

# Ortho Clinical Diagnostics

403, Leela Business Park,  
Andheri Kurla Road, Andheri  
East, Mumbai - 400059  
T : +91 22 67879300  
F : +91 22 67879333

## CALIBRATION CERTIFICATE

CERTIFICATE NO : OCD/PRIMA/02  
CALIBRATED FOR : PRIMA DIAGNOSTICS  
LOCATION : BANGLORE

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

### SPECIFICATION OF INSTRUMENT :

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

### Specification of Software:

SOFTWARE NAME	SOFTWARE VERSION	UPDATED ON
DOS Rmx os	V9.6	March 2019

*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

1. 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:

- \* 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:

- \* Incubator Disk Sizing
- \* Incubator Disk Stopping
- \* PM Slide Insertion Depth
- \* Slide Read Position (RT/CM Depth & Read Sync)
- \* Potentiometric Eject Blade Depth



## 7. Reflectometer

- \* IRIS Lamp Output Voltage
- \* Correction Factor



## 9. Master Computer

- \* Touch Screen Calibration
- \* System Full Backup



CALIBRATED BY



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.



**Kiran Date**  
(General Manager-Global Service)

**Sensa Core Medical Instrumentation Pvt. Ltd.**

Plot No: 3, Export Promotion Industrial Park, Pashamylaram, Sangareddy (District), Hyderabad - 502307.  
Telangana, INDIA. Telephone : +91 - 8455 - 223400, Email : info@sensacore.com, web : www.sensacore.com

CIN Number : U74999TG2006PTC051992



**Instrument Name : ST 200 CL Na/K/Cl Electrolyte Analyzer**

**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

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

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

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP  
TESTING COMPLETE  
OPTIONS - Calibration Parameters

SAMPLING  
ON OFF

Seq 15 21  
13:58:59  
V9.7 1264  
OP1E

Lot Number	:	00097440
Intercept	:	9.67862
Slope	:	9.78233 E+01
Curvature or Slope 2	:	2.54765
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	08/26/21
Time of Last Calibration	:	18:59
Site Temperature at Cal	:	2.78799 E+01

GLU SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE

SAMPLING  
ON OFF

Seq 15 21  
14:03:22  
V9.7 1264  
OP186

OPTIONS - Calibration Parameters

Lot Number	:	01317447
Intercept	:	5.34016 E-01
Slope	:	1.04896 E+02
Curvature or Slope 2	:	6.82954
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	09/11/21
Time of Last Calibration	:	17:49
Site Temperature at Cal	:	2.78799 E+01

UREA SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE  
OPTIONS - Calibration Parameters

SAMPLING  
ON OFF

Sep 15 21  
14:03:43  
V9.7 1264  
OP15

Lot Number	:	15367451
Intercept	:	2.22177 E-02
Slope	:	1.04804 E+02
Curvature or Slope 2	:	0.00000
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	09/01/21
Time of Last Calibration	:	13:53
Site Temperature at Cal	:	2.85599 E+01
Sub Dep Check. Density	:	4.36638 E-01

UREA SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP



MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE  
OPTIONS - Calibration Parameters

SAMPLING ON OFF

Sep 15 2  
14:04:00  
V9.2 126  
OP11

Lot Number	:	05484582
Intercept	:	-3.06994 E-02
Slope	:	1.11722 E+02
Curvature or Slope 2	:	-4.60505 E+01
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	05/09/21
Time of Last Calibration	:	10:04
Site Temperature at Cal	:	2.80499 E+01

URIC SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF

Sep 15 2  
14:04:21  
V9.7 126  
OPI

OPTIONS - Calibration Parameters

Lot Number : 06058182  
Intercept : 7.64910 E-02  
Slope : 1.17565 E+02  
Curvature or Slope 2 : -1.96592 E+02  
Blank Correction Coef : 0.00000  
User Modified Calibration : N  
Date of Last Calibration : 08/06/21  
Time of Last Calibration : 11:30  
Site Temperature at Cal : 2.67400 E+01

