ISO/IEC 17025:2017
Certificate No.: CC-2705

CALIBRATION REPORT

Print Date: 18/10/202

STATUS : PASSED

DESCRIPTION : Single Channel Micropipette 20-200 µl

DEVICE ID : 22401818

Method ID : VV/20-200

ULR No. : CC270522000162912F

CALIBRATION DATE : 18/10/2022 12:00 PM

TERMINAL ID : 52

Location : Lucknow (Permanent Lab)

ENVIRONMENTAL FACTORS

TEMP : 25.00 °C **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

Vol (µl)	No	Cum Wt (mg)	Vol (µl)	Mean (µl)	SD (µl)	Inaccuracy E%		Imprecision CV%		
						Actual	Target	Actual	Target	Status
20.000	1	20.400	20.453	20.486	0.058	2.432	6.00	< 2.00	2.00	PASSED
	2	40.800	20.453							
	3	61.300	20.553							
100.000	1	99.300	99.558	99.658	0.265	0.342	1.20	< 0.40	0.40	PASSED
	2	198.500	99.458							
	3	298.200	99.959							
200.000	1	198.900	199.417	199.718	0.521	0.141	0.60	< 0.20	0.20	PASSED
	2	398.700	200.319							
	3	597.600	199.417							

Incharge Quality Control

Volume	Above 10 µl to 100 µl	Above 100 µl to 1000 µl	Above 1 ml to 10 ml	Above 10 ml to 100 ml
Uncertainty (k=2)	0.1 µl	0.1 µl	0.1 µl	4 µl

Based on data in the records.

- Specifications conform to ISO:8655 standards.
- Each instrument is individually calibrated on electronic balance.
- 750 mmHg = 99.98 kPa.
- Weight in mg or g.
- Volume, Mean & S.D. in ml or µl.

Reference standard

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.

ISO/IEC 17025:2017
Certificate No.: CC-2705

Print Date: 10/12/2022

CALIBRATION REPORT

STATUS : PASSED

DESCRIPTION : Single Channel Micropipette 2-20 µl

DEVICE ID : 22410831

CALIBRATION DATE : 10/12/2022 11:35 AM

Method ID : VV/2-20

TERMINAL ID : 52

ULR No. : CC270522000171108F

Location : Lucknow (Permanent Lab)

ENVIRONMENTAL FACTORS

TEMP : 25.00 °C **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

						Inaccuracy E%		Imprecision CV%		
Vol (µl)	No	Cum Wt (mg)	Vol (µl)	Mean (µl)	SD (µl)	Actual	Target	Actual	Target	Status
2.000	1	1.900	1.905	1.905	0.000	4.750	8.00	< 4.00	4.00	PASSED
	2	3.800	1.905							
	3	5.700	1.905							
10.000	1	10.000	10.026	9.959	0.058	0.407	1.60	< 0.80	0.80	PASSED
	2	19.900	9.926							
	3	29.800	9.926							
20.000	1	19.900	19.952	19.985	0.058	0.073	0.80	< 0.40	0.40	PASSED
	2	39.800	19.952							
	3	59.800	20.052							

Incharge Q.C. ISO:8655 Standards Quality Control

Volume	Above 10 µl to 100 µl	Above 100 µl to 1000 µl	Above 1 ml to 10 ml	Above 10 ml to 100 ml
Uncertainty (k=2)	0.1 µl	0.1 µl	0.1 µl	4 µl

Based on data in our records.

* Specifications conform to ISO:8655 standards.
* Each instrument is individually calibrated on electronic balance.
* 750 mmHg = 99.98 kPa.
* Weight in mg or g.
* Volume, Mean & S.D. in ml or µl.

Reference standard

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.

ISO/IEC 17025:2017
Certificate No.: CC-2705

Print Date: 8/10/2022

CALIBRATION REPORT

STATUS : PASSED

DESCRIPTION : Single Channel Micropipette 100-1000 µl

DEVICE ID : 22400095 **CALIBRATION DATE :** 8/10/2022 3:59 PM

Method ID : VV/100-1000 **TERMINAL ID :** 19

ULR No. : CC270522000161421F **Location :** Lucknow (Permanent Lab)

