

Ortho Clinical Diagnostics

403, Leela Business Park, Andheri Kurla Road,
Andheri East, Mumbai – 400059
T : +91 22 6787 9300
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CALIBRATION CERTIFICATE

CERTIFICATE NO : OCD/PRIMA /002
CALIBRATED FOR : PRIMA DIAGNOSTICS
LOCATION : BANGALORE

CALIBRATION DATE : 07/05/2021
CALIBRATION DUE. : 06/11/2021
CALIBRATED AT : AT SITE

SPECIFICATION OF INSTRUMENT :

INSTRUMENT	MODEL	SERIAL NO
VITROS CHEMISTRY SYSTEM	VITROS 250	27001765
	J NUMBER	J27001765

Specification of Software:

SOFTWARE NAME	SOFTWARE VERSION	UPDATED ON
DOS Rmx os	V9.7	Nov 2019

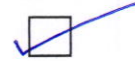
The Reference of Calibration: The performance/Adjustments of various subsystems has been calibrated/tested by trained site engineer with pre-designed /calibrated tools provided for the particular subsystems by the company.

PM Procedure Checklists:

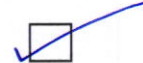
Subsystem Name

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
Software Adjustment:



Ortho Clinical Diagnostics

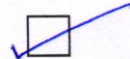
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- * Tip Pickup X,Y and Height
- * Sample Tray at Sample Position –Auto Sample Tray
- * Proboscis Centering and Sample Cup Depth
- * Mixing Cup X,Y and its Depth
- * Diluents Tray
- * Rate / Colorimetric Metering Position
- * Potentiometric Metering 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



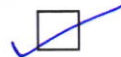
7. Reflectometer

- * IRIS Lamp Output Voltage
- * Correction Factor



9. Master Computer

- * Touch Screen Calibration
- * System Full Backup



CALIBRATED BY



Mr. Sayandh Parayil (Service Engineer)

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.

READY

LAB COMP:
TESTING COMPLETE

SAMPLING Aug 30 2
ON OFF 20:33:38
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 15364121
Intercept : -3.08653 E-02
Slope : 1.03835 E+02
Curvature or Slope 2 : 0.00000
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 06/02/21
Time of Last Calibration : 08:22
Site Temperature at Cal : 2.69000 E+01
Sub Dep Check, Density : 4.41521 E-01

CREA SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF

Aug 30 20:34:13
V9.7 176
OP18

OPTIONS - Calibration Parameters

Lot Number : 05484582
Intercept : 1.35205 E-02
Slope : 9.85027 E+01
Curvature or Slope 2 : 5.12093 E+01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 06/19/21
Time of Last Calibration : 11:20
Site Temperature at Cal : 2.92700 E+01

URIC SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:32:34
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 00097440
Intercept : 2.33133 E-01
Slope : 1.02248 E+02
Curvature or Slope 2 : 1.27390
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 08/05/21
Time of Last Calibration : 17:00
Site Temperature at Cal : 2.72199 E+01

GLU SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:33:01
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 01314257
Intercept : 4.35704 E-01
Slope : 1.00605 E+02
Curvature or Slope 2 : 7.82421 E-01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 05/05/21
Time of Last Calibration : 14:15
Site Temperature at Cal : 2.46299 E+01

UREA SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

SAMPLING
ON OFF

Aug 30 21
20:34:53
V9.7 1765
OF18

LAB COMP:
TESTING COMPLETE

READY

OPTIONS - Calibration Parameters

Lot Number : 06058182
Intercept : 1.98591 E-01
Slope : 1.06677 E+02
Curvature or Slope 2 : -5.97597 E+01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 07/24/21
Time of Last Calibration : 16:49
Site Temperature at Cal : 2.72199 E+01

TP SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 21
20:35:18
V9.7 1765
OP18

