

BIOMÉRIEUX

CALIBRATION CERTIFICATE

Customer Details

Customer Name : St. Joseph Hospital
Address : Calicut
Contact Person : Sr. Kavitha
Contact No. : 9744061868

Instrument Details

Instrument Type : MiniVIDAS
Serial No. : IVD1208032
S/w Version : 5.6.1

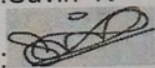
Calibration Details

Calibration Date : 28-Jan-2020
Next Calibration Due Date : 27-Jan-2021

Calibration Report

1. All the alignments are in the specified range : Yes
2. All the voltages are in the specified range : Yes
3. The Trays & SPRs block are in the specified range
a. The Tray temperature is $37^{\circ}\text{C} \pm 1.7^{\circ}\text{C}$ & the average of all is $\leq 0.7^{\circ}\text{C}$: Yes
b. The SPR block temperature is $37^{\circ}\text{C} \pm 1.5^{\circ}\text{C}$ & the average of all is $\leq 0.5^{\circ}\text{C}$: Yes
4. The Solid Standard value is within 2700RFUs to 3500 RFUs : Yes
5. The Air Reading is 5 ± 2 : Yes

Authorised Signatory

Engineer's Name : Suvin K
Signature : 
Date : 28-Jan-2020

bioMérieux India Pvt. Ltd

mini VIDAS REPORT

MASTER LOT ENTERED AT:
08:35:31 24Sep20

Assay: CEAS
Strip Lot: 210514-0
Standard RFV Values:
27, 1889, 2886, 3576
Calibration Method: 7
Calibrator S1 Dose Value:
99.12 ng/ml
Control 1 Dose Value Range:
25.96 -- 34.82 ng/ml
Calibrator S1 RFV Ranges:
1730 -- 3090
Calibrator S1 Max CV % :
10.0

mini VIDAS Report
Section: A

Completed: 09:48:16 24Sep20

CEA (S) (CEAS)

Ver: R5.6.1

Lot#: 210514-0

Standard used:

Completed: 09:48:16 24Sep20

RFV = 2251

Position: A1 Standard 1
Background: 160 RFV: 2251

Position: A2 Control 1
Background: 158 RFV: 982
Result: 30.25 ng/ml

mini VIDAS REPORT

MASTER LOT ENTERED AT:
07:53:36 14Jan21

Assay: HCG
Strip Lot: 210924-0
Standard RFV Values:
22, 453, 1476, 5248
Calibration Method: 7
Calibrator S1 Dose Value:
335.47 mUI/ml
Control 1 Dose Value Range:
16.71 -- 28.75 mUI/ml
Calibrator S1 RFV Ranges:
993 -- 1774
Calibrator S1 Max CV % :
10.0

mini VIDAS Report
Section: B

Completed: 08:52:38 14Jan21
HCG (HCG)
Ver: R5.6.1
Lot#: 210924-0
Standard used:
Completed: 08:52:38 14Jan21
RFV = 1415

Position: B1 Control 1
Background: 172 RFV: 100
Result: 21.35 mUI/ml

Position: B2 Standard 1
Background: 173 RFV: 1415

mini VIDAS REPORT

MASTER LOT ENTERED AT:
09:24:06 14Jan21

Assay: FER
Strip Lot: 210916-0
Standard RFV Values:
48, 1295, 3419, 5672
Calibration Method: 7
Calibrator S1 Dose Value:
647.26 ng/ml
Control 1 Dose Value Range:
66.98 -- 101.26 ng/ml
Calibrator S1 RFV Ranges:
2633 -- 5265
Calibrator S1 Max CV % :
10.0

mini VIDAS Report
Section: B

Completed: 09:58:27 14Jan21

Ferritin (FER)

Ver: R5.6.1

Lot#: 210916-0

Standard used:

Completed: 09:58:27 14Jan21

RFV = 3747

Position: B1 Control 1
Background: 179 RFV: 692
Result: 83.04 ng/ml

Position: B2 Standard 1
Background: 176 RFV: 3696

Position: B3 Standard 1
Background: 176 RFV: 3799

mini VIDAS REPORT

MASTER LOT ENTERED AT:
09:05:52 14Jan21

Assay: T4
Strip Lot: 211012-0
Standard RFV Values:
3779, 2400, 1251, 745
Calibration Method: 7
Calibrator S1 Dose Value:
32.86 nmol/l
Control 1 Dose Value Range:
65.84 -- 102.78 nmol/l
Calibrator S1 RFV Ranges:
1850 -- 3700
Calibrator S1 Max CV % :
10.0

mini VIDAS Report
Section: A

Completed: 09:47:54 14Jan21

T4 (T4)

Ver: R5.6.1

Lot#: 211012-0

Standard used:

Completed: 09:47:54 14Jan21

RFV = 2599

Position: **A4** Control 1
Background: 149 RFV: 1650
Result: **6.61** ug/dl

Position: **A5** Standard 1
Background: 149 RFV: 2632

Position: **A6** Standard 1
Background: 154 RFV: 2566

mini VIDAS REPORT

MASTER LOT ENTERED AT:
12:01:20 31Dec20

Assay: TSH
Strip Lot: 210906-0
Standard RFV Values:
106, 903, 3081, 7427
Calibration Method: 7
Calibrator S1 Dose Value:
37.12 uIU/ml
Control 1 Dose Value Range:
3.35 -- 4.67 uIU/ml
Calibrator S1 RFV Ranges:
3594 -- 6417
Calibrator S1 Max CV % :
10.0

mini VIDAS Report
Section: A

Completed: 09:47:54 14Jan21

TSH (TSH)

