

Ortho Clinical Diagnostics

CALIBRATION CERTIFICATE

CERTIFICATE NO : OCD/SRI BALAJI CLINICAL
LABORATORY/002

CALIBRATION DATE : 14/03/2019

CALIBRATED FOR : SRI BALAJI CLINICAL
LABORATORY

CALIBRATION DUE : 13/09/2019

LOCATION : MANNARGUDI

CALIBRATED AT : LABORATORY

SPECIFICATION OF INSTRUMENT :

INSTRUMENT	MODEL	SERIAL NO
VITROS INTEGRATED SYSTEM	VITROS 5600	56001147

Specification of Software:

SOFTWARE NAME	SOFTWARE VERSION	UPDATED ON
<i>Qnx OS</i>	<i>V3.3.2</i>	<i>2019</i>

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.

Preventive Maintenance Procedure Checklists:

Subsystem Name

Adjusted/Verified

1. Sample Supply Inspection

2. Sample Metering

2.1. Micro Slide Metering

- * Versa Tip Pickup X, Y & Z
- * Versa Tip Eject X, Y & Z
- * Sample & Stat Tray X,Y & Z Position
- * Micro Slide CM/RT Tip Locator X, Y & Z
- * Tip Sealer X, Y & Z
- * Sample Metering Leak Test

2.2. Micro Immunoassay Metering

- * Versa Tip Pickup X, Y & Z
- * Versa Tip Eject X, Y & Z
- * Sample & Stat Tray X, Y & Z Position
- * Micro Well & Micro Tip Sample Dispense
- * Tip Sealer X, Y & Z
- * Cuvette Incubator X, Y & Z
- * Micro Well Incubator Mapping

3. ERF Metering & Wash Fluid Assembly

- * Metering Center

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- * Leak Test
- * WF Shuttle Home & Z
- * WF Metering Theta
- * WF Re-insert Blade
- * WF Shuttle Discard Position
- 4. Reagent Supply & Reagent Metering
 - * Versa Tip Pickup
 - * Supply 3 & 4 Pack Opener Theta & Z
 - * Supply 3 Ring Aspirate Position
 - * Supply 3 & 4 Z Mapping
 - * Supply 4 Well Dispensers
 - * Well Shuttle to Incubator
- 5. Slide Transport
 - * Dispense Blade Tip Locator
 - * Dispense Blade Centering Position
 - * PM Ring Depth
- 6. Processing Center
 - 6.1. Micro Slide Incubator
 - * PM Ring Stopping
 - * CM/RT Ring Stopping
 - * Depth of Insert Blades, CM & RT.
 - * Read Sync
 - 6.2. Micro Well Incubator
 - * Lift Pin Home Position (Inner, Middle, Outer & Read)
 - * Inner, Middle & Outer rings Home Position
 - * Outer & Middle Ring Well Drop
 - * Micro Immuno Assay Metering X, Y & Z
 - * Reagent Metering Dispense & Z (Outer & Middle)
 - * Micro Well Incubator Shuttle to Inner & Read
 - * Micro Well Incubator Outer & Middle Ring Mapping
 - * Read Lift Pin Measure
 - * Theta for Preliminary & Final Well Wash
 - * Station for Preliminary & Final Well Wash
 - * Inner Ring Mapping (Preliminary & Final Well Wash)
 - * Signal Reagent Dispense & Horizontal
 - * Signal Reagent Station
 - * Incubator Thermal calibration
 - 6.3. Cuvette Incubator
 - * Transport Arm (Pickup, Read, Discard)
 - * Transport Arm to Incubator Slot X, Y
- 7. Reflectometer Assembly
 - *Slide Dynamic Test

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- * Continuity Test
- 8. Fluid Supply
- * Pressure Regulator Calibration
- 9. Well Wash Assembly
- * Well Wash Dispense & Aspiration
- * Soak Volume Verification
- 10. Signal Reagent Assembly
- * SR Dispense Calibration
- 11. Luminometer
- * Full Calibration (optional)
- * IRS Calibration
- 12. Master Computer
- * Touch Screen Calibration
- * System Full Backup

The results of comparison are as follows:

SUBSYSTEM NAME	CALIBRATION ACCURACY		CORRECTION
	RANGE	OBTAINED	
PREWELL WASH ASPIRATION	2.0ML-3.0ML	2.7ML	0.1ML
FINALWELL WASH ASPIRATION	2.0ML-3.0ML	2.8 ML	0.0ML
PREWELL WASH DISPENSE	6.8ML-7.4ML	7.0ML	0.2ML
FINALWELL WASH DISPENSE	6.8ML-7.4ML	7.0ML	0.0ML
SIGNAL REAGENT DISPENSE PUMP A	9.99ML-10.01ML	10.0ML	0.0MI
SIGNAL REAGENT DISPENSE PUMP B	9.99ML-10.01ML	10.0MI	0.0MI

CALIBRATED BY



G.Karthikeyan.
Senior Territory Manager.
Ortho Care Service Support.

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.