ENVIRONMENTAL FACTORS

TEMP : 25.00 ℃ **Z FACTOR :** 1.0026 mm³/mg **BARO. PRESSURE :** 80.00 KPa **REL. HUMIDITY :** 60.00%

CALIBRATION STATISTICS

Vol (µl)	No	Cum Wt (mg)	Vol (µl)	Mean (µl)	SD (µl)	Inaccuracy E%		Imprecision CV%		
						Actual	Target	Actual	Target	Status
100.000	1	99.000	99.257	99.191	0.209	0.809	6.00	< 2.00	2.00	PASSED
	2	197.700	98.957							
	3	296.800	99.358							
500.000	1	496.600	497.891	498.092	0.919	0.382	1.20	< 0.40	0.40	PASSED
	2	992.600	497.290							
	3	1490.400	499.094							
1000.000	1	995.300	997.888	998.122	0.405	0.188	0.60	< 0.20	0.20	PASSED
	2	1990.600	997.888							
	3	2986.600	998.590							

Incharge Of Quality Control

Volume	Above 10 µl to 100 µl	Above 100 µl to 1000 µl	Above 1 ml to 10 ml	Above 10 ml to 100 ml	
Uncertainty (k=2)	0.1 µl	0.1 µl	0.1 µl	4 µl	Based on data in the records

* Specifications conform to ISO:8655 standards.
* Each instrument is individually calibrated on electronic balance.
* 750 mmHg = 99.98 kPa.
* Weight in mg or g.
* Volume, Mean & S.D. in ml or µl.

Reference standard

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.

||M & P||

Measure & Precision Engineers

a unit of Institute of Applied Quality Management

ISO/IEC 17025 Accredited by NABL

CC-306

Issued to,
M/s: HLM Jeebansuraksha Hospital (Lupin Diagnostics)
Katjuridanga , Chhatna Road,
Bankura - 722102.

Form No.: M&P/LAB/FM/41
Cert. No M&P/LAB/LDL-HLMJ/02/CF-02/22-2
Issue Date: 11-Feb-2023
ULR : CC305923000000819F

CALIBRATION CERTIFICATE

Date of Calibration	Calibration Due on	Page No.
10-Feb-2023	**9-Feb-2024**	1 of 1

Service Request No. / Order No. : ---

Location of Calibration : At Site

Date of Receipt : 10-Feb-2023

Description of Instrument : **Centrifuge**
Make : REMI (Sl. No. ZHJN-38262)
Type/Model : R-8C
Range : Upto 4200 rpm
L/c. : 10 rpm

Identification No. : **LDL / HLMJ / SRA / CEN / 01**

Method of Calibration : M&P/LAB/SOP/01/MECH/19 (Comparison Method)

Details of Standard Equipment used for Calibration :

Description	Traceability certificate No.& Calibration Date	Valid upto	Calibration Agency
Digital Tachometer (I/d. MPE/S/DTM/01)	**2202084/M926/01,** Dated: 12.02.2022	12.02.2023	Essjay Technomeasure pvt.Ltd.
Traceability:Standard used for calibration traceable to national standards through NABL accredited laboratory			

Environmental Condition : Temperature: (25 ± 2) °C Humidity: (50 ± 10)%RH

CALIBRATION RESULTS

Sl. No.	Average DUC Value (Avg. of five Readings)	Average Std. Value (Avg. of five Readings)	Absolute Error	Expanded Uncertainty
	(rpm)	(rpm)	(rpm)	± (%)
1	2500	2498.9	1.1	
2	3000	2998.5	1.5	
3	3520	3518.1	1.9	**2.44**
4	3980	3977.5	2.5	
5	4200	4196.4	3.6	

*Measurement uncertainty at 95 % of confidence level & at a coverage factor of $k = 2$

Remarks: The above DUC has been calibrated over its above range & the readings obtained are tabulated above.

Note:
1. This certificate is refers only to the particular item submited for calibration.
2. Result reported are valid at the time of and under stated condition of measurement.
3. Next calibration due date is given as requested by the customer.
4. DUC*= Device Under Calibration.
5. Physical Status of the DUC is found OK.
6. This certificate shall not be reproduced except in full with out permission of head of laboratory.

Calibrated By:
S.Sardar
(Calibration Engineer)

Approved By:
S.Sen
(Technical Manager)

386/1 Diamond Harbour Road, Thakurpukur, Kolkata - 700 063
Phone : 033 24976080| Mobile : 9830562626, 9830953535, 8584885701| Email : mandpcal@gmail.com

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CC-3081

Issued to,
M/s: HLM Jeebansuraksha Hospital (Lupin Diagnostics)
Katjuridanga , Chhatna Road,
Bankura - 722102.