TP SERUM  
>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

SAMPLING  
ON OFF

Sep 15 21  
14:05:00  
V9.7 1264  
OP18A

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE

OPTIONS - Calibration Parameters

Lot Number	:	09286891
Intercept	:	-8.85108 E-02
Slope	:	1.11004 E+02
Curvature or Slope 2	:	2.73398 E-02
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	05/25/21
Time of Last Calibration	:	11:08
Site Temperature at Cal	:	2.73899 E+01

ALB SERUM  
>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF

Sep 15 21  
14:05:23  
V9.7 1264  
OP1E

OPTIONS -- Calibration Parameters

Lot Number : 03018060  
Intercept : 1.23748 E-01  
Slope : 1.01641 E+02  
Curvature or Slope 2 : 0.00000  
Blank Correction Coef : 0.00000  
  
User Modified Calibration : N  
Date of Last Calibration : 09/01/21  
Time of Last Calibration : 13:54  
Site Temperature at Cal : 2.85599 E+01

Ca SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

LAB COMP:  
TESTING COMPLETE

SAMPLING  
ON OFF

Sep 15 21  
14:06:11  
V9.7 1264  
OP186

INC ENVIR MON DISABLED

OPTIONS - Calibration Parameters

Lot Number : 02035050  
Intercept : 3.23329  
Slope : 2.79197 E+02  
Curvature or Slope 2 : -2.13786 E+02  
Blank Correction Coef : 0.00000  
  
User Modified Calibration : N  
Date of Last Calibration : 05/25/21  
Time of Last Calibration : 11:09  
Site Temperature at Cal : 2.73899 E+01

Bu SERUM

>Press the ENTER key to move the cursor.

HELP

RETURN

MASTER COMPUTER DATA \* file in use

SAMPLING  
ON OFF

Sep 15 21  
14:05:55  
V9.7 1264  
OP18

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE

OPTIONS - Calibration Parameters

Lot Number : 02035050  
Intercept : -6.01753  
Slope : -1.23422 E+02  
Curvature or Slope 2 : 3.09953 E+02  
Blank Correction Coef : 0.00000  
  
User Modified Calibration : N  
Date of Last Calibration : 05/25/21  
Time of Last Calibration : 11:09  
Site Temperature at Cal : 2.73899 E+01

Bc SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE  
OPTIONS - Calibration Parameters

SAMPLING  
ON OFF

Seq 15 2  
14:06:26  
V9.7.126  
OP1:

Lot Number	:	14455439
Intercept	:	-2.84619
Slope	:	3.47485 E+01
Curvature or Slope 2	:	-2.32131
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	05/25/21
Time of Last Calibration	:	11:08
Site Temperature at Cal	:	2.73899 E+01

TBIL SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

SAMPLING  
ON OFF

Sep 15 21  
14:06:27  
V9.7 1264  
OP18

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE

OPTIONS - Calibration Parameters

Lot Number	:	14455439
Intercept	:	-2.84619
Slope	:	3.47485 E+01
Curvature or Slope 2	:	-2.32131
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	05/25/21
Time of Last Calibration	:	11:08
Site Temperature at Cal	:	2.73899 E+01

TAIL SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP



MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF

Sep 15 2  
14:06:45  
V9.7 126  
OP1

OPTIONS - Calibration Parameters

Lot Number : 73274374  
Intercept : 1.32002  
Slope : 1.00744 E+02  
Curvature or Slope 2 : 1.63737  
Blank Correction Coef : 0.00000  
  
User Modified Calibration : N  
Date of Last Calibration : 05/10/21  
Time of Last Calibration : 12:53  
Site Temperature at Cal : 2.73999 E+01  
Sub Dep Check. Density : 5.61270 E-01  
  
First Pt Reference Value : 7.90285

AST SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED .

