u>150</u> uL	5. Others <input checked="" type="checkbox"/> Quality of printed letters <input checked="" type="checkbox"/> Parameters settings <input checked="" type="checkbox"/> AC voltage L-N <u>226</u> N-E <u>225</u> L-E <u>1.2</u> <input checked="" type="checkbox"/> DC voltage 12V <u>12.4</u> 24V <u>23.98</u> 5V <u>5.2</u> <input checked="" type="checkbox"/> Check of Smart Media <input checked="" type="checkbox"/> Clean up
3. Detector Column oven Temperature <u>259</u> Allowed: +/- 2 <input type="checkbox"/> Check noise at buffer changes <input type="checkbox"/> Baseline stability <input type="checkbox"/> Detector adjustment Lamp Initial Intensity <u>36 ml</u> Lamp Current Intensity _____ REF % <u>98%</u>	6. Receiving inspections <input checked="" type="checkbox"/> CALIB.std. 1: _____ % 2: _____ Calib. factors $Y = (1.733)X + (0.257)$ <input checked="" type="checkbox"/> CALIB 1, RT A1a: <u>0.23</u> A1b: <u>0.39</u> F: <u>0.17</u> L-A1c: <u>0.56</u> S-A1c: <u>0.69</u> A0: <u>1.03</u> <input checked="" type="checkbox"/> Cntl assigned values L: <u>5.0 ±0.3%</u> H: <u>10.0 ±0.5%</u> Observed Cntl values L: <u>5.1</u> % H: <u>9.9</u> <input checked="" type="checkbox"/> Total-Area <input checked="" type="checkbox"/> 700-3,000 <input type="checkbox"/> NG <input checked="" type="checkbox"/> Chromatogram <input checked="" type="checkbox"/> Good <input type="checkbox"/> NG <input checked="" type="checkbox"/> Check if all the items on this sheet have been filled out.
7. Remarks <u>Machine is working fine.</u>	



Issued to,

M/s: Lupin Diagnostics Limited
PCL Berhampur,
29, K.P Chattaraj Road, Gorabazar Nimtala,
Berhampur, Murshidabad West Bengal.

Form No.: M&P/LAB/FM/41

Cert. No. M&P/LAB/LDL-B/01/MP-01/24-25

Issue Date: 15-Oct-2024

ULR : CC392324000002361F

CALIBRATION CERTIFICATE

Date of Calibration	Calibration Due on	Page No.
7-Oct-2024	6-Apr-2025	1 of 1

Service Request / Order No. : ---
Location of Calibration : At Laboratory
Date of Receipt : 05.10.2024
Description of Instrument : **Micropipette**
Make : MICROLIT (Sl. No. 23304970)
Model /Type : Variable
Range : (100-1000) μ l
L/c : 5 μ l
Identification No. : LDL / BHPL / LAB / PIPT / 01
Method of Calibration : M&P/LAB/SOP/01/MECH/13 (Gravimetric Method)

Details of Standard Equipment used for Calibration :

Description	Traceability Certificate No. & Calibration Date	Valid upto	Calibration Agency
Electronic Balance (Sl.No.14252668)	M&P/LAB/INT/03/EB-03/24-25, Dated: 22.08.2024	21.08.2025	Amenity Measures & Precisions Engineers Pvt. Ltd.
Digital Thermometer with Sensor (Sl.No.1802250)	TSC/23-24/15715-2, Dated:02.03.2024	01.03.2025	Transcal

Traceability: Standard used for calibration traceable to national standards through NABL accredited laboratory

Environmental Condition : Temperature: (25 \pm 2) $^{\circ}$ C Humidity: (50 \pm 10)%RH

CALIBRATION RESULTS

Sl. No.	Value Set on DUC*	Average Reading Observed through Ref. Std. at 27 $^{\circ}$ C (Avg. of Ten Readings)	Systematic Error	Random Error	Expanded Uncertainty
	μ l	μ l	μ l	μ l	(\pm) μ l
1	100.0	100.91	-0.91	0.68	2.62
2	500.0	501.74	-1.74		
3	1000.0	1002.02	-2.02		

*Measurement uncertainty at 95% of confidence level for the maximum reported range & at a coverage factor of $k = 2$

Remarks: The above DUC has been calibrated over its above range & the readings obtained are tabulated above.

- Note:**
1. This certificate refers only to the particular item submitted for calibration.
 2. Result reported are valid at the time of and under stated condition of measurement.
 3. Next calibration due date is given as requested by the customer.
 4. DUC* = Device Under Calibration.
 5. Physical Status of the DUC is found OK.
 6. This certificate shall not be reproduced except in full with out permission of head of laboratory.

Calibrated By:

S. Sardar
(Calibration Engineer)



Approved By:

S. C Das
(Head of Laboratory)