Form No.: **M&P/LAB/FM/41**
Cert. No: M&P/LAB/LDL-HLMJ/04/TM-02/22-23
Issue Date: 11-Feb-2023
ULR : CC305923000000821F

CALIBRATION CERTIFICATE

Date of Calibration	Calibration Due on	Page No.
10-Feb-2023	**9-Feb-2024**	1 of 1

Service Request / Order No. : ---
Location of Calibration : At Site
Date of Receipt : 10.02.2023
Description of Instrument : **Digital Timer of Centrifuge**
Make: : REMI (Sl. No. ZHJN-38262)
Model / Type: : R-8C
Range: : Upto 30 min
L/c.: : 1 min
Identification No. : **LDL / HLMJ / SRA / CEN / TM / 01**
Method of Calibration : M&P/LAB/SOP/03/ELECT/02 (Comparison Method)

Details of Standard Equipment used for Calibration :

Description	Traceability certificate No. & Calibration Date	Valid upto	Calibration Agency
Dig Time Totalizer (CTR-49)	**2205284/M926/MB/01,** Dated:27.05.2022	27.05.2023	Essjay Technomeasure Pvt. Ltd.
Traceability:Standard used for calibration traceable to national standards through NABL accredited laboratory			

Environmental Condition : Temperature: (25 ± 4) °C Humidity: (50 ± 20)%RH

CALIBRATION RESULTS

Sl. No.	Time set on DUC* (min)	Avg. Standard Value Shown by the Totalizer (Avg. of five Readings) (Sec:1/100Sec)	Absolute Error (s)	Expanded Uncertainty ± (s)
1	2	120.16	-0.16	35.01
2	5	300.26	-0.26	
3	8	480.31	-0.31	
4	10	600.45	-0.45	
5	15	900.48	-0.48	
6	20	1201.11	-1.11	
7	25	1501.22	-1.22	
8	30	1801.25	-1.25	

*Measurement uncertainty at 95 % of confidence level & at a coverage factor of $k = 2$

Remarks: The above DUC has been calibrated over its above range & the readings obtained are tabulated above.

Note:
1. This certificate is refers only to the particular item submited for calibration.
2. Result reported are valid at the time of and under stated condition of measurement.
3. Next calibration due date is given as requested by the customer.
4. DUC*= Device Under Calibration.
5. Physical Status of the DUC is found OK.
6. This certificate shall not be reproduced except in full with out permission of head of laboratory.

Calibrated By:
S.Bala
(Calibration Engineer)

Approved By:
S.Sen
(Technical Manager)

386/1 Diamond Harbour Road, Thakurpukur, Kolkata - 700 063
Phone : 033 24976080| Mobile : 9830562626, 9830953535, 8584885701| Email : mandpeel@...

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ISO/IEC 17025 Accredited by NABL

CC-3069

Issued to,
M/s: HLM Jeebansuraksha Hospital (Lupin Diagnostics)
Katjuridanga , Chhatna Road,
Bankura - 722102.

Form No.: M&P/LAB/FM/41
Cert. No M&P/LAB/LDL-HMLJ/01/CF-01/22-23
Issue Date: 11-Feb-2023
ULR : CC305923000000818F

CALIBRATION CERTIFICATE

Date of Calibration	Calibration Due on	Page No.
10-Feb-2023	**9-Feb-2024**	1 of 1

Service Request No. / Order No. : ---
Location of Calibration : At Site
Date of Receipt : 10-Feb-2023
Description of Instrument : **Centrifuge**
Make : REMI (Sl. No. ZHJN-38259)
Type/Model : R-8C
Range : Upto 4200 rpm
L/c. : 10 rpm
Identification No. : **LDL / HLMJ / CLP / CEN / 01**
Method of Calibration : M&P/LAB/SOP/01/MECH/19 (Comparison Method)

Details of Standard Equipment used for Calibration :

Description	Traceability certificate No.& Calibration Date	Valid upto	Calibration Agency
Digital Tachometer (I/d. MPE/S/DTM/01)	**2202084/M926/01,** Dated: 12.02.2022	12.02.2023	Essjay Technomeasure pvt.Ltd.
Traceability:Standard used for calibration traceable to national standards through NABL accredited laboratory			