LAB COMP:  
TESTING COMPLETE

SAMPLING  
ON OFF

Sep 15 21  
14:07:05  
V9.7 1264  
GP18

OPTIONS - Calibration Parameters

Lot Number : 56044323  
Intercept : 1.57633 E-01  
Slope : 1.03829 E+02  
Curvature or Slope 2 : -5.21536 E-02  
Blank Correction Coef : 0.00000

User Modified Calibration : N  
Date of Last Calibration : 05/10/21  
Time of Last Calibration : 12:52  
Site Temperature at Cal : 2.73899 E+01  
Sub Dep Check. Density : 5.99607 E-01

First Pt Reference Value : 3.74379

ALTV SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE

SAMPLING  
ON OFF

Sep 15 21  
14:07:20  
V9.7 1264  
OP18

OPTIONS - Calibration Parameters

Lot Number	#	65233419
Intercept	#	-4.90755
Slope	#	1.01206 E+02
Curvature or Slope 2	#	-4.21745 E-01
Blank Correction Coef	#	0.00000
User Modified Calibration	#	N
Date of Last Calibration	#	05/10/21
Time of Last Calibration	#	12:53
Site Temperature at Cal	#	2.73899 E+01
Sub Dec Check. Density	#	2.83107 E-01
First Pt Reference Value	#	9.29890

ALKP SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE  
OPTIONS - Calibration Parameters

SAMPLING  
ON OFF

Sep 15 2  
14:08:12  
V9.7 126  
OP1

Lot Number : 67022937  
Intercept : -2.67655  
Slope : 1.04728 E+02  
Curvature or Slope 2 : -1.09919 E-01  
Blank Correction Coef : 0.00000  
  
User Modified Calibration : N  
Date of Last Calibration : 05/10/21  
Time of Last Calibration : 12:54  
Site Temperature at Cal : 2.75499 E+01  
Sub Deo Check. Density : 3.72535 E-01  
  
First Pt Reference Value : 9.69003

GGT SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF

Sep 15 2  
14:10:15  
V9.7 126  
OF11

OPTIONS - Calibration Parameters

Lot Number	:	07432833
Intercept	:	1.99987
Slope	:	9.64455 E+01
Curvature or Slope 2	:	1.89847
Blank Correction Coef	:	0.00000
User Modified Calibration	:	UC
Date of Last Calibration	:	07/17/21
Time of Last Calibration	:	09:50
Site Temperature at Cal	:	2.82299 E+01

TRIG SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

LAB COMP:

SAMPLING  
ON OFF

Seq 15 21  
14:12:19  
V9.7 1264  
OP18

INC ENVIR MON DISABLED

TESTING COMPLETE

OPTIONS - Calibration Parameters

Lot Number	:	08435124
Intercept	:	4.42140
Slope	:	1.02212 E+02
Curvature or Slope 2	:	9.23837 E-01
Blank Correction Coef	:	0.00000
User Modified Calibration	:	UC
Date of Last Calibration	:	07/17/21
Time of Last Calibration	:	09:49
Site Temperature at Cal	:	2.82299 E+01

CHOL SERUM

>Press the ENTER key to move the cursor.

HELP

RETURN

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP:  
TESTING COMPLETE

SAMPLING  
ON OFF

Seq 15 2  
14:08:56  
V9.7 126  
OP1

OPTIONS - Calibration Parameters

Lot Number	:	11294918
Intercept	:	7.88777 E-02
Slope	:	9.33215 E+01
Curvature or Slope 2	:	8.14828
Blank Correction Coef	:	0.00000
User Modified Calibration	:	N
Date of Last Calibration	:	05/28/21
Time of Last Calibration	:	12:11
Site Temperature at Cal	:	2.85599 E+01

dHDL SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

MASTER COMPUTER DATA \* file in use

INC ENVIR MON DISABLED

LAB COMP: TESTING COMPLETE

SAMPLING  
ON OFF

Sen. 15 2  
13:58:59  
V9-2 1264  
OP15

OPTIONS - Calibration Parameters

Lot Number : 00097440  
Intercept : 9.67862  
Slope : 9.78233 E+01  
Curvature or Slope 2 : 2.54765  
Blank Correction Coef : 0.00000  
  
User Modified Calibration : N  
Date of Last Calibration : 08/26/21  
Time of Last Calibration : 18:59  
Site Temperature at Cal : 2.78799 E+01

GLU SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP