

To Whom It May Concern

CALIBRATION CERTIFICATE

This is to certify that the system Preventive maintenance & calibration was performed on date 11 Aug 2024 for the machine, VITROS 250 Chemistry System, installed at Lupin Diagnostics Ltd., Prayagraj, bearing Serial No. 27001670.

The system's calibration includes optics calibration and checking the reproducibility performance of the instrument as per the guidelines provided by the manufacturer.

Validity: Six months



Anurag Singh
Sr. Engineer
Ortho Clinical Diagnostics

CALIBRATION REPORT

Name of Instrument : VITROS 250 Chemistry System
Serial Number : 27001670
Installed at : Lupin Diagnostics Ltd
Department : Laboratory
Date of PM : 11 Aug 2024
Validity : 6 months

SECTION / TEST **RESULT****SAMPLE METERING**

Leak Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Dispense Leak Rate must < 0.210 V dc	Pass
The read-to-read leak rate should be < 0.030 V dc	Pass

Hysteresis Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Maximum Hysteresis Value must be < 5.0 steps	Pass
Combined Hysteresis values of any 3 consecutive readings must be < 9.0 steps	Pass

REFERENCE METERING

Leak Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Aspirate Value < 0.175 V dc	Pass
The Ambient Pressure must in range of 2.25–2.75 V dc	Pass
Consecutive reading should not fall > 0.030 V dc	Pass

Hysteresis Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Mean Value of Hysteresis should be <= 5.0 V dc	Pass
Maximum Value of Hysteresis should be <= 10.0 V dc	Pass

IMMUNO WASH METERING

Leak Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
The Aspirate Value < 0.175 V dc	Pass
The Ambient Pressure must in range of 2.25–2.75 V dc	Pass
Consecutive reading should not fall > 0.030 V dc	Pass

Hysteresis Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Mean Value of Hysteresis should be <= 5.0 V dc	Pass
Maximum Value of Hysteresis should be <= 10.0 V dc	Pass

INCUBATORPad Reflectance Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Grand Mean Value must be in range of 0.75 – 0.99	Pass
Range must be ≤ 0.03	Pass

ELECTROMETERBasic Mode Verification Test: PASS / FAIL

Parameters	Test 1	Test 2	Test 3	Test 4
Input	Test	Test	Test	Test
Source	Zero 0	Zero 0	Ref 1	Ref 1
Polarity	Neg 0	Neg 0	Neg 0	Neg 0
Ohm -	Low 0	High 1	Low 0	High 1
Ohm +	Low 0	High 1	Low 0	High 1
Read Type	One 0	One 0	One 0	One 0
Specifications	0.0 mv \pm 2.4mv	0.0 mv \pm 2.4mv	-200 mv \pm 8mv	-200 mv \pm 8mv

REFLECTOMETER

IRIS Adjustment : PASS / FAIL

SPECIFICATIONS	OBSERVATION
Lamp Output range 3.5 to 8.0 across all Filters	Pass

Static Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
All "%CV*K" must be <= 18.0	Pass
All "SD Dark" must be <= 1.3	Pass

Interleaved Static Test: PASS / FAIL

SPECIFICATIONS	OBSERVATION
All "%CV*K" must be <= 18.0	Pass
All "SD Dark" must be <= 1.3	Pass

Dynamic Test : PASS / FAIL

SPECIFICATIONS	OBSERVATION
All "%CV*K" must be <= 18.0	Pass
All "SD Dark" must be <= 1.3	Pass

OPTICS: CORRECTION FACTOR

SPECIFICATIONS	OBSERVATION
Automatic - set by software	Pass

NOTE:

1. This certificate refers only to the particular item submitted for calibration.
2. The calibration result reported in the certificate is valid at the time of and under the stated condition of the measurement.