Environmental Condition : Temperature: (25 ± 2) °C Humidity: (50 ± 10)%RH

CALIBRATION RESULTS

Sl. No.	Average DUC Value (Avg. of five Readings) (rpm)	Average Std. Value (Avg. of five Readings) (rpm)	Absolute Error (rpm)	Expanded Uncertainty ± (%)
1	2500	2498.6	1.4	**2.44**
2	3000	2997.6	2.4	
3	3520	3517.1	2.9	
4	3980	3976.2	3.8	
5	4200	4195.4	4.6	

*Measurement uncertainty at 95 % of confidence level & at a coverage factor of $k = 2$

Remarks: The above DUC has been calibrated over its above range & the readings obtained are tabulated above.

Note:
1. This certificate is refers only to the particular item submited for calibration.
2. Result reported are valid at the time of and under stated condition of measurement.
3. Next calibration due date is given as requested by the customer.
4. DUC*= Device Under Calibration.
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Calibrated By:
S.Sardar
(Calibration Engineer)

Approved By:
S.Sen
(Technical Manager)

386/1 Diamond Harbour Road, Thakurpukur, Kolkata - 700 063
Phone : 033 24976080 | Mobile : 9830562626, 9830953535, 8584885701 | Email : [illegible]

||M & P||

Measure & Precision Engineers

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ISO/IEC 17025 Accredited by NABL

Issued to,

M/s: HLM Jeebansuraksha Hospital (Lupin Diagnostics)
Katjuridanga , Chhatna Road,
Bankura - 722102.

Form No.: **M&P/LAB/FM/41**
Cert. No: M&P/LAB/LDL-HLMJ/03/TM-01/22-23
Issue Date: 11-Feb-2023
ULR : CC305923000000820F

CALIBRATION CERTIFICATE

Date of Calibration	Calibration Due on	Page No.
10-Feb-2023	**9-Feb-2024**	1 of 1

Service Request / Order No. : ---

Location of Calibration : At Site

Date of Receipt : 10.02.2023

Description of Instrument : **Digital Timer of Centrifuge**

Make: : REMI (Sl. No. ZHJN-38259)
Model / Type: : R-8C
Range: : Upto 30 min
L/c.: : 1 min

Identification No. : **LDL / HLMJ / CLP / CEN / TM / 01**

Method of Calibration : M&P/LAB/SOP/03/ELECT/02 (Comparison Method)

Details of Standard Equipment used for Calibration :

Description	Traceability certificate No. & Calibration Date	Valid upto	Calibration Agency
Dig Time Totalizer (CTR-49)	**2205284/M926/MB/01,** Dated:27.05.2022	27.05.2023	Essjay Technomeasure Pvt. Ltd.
Traceability:Standard used for calibration traceable to national standards through NABL accredited laboratory			

Environmental Condition : Temperature: (25 ± 4) °C Humidity: (50 ± 20)%RH

CALIBRATION RESULTS

Sl. No.	Time set on DUC* (min)	Avg. Standard Value Shown by the Totalizer (Avg. of five Readings) (Sec:1/100Sec)	Absolute Error (s)	Expanded Uncertainty ± (s)
1	2	120.21	-0.21	**35.01**
2	5	300.36	-0.36	
3	8	480.39	-0.39	
4	10	600.45	-0.45	
5	15	900.49	-0.49	
6	20	1201.02	-1.02	
7	25	1501.24	-1.24	
8	30	1801.32	-1.32	

*Measurement uncertainty at 95 % of confidence level & at a coverage factor of $k = 2$

Remarks: The above DUC has been calibrated over its above range & the readings obtained are tabulated above.

Note:
1. This certificate is refers only to the particular item submited for calibration.
2. Result reported are valid at the time of and under stated condition of measurement.
3. Next calibration due date is given as requested by the customer.
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Calibrated By:

S.Bala
(Calibration Engineer)

Approved By:

S.Sen
(Technical Manager)

386/1 Diamond Harbour Road, Thakurpukur, Kolkata - 700 063
Phone : 033 24976080 | Mobile : 9830562626, 9830953535, 8584885701 | Email : mandpcal@gmail.com

Ortho Clinical Diagnostics

INSTALLATION QUALIFICATION

For

VITROS 250

Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. Approval of the IQ procedure

Both **Lupin Health Care Ltd.** and Ortho-Clinical Diagnostics are jointly responsible for the installation of VITROS 250, **Sr. No. 27001093** in the Central Laboratory of **Jeevan Surakha Hospital, Bankura.**