Ver: R5.6.1

Lot#: 210906-0

Standard used:

Completed: 09:47:54 14Jan21

RFV = 5148

Position: A1 Control 1
Background: 168 RFV: 674
Result: 3.61 uIU/ml

Position: A2 Standard 1
Background: 170 RFV: 5143

Position: A3 Standard 1
Background: 168 RFV: 5153

MASTER LOT ENTERED AT:
17:29:30 13Jan21

Assay: T3
Strip Lot: 210929-0
Standard RFV Values:
2911, 2359, 1245, 610
Calibration Method: 7
Calibrator S1 Dose Value:
0.98 nmol/l
Control 1 Dose Value Range:
1.58 -- 2.26 nmol/l
Calibrator S1 RFV Ranges:
1539 -- 3078
Calibrator S1 Max CV % :
10.0

mini VIDAS Report
Section: A

Completed: 08:54:22 14Jan21
T3 (T3)

Ver: R5.6.1
Lot#: 210929-0

Standard used:
Completed: 08:54:22 14Jan21
RFV = 2397

Position: A1 Control 1
Background: 161 RFV: 1882
Result: 1.24 ng/ml

Position: A2 Standard 1
Background: 160 RFV: 2449

Position: A3 Standard 1
Background: 160 RFV: 2346

CERTIFICATE OF CALIBRATION

Ref. No.: SJH 175
Applicant: DHARMAGIRI ST. JOSEPH'S HOSPITAL
Device Calibrated: HORMONE ANALYSER
Make/Model: MINI VIDAS
Sl. No: IVD1208032

Condition at receipt: Functional
Calibrated at : Onsite
Date of Calibration : 3/06/2020
Calibration due date : 2/06/2021

Certified that the above Instrument has been calibrated by trained technical personnel of this centre using a calibration system traceable to National Standards. The calibration details attached with the certificate are authentic quantitative analysis of the instrument's credibility on the date of calibration and relate only to the Instrument calibrated.

Date of Issue : 4/06/2020


Approved Signatory



Cyrix Healthcare Pvt. Ltd.,
30/641 B Petta Junction, Poonithura, Kochi-38.
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CYRIXTM
HEALTHCARE PVT LTD

www.cyrixhealthcare.com

ISO Certified Company

AERB Approved
QA Agency

NABL Accredited
Calibration Agency

CERTIFICATE OF CALIBRATION

Customer Name & Address	DHARMAGIRI ST. JOSEPH'S HOSPITAL, AGASTIAMUZHI MUKKAM, KOZHIKKODE KERALA - 673602	Certificate No.	SJH 175
		Date of Calibration	3/06/2020
		Valid Up to	2/06/2021
		Date of Issue	4/06/2020

Instruments Details			
Instrument Name	HORMONE ANALYSER	S No.	IVD1208032
Make/Model No.	MINI VIDAS	Location	LABORATORY
ID No.	SJH/LAB/HA/01	Visual Inspection	OK

Details of Reference Standards & Major Equipment's Used			
Equipment Name	ELECTRICAL SAFETY ANALYZER	THERMO HYGROMETER	
Make	RIGEL MEDICAL	...	
Model/SR No.	288+/05L-0407	HTC-2	
Calibration Validity	14/06/2020	23/09/2020	
Calibration By	ARAGON CALIBRATION	STIC	

Environmental Condition			
Temperature	27°C	Relative Humidity	54%

Calibration Results	
ELECTRICAL SAFETY REPORT ATTACHED	

REMARKS: -

- ❖ This result of calibration refers to only to the particular items submitted for calibration.
- ❖ The above result is valid at the time of and under the stated conditions measurement.
- ❖ Calibration certificate issued for weight & measure parameters like mass, weighting balance, volumetric equipment, measuring scales/tapes etc. Are scientific purpose only and should not used for commercial.

Calibrated By

(SE)

Approved By

(QM)



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CERTIFICATE OF CALIBRATION

ELECTRICAL SAFETY TEST VALUES

TEST NO.	NAME OF THE TEST	READING	HIGH LIMIT	LOW LIMIT	UNIT	STATUS
1	MAIN VOLTAGE -LIVE TO NEUTRAL	229	250	225	V	P
2	MAIN VOLTAGE -LIVE TO EARTH	228	240	220	V	P
3	MAIN VOLTAGE-NEUTRAL TO EARTH	0.4	3	0	V	P
4	EQUIPMENT CURRENT	0.6	16	0.1	mA	P
5	PROTECTIVE EARTH RESISTANCE	0.4	3	0	Ω	P
6	EARTH LEAKAGE CURRENT - NC	182	250	50	μ A	P
7	EARTH LEAKAGE CURRENT - OC	289	500	250	μ A	P
8	ENCLOSURE LEAKAGE CURRENT -NC	0.1	10	0	μ A	P
9	ENCLOSURE LEAKAGE CURRENT -OC	0.4	10	0	μ A	P
10	INSULATION RESITANCE					
	1.MAINS-PROTECTIVE EARTH	OL	100	0	M Ω	P
	2.APPLIED PART TO PROTECTIVE EARTH	NA	100	0	M Ω	P
	3.MAINS TO APPLIED PART	NA	100	0	M Ω	P
	4.MAINS TO NEUTRAL	OL	100	0	M Ω	P
	5.APPLIED PART TO NEUTRAL	NA	100	0	M Ω	P

* NOTE (NC -NORMAL CONDITION, OC-OPEN CONDTION)

Service Engineer

Quality Manager

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