Ortho Clinical Diagnostics

403, Leela Business Park, Andheri Kurla Road, Andheri East, Mumbai - 400059 T:+91 22 6787 9300 F: +91 22 6787 9333

CALIBRATION CERTIFICATE

CERTIFICATE NO: OCD/PRIMA/02

CALIBRATED FOR: PRIMA DIAGNOSTICS

CALIBRATION DATE: 13/04/2021 CALIBRATION DUE: 12/10/2021 CALIBRATED AT : AT SITE

LOCATION

: BANGLORE

SPECIFICATION OF INSTRUMENT:

INSTRUMENT	MODEL	SERIAL NO
VITROS CHEMISTRY	VITROS 250	27001264
System	J NUMBER	J20705

Specification of Software:

SOFTWARE NAME	SOFTWARE VERSION	UPDATED ON
DOSRmx os	V9.6	March 2019
	17.0	

The Reference of Calibration: The performance/Adjustments of various subsystems has been calibrated/tested by trained site engineer with pre-designed /calibrated tools provided for the particular subsystems by the company.

PM Procedure Checklists:

Subsystem Name	Adjusted/Verified
Sample Supply * Hook Drive Belt	
2. Slide Supply 1, 2 & slide transport Mechanical Adjustment: * Dispense Blade Centering Adjustment * Dispense Blade Drive Belt Tension * Plunger Centering Alignment Software Adjustment: * Dispense To Metering Position	
3. Sample Metering Mechanical Adjustment: * Truck Sensor	

- * Truck Guide Button
- * Metering Truck

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Software Adjustment:	1
* Tip Pickup X,Y and Height	
* Sample Tray at Sample Position –Auto Sample Tray	
* Proboscis Centering and Sample Cup Depth	
* Mixing Cup X,Y and its Depth	
* Diluents Tray	
* Rate / Colorimetric Metering Position	
* Potentiometric Metering Position	
* Proboscis Compression	
* Wetness Detector	
6. Slide Incubator	
Software Adjustment:	L
* Incubator Disk Sizing	
* Incubator Disk Stopping	190
* PM Slide Insertion Depth	
* Slide Read Position (RT/CM Depth & Read Sync)	
* Potentiometric Eject Blade Depth	
7. Reflectometer	
* IRIS Lamp Output Voltage	
* Correction Factor	
Concetion 1 actor	
9. Master Computer	
* Touch Screen Calibration	
* System Full Backup	

CALIBRATED BY

K. Kur

Yogeesh K SR.Service engineer Orthoclinical diagnostics Banglore

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.



Calibration Report

Customer Name :- Prima Diagnostics, Bangalore

Address:-Siddapura Village, Varthur, White Field Main Road, Bangalore 560 066.

Instrument Model:- ST-200 CL Electrolyte Analyzer /Sr. No.:-ST-4537

Calibration Date: 19/08/2021

Calibration Due Date: - 18/08/2022

As per the Standard Operating procedure of ST-200 CL Electrolyte Analyzer, the instrument has been calibrated at the factory.

As per method mentioned into manuals/sop, the Known Value Sample/Control run on the analyzer for five times for the Electrolyte parameters. All obtained values are in the range and CV values were checked. CV values were within a normal range as mentioned in performance certificate. This indicated that an instrument is performing accurately and precisely.

Hence, we certified that ST-200 CL Electrolyte Analyzer is calibrated.





<u>Instrument Name: ST 200 CL Na/K/Cl Electrolyte Analyzer</u>

Instrument Number: ST-4537 "K" Electrode: 21FF26

"Na" Electrode: 21FC25 "Cl" Electrode: 21FC30

Calibration Slope:

S.No	Na+	K+	Cl-
1	64.33	66.88	54.97
2	64.98	66.53	55.34
3	64.65	66.65	55.75
Mean	64.65	66.69	55.35
Ranges	35 - 100 mV/decade	35 - 100 mV/decade	30 - 100 mV/decade
Status	OK	OK	OK

Quality Control (I): Lot:UQC21F-L1

Q	201.0 Q 0 = 11 21		
S.No	Na+	K+	Cl-
1	126.01	2.14	75.50
2	126.02	2.15	75.51
3	126.50	2.16	75.53
Mean	126.18	2.15	75.51
Ranges	112 - 132 mmol/L	1.48 - 2.48 mmol/L	74 - 92 mmol/L
Status	OK	OK	OK

Quality Control (II): Lot:UQC21F-L2

	_		
S.No	Na+	K+	Cl-
1	141.01	3.87	96.40
2	140.90	3.88	96.41
3	141.30	3.89	97.45
Mean	141.07	3.88	96.75
Ranges	132 - 149 mmol/L	3.49 - 4.49 mmol/L	95 - 110 mmol/L
Status	OK	OK	OK

Quality Control (III): Lot:UQC21F-L3

()			
S.No	Na+	K+	Cl-
1	159.40	5.75	120.20
2	159.41	5.76	121.20
3	159.45	5.78	122.10
Mean	159.42	5.76	121.17
Ranges	150 -169 mmol/L	5.45 - 6.45 mmol/L	114 - 128 mmol/L
Status	OK	OK	

BIO RAD Level (I): Lot: 26431

S.No	Na+	K+	Cl-
1	150.50	4.11	95.70
2	150.80	4.13	94.90
3	150.65	4.11	96.65
Mean	150.65	4.12	95.75
Ranges	140 - 161 mmol/L	3.79 -4.43 mmol/L	91 - 113 mmol/L
Status	OK	OK	OK

BIO RAD Level (II) : Lot: 26432

S.No	Na+	K+	Cl-
1	134.90	6.22	83.50
2	134.90	6.24	83.50
3	134.65	6.23	84.65
Mean	134.82	6.23	83.88
Ranges	123 - 137 mmol/L	5.78 - 6.80 mmol/L	77 - 94 mmol/L
Status	OK	OK	OK

Urine Quality Control (I): Lot:UQC21F-UL-1

S.No	Na+	K+	Cl-
1	383.26	67.35	359.12
2	382.65	68.27	356.77
3	379.46	68.05	358.61
Mean	381.79	67.89	358.17
Ranges	280 – 450 mmol/L	55 -85 mmol/L	300-450 mmol/L
Status	OK	OK	OK

Urine Quality Control (II): Lot:UQC21F-UL-2

office Quality Control (II): Ect. 6 QC211 CE 2			
S.No	Na+	K+	Cl-
1	671.88	358.37	819.22
2	674.57	360.19	819.42
3	672.95	359.65	820.65
Mean	673.13	359.40	819.76
Ranges	580 -750 mmol/L	280 - 500 mmol/L	700 - 900 mmol/L
Status	OK	OK	OK

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