Protocol Performed By: **Ortho-Clinical Diagnostics Representative**

Name	:	Mr. JAYANTA PAUL	Signature:
Designation	:	Service Engineer	Date: 25-10-2021
Company	:	Ortho-Clinical Diagnostics	

Validation Team from:

Name	:	Amit Lava	Signature:
Designation	:	Lab Tech.	Date: 25-10-2021
Department	:	Bio Chemistry	
Name	:	Mousumi Ghel	Signature :
Designation	:	Lab Technician	Date : 25/10/2021
Department	:	Biochemistry	

Customer Authorizations:

Name	:	Swarup Saini	LUPIN DIAGNOSTICS Katjuridanga, Chhatna Road Bankura, Pin- 722102
Designation	:	Sr. Lab Tech.	Signature:
Site	:	Lupin Diagnostics (Bankura)	Date: 25-10-2021

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is installed and set up for operation.

2. An authorized Ortho Clinical Diagnostics representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be initialed and dated.

3. Employees of (customer) **Lupin Health Care Ltd.** will verify each result and sign in the last page.

4. ALL deviations from normal specification to include any problems with installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this installation protocol for the same.

5. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization from Ortho-Clinical Diagnostics and **Lupin Health Care Ltd.**

III. SCOPE

This Installation Qualification protocol will be performed on the VITROS 250 bearing Sr. No. **27001093** located at Central lab Department, **Lupin Health Care Ltd.** This Installation protocol will define the documentation that will be used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the Instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

IV. Ancillary Information.

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument installed on 23/10/2021 is in compliance with the specifications of the purchase order.

Verified By: Mr. JAYANTA PAUL Date: 23/10/2021

b. Utilities

Sr. No	Utility	Verified by	Date
1.	**Environmental conditions:**	Mr. JAYANTA PAUL	23/10/2021
	a. Analyzer will be placed away from the direct sunlight.	,,	,,
	b. Installation site shall be free from dust, significant vibrations and shall be well ventilated.	,,	,,
	c. Installation site floor construction shall be able to support approximately 272 kg.	,,	,,
	d. Room temperature will be maintained between 15^0C to 27^0C and the temperature fluctuation during analysis shall not be more than ± 2^0C.	,,	,,
	e. The analyzer shall be kept away from strong electromagnetic sources and electrical interferences.	,,	,,
	f. It will be kept near to the power sources.	,,	,,
	g. Maximum relative humidity allowed up to 70%.	,,	,,
	h. If the temperature and humidity fluctuations are not within the specified range, the analyzer cannot maintain data reliability.	,,	,,
2.	Adequate space for installation will be provided on all 5 sides of the instrument [1.15m (L) x 71m (W) x 1.2m (H)]	,,	,,
3.	Electrical Outlets: Actual Voltage on site [AC 220-230 Volts 16A 50 HZ]	,,	,,

Note: Document any significant changes in Comments section on page 12.

c. The instrument has been verified for the following

Sr. No.	Verification		Verified by	Date
1.	Instrument is identified	Yes	Mr. JAYANTA PAUL	23/10/2021
2.	Manufacturer's specifications are included	Yes	"	"
3.	Accessories / Consumables are listed	Yes	"	"
4.	Equipment manual from the manufacturer is documented	Yes	"	"
5.	Manufacturer's Certificate attached	Yes	"	"

V. Installation Qualification

a. Equipment Description

The VITROS 250 is a fully automated Dry chemistry analyzer

Instrument Identification		Verified by	Date
Equipment Name:	Dry Chemistry Analyzer	Mr. JAYANTA PAUL	23/10/2021
Manufacturer:	Ortho-Clinical Diagnostics	"	"
Model:	*VITROS 250*	"	"
Serial Number:	27001093	"	"
Size (in cm):	115 (L) x 71 (W) x 120 (H)	"	"
Power:	AC 220-230 V 16A 50Hz±2Hz	"	"
Power consumption:	6880KW hours per year	"	"

b. Accessories/Consumables

The following accessories were supplied with the instrument. Check (✔) 'verified by' in case they are found to be in order.

