Ortho Clinical Diagnostics
India Private Limited

# CALIBRATION CERTIFICATE

CERTIFICATE NO : OCD/MTH/5601
CALIBRATED FOR : MEDICAL TRUST HOSPITAL
LOCATION : KOCHI

CALIBRATED DATE : 26/07/2022
CALIBRATION DUE : 25/01/2023
CALIBRATED AT: LABORATORY

SPECIFICATION OF INSTRUMENT :

| INSTRUMENT | MODEL | SERIAL NO |
|---|---|---|
| VITROS INTEGRATED SYSTEM | VITROS 5600 | 56001407 |

*Specification of Software:*

| SOFTWARE NAME | SOFTWARE VERSION | UPDATED ON |
|---|---|---|
| *Qnx OS* | *V3.7.1* | *APR 2022* |

*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. MicroSlide 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 | |
| * Sample Metering Leak Test | |
| 3. ERF Metering & Wash Fluid Assembly | |
| * Metering Center | ☑ |
| * 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
* 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 | 0.0ML |
| FINALWELL WASH ASPIRATION | 2.0ML-3.0ML | 2.7 ML | 0.0ML |
| PREWELL WASH DISPENSE | 6.8ML-7.4ML | 7.1ML | 0.1ML |
| FINALWELL WASH DISPENSE | 6.8ML-7.4ML | 7.0ML | 0.0ML |
| SIGNAL REAGENT DISPENSE PUMP A | 9.99ML-10.01ML | 10.0ML | 0.0Ml |
| SIGNAL REAGENT DISPENSE PUMP B | 9.99ML-10.01ML | 10.0Ml | 0.0Ml |

CALLIBRATED BY

Mathew Abraham (Service Engineer)

CERTIFIED BY

Sherin Eapen (Zonal Manager –CTS)

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.