OPTIONS - Calibration Parameters

Lot Number : 09286891
Intercept : 2.32613 E-02
Slope : 1.06827 E+02
Curvature or Slope 2 : 1.85589 E-02
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 05/20/21
Time of Last Calibration : 16:40
Site Temperature at Cal : 2.59599 E+01

ALB SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:35:44
V9.7 176
OF1

OPTIONS - Calibration Parameters

Lot Number : 03473485
Intercept : 3.64875 E-03
Slope : 9.51169 E+01
Curvature or Slope 2 : 0.00000
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 03/18/21
Time of Last Calibration : 10:59
Site Temperature at Cal : 2.52099 E+01

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

RETURN

HELP

SAMPLING
ON OFF

Aug 30 21
20:36:09
V9.7 1765
OP18

LAB COMP:
TESTING COMPLETE

READY

OPTIONS - Calibration Parameters

Lot Number : 02035050
Intercept : 3.23989
Slope : 2.81006 E+02
Curvature or Slope 2 : -2.18103 E+02
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 05/20/21
Time of Last Calibration : 16:41
Site Temperature at Cal : 2.59599 E+01

Bu SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:36:28
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 02035050
Intercept : -6.32910
Slope : -1.26827 E+02
Curvature or Slope 2 : 3.12078 E+02
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 05/20/21
Time of Last Calibration : 16:41
Site Temperature at Cal : 2.59599 E+01

Bc SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

SAMPLING
ON OFF

Aug 30 2
20:36:45
V9.7 176
OF10

LAB COMP:
TESTING COMPLETE

READY

OPTIONS - Calibration Parameters

Lot Number : 14455439
Intercept : -2.89140
Slope : 3.31061 E+01
Curvature or Slope 2 : -4.40866 E-01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 05/20/21
Time of Last Calibration : 16:40
Site Temperature at Cal : 2.59599 E+01

TBIL SERUM

>Press the ENTER key to move the cursor.

RETURN

RETURN HELP

READY

LAB COMP: TESTING COMPLETE
OPTIONS - Calibration Parameters

SAMPLING Aug 30 2
ON OFF 20:37:06
V9.7 176
OP1

Lot Number : 73274374
Intercept : 7.37548 E-01
Slope : 1.01395 E+02
Curvature or Slope 2 : 2.16937
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 04/17/21
Time of Last Calibration : 09:33
Site Temperature at Cal : 2.58099 E+01
Sub Dep Check, Density : 5.42432 E-01

First Pt Reference Value : 7.67695

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

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:37:26
V9.7 176
DP1

OPTIONS - Calibration Parameters

Lot Number : 65233419
Intercept : -4.25362
Slope : 1.00966 E+02
Curvature or Slope 2 : -7.95791 E-01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 03/26/21
Time of Last Calibration : 12:09
Site Temperature at Cal : 2.70599 E+01
Sub Dep Check, Density : 2.95009 E-01
First Pt Reference Value : 9.55418

ALKP SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:37:48
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 67022937
Intercept : -2.47843
Slope : 1.04063 E+02
Curvature or Slope 2 : -4.81729 E-02
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 04/17/21
Time of Last Calibration : 09:34
Site Temperature at Cal : 2.58099 E+01
Sub Dep Check, Density : 3.71189 E-01

First Pt Reference Value : 9.66870

GGT SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:38:10
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 07473876
Intercept : 5.26074
Slope : 1.01590 E+02
Curvature or Slope 2 : 5.01593 E-01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 08/27/21
Time of Last Calibration : 16:12
Site Temperature at Cal : 2.72199 E+01

TRIG SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

SAMPLING
ON OFF

Aug 30 2:
20:38:28
V9.7 176!
0P18

LAB COMP:
TESTING COMPLETE

READY

OPTIONS - Calibration Parameters

Lot Number : 08453757
Intercept : 2.92492
Slope : 9.30539 E+01
Curvature or Slope 2 : 1.35454
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 04/30/21
Time of Last Calibration : 13:50
Site Temperature at Cal : 2.67400 E+01