START UP KIT	**1H4182**		
	353999	250 TIP RACK	1 no.
	354009	250 MICRO COLLECTION TUBE ADAPTER	1 no.
	354007	250 SAMPLE CUP ADAPTER	1 no.
	354000	250 UNIVERSAL SAMPLE TRAY	1 no.
	354011	250 DILUENT TRAY	1 no.
	354002	250 HEIGHT ADAPTER	1 no.
	353671	LINE CORD CONTINENTAL	1 no.
	354004	MIXING CUP ARRAY	1 no.
	8251878	CAL DISK (ver. 5609)	1 no.
	8321622	CLIN CHEM PROD INSTRUCTION USE	1 no.
	6801855/8175333	250 SYS SOFTWARE (ver. 9.2)	1 no.

250 ANALYZER SPARE PART KIT	**356704**		
	355637	Air Filter	1 no.
	TL 3225	Serial Loop Back Connector TL 3225	1 no.
	999339	10 ml Diluent Vials (3 Nos)	1 no.
	999340	5 ml Diluent Vials (3 Nos)	1 no.
	1C3197	Dispense blade	1 no.
	3380/3381	Wrist strap Elastic	1 no.
	J02315	White Reference Slide Box	1 no.
	J02316	Black Reference Slide Box	1 no.
	356666	Lamp	1 no.
	583561	Lamp Extractor	1 no.
	995298	RM / IR TL 4538	1 no.
	356864	Reservoir Seal (3 Nos)	1 no.
	356497	Reservoir Cap (3 Nos)	1 no.
	J02253 / J02255	Evaporation Cap (23 Nos)	1 no.
	1H0116	Evaporation Cap Spring (5 Nos)	1 no.
	339739	Proboscis Screw (2 Nos)	1 no.
	994654	Tubing (2 Nos)	1 no.
	356526	Read Sync Tool TL 4502	1 no.

Monitor with stand	1 no.
Touch Screen	1 no.

A. List of Manuals, Certificates and Drawings:

Ortho Clinical Diagnostics provides the following with the instrument.

8986507	250 REFERENCE SET consist of:	1 set
	119017 - Operators Manual	1 no.
	1053032 - Operators Quick Guide	1 no.
	8044505 - Maintenance & Diag. Guide	1 no.
	J04190 - Accessories Guide	1 no.

B. Change Control Procedure:

The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Ortho Clinical Diagnostics and Micro Therapeutic Research Labs Pvt. Ltd., Chennai.

C. Maintenance:

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the operations manual. The maintenance procedures will be filed separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Ortho Clinical Diagnostics offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining GLP/GMP compliance. Contacting your local representative and requesting for additional Service Agreement can supply additional information.

D. Spare Parts:

Ortho Clinical Diagnostics recommends the end user to maintain a basic of consumable parts onsite to minimize down time due to minor failures. The list of such consumable parts provided by them is included in the Operator's Manual.

G. Installation Procedure:

1. Installation Process:

The analyzer PC comes with preinstalled Analyzer Application Software. For any reasons, if the software is to be installed on another PC, the PC will meet the following requirements.

Environment	System Requirement
Desktop	PII
Key Board	English Key Board or Standard 101/102 or Microsoft Natural Key Board
Operating System	Qunix
Port	➢ 2 ports for printer ➢ One port for LIS
Regional settings	➢ Language English.

The system has a preloaded operating software

The Analyser has been installed satisfactorily: No ☐ Yes ☑

Verified by : Mr. JAYANTA PAUL Date: 23/10/2021

VI. COMMENTS:

VII. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. JAYANTA PAUL

Designation : Service Engineer

Company : Ortho Clinical Diagnostics

Signature:

Date: 25-10-2021

Customer Authorizations:

Name : Saramp saini

Designation : Sr. Lab Tech.

Organization : Lupin Diagnostics (Bankura)

LUPIN DIAGNOSTICS
Katjuridanga, Chhatna Road
Bankura, Pin- 722102

Signature:

