

CALIBRATION CERTIFICATE

This is to certify that ADVIA CENTAUR CP bearing Serial No: ROB30006116 installed at IMPULSE DIADNOSTICS, HAILAKANDI ROAD, MEHERPUR, SILCHAR, ASSAM, has been calibrated on 17th August 2021.

The complete hardware calibration has been carried out for the best performance of the instrument as per the procedure. The following are the instrument calibration details.

System Software – Ver. 6.2

Temperature

| Module | Result (°C) | Range (°C) | Status |
|--------------------|-------------|------------|--------|
| Cuvette Ring | 37.1 | 36 – 38 | Passed |
| Sample Environment | 23.17 | 18 – 30 | Passed |
| Reagent | 9.4 | 8 – 11.3 | Passed |

Luminometer

Luminometer High Voltage ON – 1000 V

High Voltage OFF – 6V

Dark Counts without Cuvettes

| Position | Result (RLU) | Range (RLU) | Status |
|----------|--------------|-------------|--------|
| Pos # 1 | 33 | 0 – 300 | Passed |
| Pos # 2 | 33 | 0 – 300 | Passed |
| Pos # 3 | 43 | 0 – 300 | Passed |
| Pos # 4 | 30 | 0 – 300 | Passed |
| Pos # 5 | 46 | 0 – 300 | Passed |
| Pos # 6 | 30 | 0 – 300 | Passed |
| Average | 35 | 0 – 300 | Passed |

Sample Probe Pressure Sensor Calibration

Sample Air pump = 29.0 % (The acceptable range is 25% to 40%)

Restricted

Reagent Probe Sensor Test

| Medium | Result (Voltage) | Range (Voltage) | Status |
|------------|------------------|-----------------|--------|
| With Water | 0.9671 | 0.85 – 1.05 | Passed |
| With Air | 3.4755 | 3.20 – 4.20 | Passed |

The instrument is working satisfactory as per above parameter calibrations. The next calibration due is on 16-02-2022.

Siemens Healthcare Private Limited

Kamal Kumar Baishya

Kamal Kr. Baishya

Manager: Customer Service

Silchar, Assam

17th August 2021.

Restricted

CALIBRATION CERTIFICATE

Dimension EXL200 bearing serial number DE272658 at **IMPULSE DIAGNOSTICS, HAILAKANDI ROAD, MEHERPUR, SILCHAR**, Assam has been duly calibrated on 17th August 2021

Final calibration results are as follows:

PHOTOMETER DARK CALIBRATION:

Reference : 9014.57 Hz
Sample (outer on) : 8794.58 Hz
Sample (outer off) : 8796.19 Hz

LAMP CALIBRATION:

Low Calib level : 55.0%
High Calib level : 68.2%

PHOTOMETER

| <u>Filters</u> | <u>System Check Wavelength</u> | <u>Acceptable Range</u> |
|----------------|--------------------------------|-------------------------|
| 293nm ---- | 1.22 | +2.5 |
| 340nm ---- | 0.81 | +1.5 |
| 383nm ---- | 0.70 | +1.5 |
| 405nm ---- | 0.79 | +1.5 |
| 452nm ---- | 0.69 | +1.5 |
| 510nm ---- | 0.60 | +1.5 |
| 540nm ---- | 0.49 | +1.5 |
| 577nm ---- | 0.53 | +1.5 |
| 600nm ---- | 0.53 | +1.5 |
| 700nm ---- | 0.50 | +1.5 |

PHOTOMETER LAMP VOLTAGE:

Set at 24.00V calibrated by DVM

PHOTOMETER ARM ALINGMENT: set at -6 Range: -3 to -9

CHK SYSTEM CHECK RESULTS:

RESULTS FROM INSTRUMENT

| | <u>OBSERVED</u> | <u>ACCEPTABLE RANGE</u> |
|-------------|---------------------------|--------------------------------|
| Reagent 1: | Mean: 396.62 SD : 0.46 | Mean: 396±15 SD : 3.80 |
| Reagent 2 : | Mean: 397.08 SD : 1.40 | Mean: 396±15 SD : 3.80 |
| Sampler : | Mean: 41.10 SD : 0.31 | Mean: 39.4±2 SD : 1.6 |

TEMPERATURE CALIBRATION:

Reagent : 5.0°C Range: 2°C to 8°C

Cuvette : 37.0°C Range: 37.0 +/- 0.2°C

The instrument is working satisfactorily, subsequent to Calibrations of the above parameters, and the Next Calibration is due on 16th February, 2022.

Note: Absorbance kit (CHK) LOT NO: GA1279 is an USFDA approved kit used in performing the system check in all Dimension systems. The carton value is a predetermined value for which the limits are defined in system check screen and operator guide of Dimension.

Siemens Healthcare Pvt Ltd.

Kamal Kr. Baishya

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17-08-2021