CHOL SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP: TESTING COMPLETE

SAMPLING ON OFF Aug 30 21 20:38:48 V9.7 1765 0P18

OPTIONS - Calibration Parameters

Lot Number : 11306859
 Intercept : 1.18445
 Slope : 7.83117 E+01
 Curvature or Slope 2 : 2.21582 E+01
 Blank Correction Coef : 0.00000

User Modified Calibration : N
 Date of Last Calibration : 07/17/21
 Time of Last Calibration : 16:20
 Site Temperature at Cal : 2.69000 E+01

dHDL SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

READY

LAB COMP:
TESTING COMPLETE

SAMPLING
ON OFF

Aug 30 2
20:39:14
V9.7 176
OP1

OPTIONS - Calibration Parameters

Lot Number : 56044323
Intercept : 3.99495 E-01
Slope : 1.02220 E+02
Curvature or Slope 2 : 3.90608 E-01
Blank Correction Coef : 0.00000

User Modified Calibration : N
Date of Last Calibration : 03/26/21
Time of Last Calibration : 12:08
Site Temperature at Cal : 2.69000 E+01
Sub Dep Check, Density : 6.04735 E-01

First Pt Reference Value : 3.77581

ALTV SERUM

>Press the ENTER key to move the cursor.

RETURN

HELP

TT3: Serum, Plasma (ng/mL)

23/8/2021
07:50:54

PROTOCOL/CAL VERSION: 01/1
REAGENT LOT NO.: 2430
CAL LOT NO.: 0148

STATUS: Complete

Level	Concentration	Light Units	Codes
1	0.059	1166.44	
2	1.09	479.042	
3	4.09	146.325	

QUALITY PARAMETERS

CURVE SHAPE PARAMETERS

Level	Spread(%)	Spread Limit(%)
1	0.00	13.00
2	0.00	13.00
3	0.00	13.00

a: 0.9696068
b: 0.4344096
c: 29.1955509
d: 0.0299530
n: 1.2915748

Level	Calibrator Signal Index
1	-0.21
2	-0.23
3	-0.28

CSL	Value
1	0.252
2	0.213
3	0.329
4	0.190

Print Date/Time: 31/8/2021 13:03:51

TT4: Serum, Plasma (ug/dL)

24/8/2021

09:13:14

PROTOCOL/CAL VERSION: 02/1
 REAGENT LOT NO.: 2462
 CAL LOT NO.: 0157

STATUS: Complete

Level	Concentration	Light Units	Codes
1	0.082	2808.04	
2	4.27	950.311	
3	15.1	353.258	

QUALITY PARAMETERS

Level	Spread(%)	Spread Limit(%)
1	0.00	26.40
2	0.00	26.40
3	0.00	26.40

CURVE SHAPE PARAMETERS

a: 0.9222108
 b: 1.5936868
 c: 36.3506126
 d: 0.0776470
 n: 1.3567666

Level	Calibrator Signal Index
1	-0.35
2	-0.32
3	-0.34

CSL	Value
1	0.110
2	0.158
3	0.289
4	0.157

Print Date/Time: 31/8/2021 13:03:23

TSH: Serum, Plasma (uIU/mL)

10/8/2021
11:11:34

PROTOCOL/CAL VERSION: 03/1
REAGENT LOT NO.: 6500
CAL LOT NO.: 0157

STATUS: Complete

Level	Concentration	Light Units	Codes
1	0.001	1.549	
2	0.082	39.305	
3	16.1	6754.39	

QUALITY PARAMETERS

Level	Spread(%)	Spread Limit(%)
1	0.00	50.00
2	0.00	12.50
3	0.00	12.50

CURVE SHAPE PARAMETERS

a: -0.0000596
b: 1.3103127
c: 0.3103172
d: 3.3506348
n: 0.9807131

Level	Calibrator Signal Index
1	0.02
2	-0.18
3	-0.18

CSL	Value
1	0.318
2	0.327
3	0.327
4	0.169

Print Date/Time: 31/8/2021 13:02:26