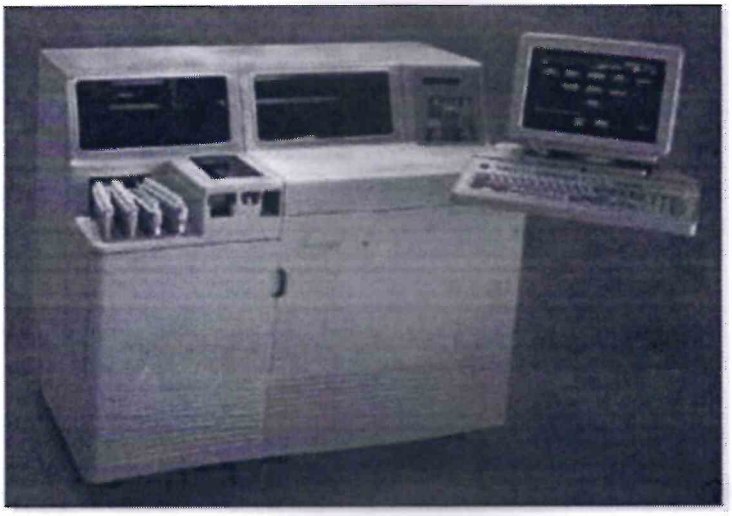
Date: 25-10-2021

Ortho Clinical Diagnostics

OPERATION QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. Approval of the IQ procedure

Both **Lupin Health Care Ltd.** and Ortho Clinical Diagnostics are jointly responsible for the Operation qualification of VITROS 250, **Sr. No. 27001093** in the Central Laboratory of **Jeevan Surakha Hospital** as per the Operational Qualification Protocol.

Protocol Performed By: **Ortho Clinical Diagnostics Representative**

Name	:	Mr. JAYANTA PAUL	Signature:
Designation	:	Service Engineer	
Company	:	Ortho Clinical Diagnostics	Date: 26-10-2021

Validation Team from:

Name	:	Amit Laha	Signature:
Designation	:	Lab Tech.	Date: 26.10.2021
Department	:	Bio chemistry	
Name	:	Mousumi Chel	Signature :
Designation	:	Lab Technician	Date : 26/10/2021
Department	:	Bio Chemistry	

Customer Authorizations:

Name	:	Swarup Saini	LUPIN DIAGNOSTICS Katjuridanga, Chhatna Road Bankura-722102
Designation	:	Sr. Lab Tech.	Signature:
Site	:	Lupin Diagnostics (Bankura)	Date: 26-10-2021

II. INSTRUCTIONS

1. An authorized Ortho Clinical Diagnostics representative will check each module and enter the specific data as outlined in the Operational Qualification. Each result will be noted and dated.

2. The concerned employees of **Lupin Health Care Ltd.** will verify each result and sign in the each page. The member of the validation team will carry this out.

3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the OQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

III. SCOPE

This Operational Qualification protocol will be performed on the VITROS 250, **Sr.No. 27001093** located at Biochemistry Department, **Lupin Health Care Ltd.** This OQ protocol will define the documentation that will be used to evaluate the completion of the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

OPERATIONAL QUALIFICATION:

A. Instrument Identification

a. **Model Name:** VITROS 250

2. **Serial Number:** 27001093

B. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Mr. JAYANTA PAUL 24/10/2021
02	Daily maintenance	To clean appropriate modules so as to maintain accuracy and precision	”
03	Inventory of reagents and consumables	To check the slide supply of installed Vitros 250	”
04	Calibration for the assays used	To calibrate the system for every new lot of assay	”
05	QC check	To confirm that systems, reagents & consumables are acceptable and working within specifications for each assay used	”
06	Sample programming and Analysis	To run the samples	”

Test: 1: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error code.

Procedure:

- Check the room temperature and switch on the Air Conditioner.
- Check the UPS.
- Switch on the Vitros V 250 system by pressing the main switch and hold it for about 10 – 15 sec.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays "READY" on the status console
- If not, initialize by pressing the initialize button on the error code screen
- Follow instructions provided for the error codes

Acceptance criteria: System to display READY status

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification: "READY" on Status console

Test: 2: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol on the display

Method:

Refer detailed procedure for Daily Maintenance

Sr No	Activity	Done by	Date
01	Empty waste container	SUMAN OJHA	25/10/2021
02	Clean ERF Reservoir Holder & Base	"	"
03	Replace ERF Reservoir	"	"
04	Replace ERF Tip	"	"
05	Clean ERF Tip Sleeve	"	"
06	Clean IWF Reservoir Holder & Base	"	"
07	Replace IWF Reservoir	"	"
08	Replace IWF Tip	"	"
09	Clean IWF Tip Sleeve	"	"
10	Load supplies and remove outdated and empty reagents	"	"
11	Perform Quality Control	"	"

Acceptance criteria System should be "Ready" after daily maintenance without any error

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification: System found "Ready" after daily maintenance

