

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 DIAGNOSTICS/01
CALIBRATED FOR : PRIMA DIAGNOSTICS
LOCATION : MYSORE

CALIBRATION DATE : 20/11/2019
CALIBRATION DUE : 20/05/2020
CALIBRATED AT : IMMUNOLOGY

SPECIFICATION OF INSTRUMENT :

INSTRUMENT	MODEL	SERIAL NO
VITROS IMMUNODIAGNOSTICS SYSTEM	VITROS ECI	30004168
	J NUMBER	J30004168

Specification of Software:

SOFTWARE NAME	SOFTWARE VERSION
QNX os	V3.9

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

Installation Procedure Checklists:

Subsystem Name	Adjusted/Verified
1.Sample Supply Inspection	<input checked="" type="checkbox"/>
2.Sample Metering	<input checked="" type="checkbox"/>
* Sample Tray Tip Pickup & Sampling Center	
* Auxiliary Tip Supply	
* Sample Dispense	
* Outer Ring Mapping	
* Sample Metering Leak Test	
3.Reagent Supply	<input checked="" type="checkbox"/>
* Carousel to Well Shuttle	
* Well Shuttle – Positioning	
* Pack Opener (Home/Open/Close)	
* Outer Reagent – Alignment	
* Inner Reagent – Alignment	
* Well Top Alignment	
4.Reagent Metering	<input checked="" type="checkbox"/>
* Wash Station	
* Dispense	

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5.Processing Center	<input checked="" type="checkbox"/>
* Inner Lift Pin (Home/Shuttle/Read)	
* Inner/Outer rings Home Position	
* Incubator Shuttle	
* Incubator Temperature calibration	
6.Well Wash Assembly	<input checked="" type="checkbox"/>
* Well Wash Probe Horizontal Alignment	
* Inner Ring Mapping	
* Station Verification	
7.Signal Reagent Assembly	<input checked="" type="checkbox"/>
* Signal Reagent Probe – Horizontal Alignment	
* SR Dispense	
* SR Station Verification	
8.Luminometer	<input checked="" type="checkbox"/>
* Full Calibration (optional)	
* IRS Calibration	
9.Fluid Supply	<input checked="" type="checkbox"/>
* Pressure Regulator Calibration	
* Supply Level Calibration	

The results of comparison are as follows:

SUBSYSTEM NAME	CALIBRATION ACCURACY	
	RANGE	OBTAINED
SAMPLE METERING	AUTOMATIC	
REAGENT METERING DISPENSE CALIBRATION	4.90ML-5.10ML	5.0
REAGENT METERING OUTER PROBE WASH	2.05ML-2.55ML	2.2
WELL WASH ASPIRATION	1.8ML-2.4ML	2.1
WELL WASH DISPENSE	6.2ML-6.4ML	6.2
SIGNAL REAGENT DISPENSE PUMP A	9.99ML-10.01ML	10.0
SIGNAL REAGENT DISPENSE PUMP B	9.99ML-10.01ML	10.0

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CALIBRATED BY



KARTHIK K
(ENGINEER)
Ortho Clinical Diagnostics

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.