Test: 3: Inventory of reagents and consumables

Purpose: To check the reagent management module of VITROS 250 Dry Chemistry system

Procedure:

Sr No	Activity	Done By	Date
01	Loading of Reagent cartridge in the appropriate slide supply – Supply 1 and Supply 2.	SUMAN OJHA	25/10/2021
02	Verify the status of reagents loaded.	”	”

Acceptance criteria:

- **No error codes**
- **All reagents should show “Ready”/cal status**

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification: No Error codes

Test: 4: Calibration of the assays used

Purpose: To calibrate the system for every new lot of assay

Procedure:

Sr. No.	Activity	Done By	Date
01	Reconstitution of the cal kits for appropriate reagent	SUMAN OJHA	26/10/2021
02	Performing Calibration with calibration programming screen	"	"
03	Verification of Calibration report	"	"

Acceptance criteria: "Calibration Successful" should come on screen

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification : "Calibration Successful" found and the report of the same from the analyzer

Test: 5: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

Sr. No.	Activity	Done By	Date
01	Preparing Liquid or Lyophilized control fluids	SUMAN OJHA	26/10/2021
02	Creating QC file	"	"
03	QC sample programming and analysis	"	"
04	Verification of QC results obtained	"	"

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification: QC values within ± 2SD

Test: 6: Sample programming and Analysis

Purpose: To run the samples

Procedure:

Sr. No.	Activity	Done By	Date
01	Loading and Processing of samples	SUMAN OJHA	26/10/2021
02	Programming samples	"	"
03	Unloading the samples	"	"
04	Viewing samples in process	"	"
05	Review results: Monitoring results	"	"

Acceptance criteria: **Samples Analysis & Report without any error**

PARAMETER	PASS	FAIL
	PASSES	

Parameter values for verification: Sample analysis & Report without any error

H. Operational procedure:

a. Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

Mr. SUMAN OJHA from Ortho Clinical Diagnostics has conducted the training.

Sr. No.	Training program	Initials	Date
1.	Instrument Setup	SUMAN OJHA	26/10/2021
2.	System Operation	"	"
3.	Calibration	"	"
4.	Quality Control	"	"
5.	Maintenance	"	"
6.	Basic trouble shooting	"	"

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

Sr. No.	Operators	Department	Initials	Date
1.	SWARUP SAINI	Central lab	SS	26.10.21
2.	ANATHBANDHU ROY	"	ABRoy	26.10.21
3.	MOUSUMI CHEL SEBAIT	"	Mousumi Chel Sebait	26.10.21

V. COMMENTS:

VI. SYSTEM CERTIFICATION:

Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. JAYANTA PAUL

Designation : Service Engineer

Company : Ortho Clinical Diagnostics

Signature:

Date: 26-10-2021

Customer Authorizations:

Name : SWARUP SAINI

Designation : SR. LAB TECHNICIAN

Organization : HIMJSH

LUPIN DIAGNOSTICS
Katjuridanga, Chhatna Road
Bankura, Pin- 722102

Signature :

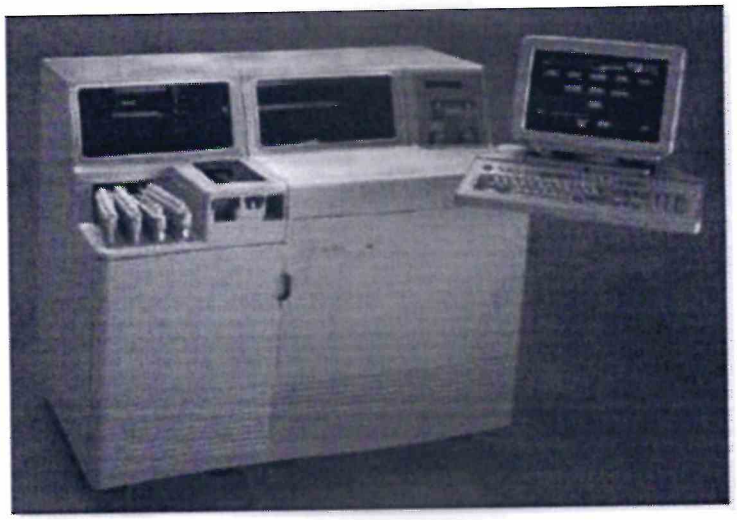
Date : 26-10-2021

Ortho Clinical Diagnostics

PERFORMANCE QUALIFICATION

For

VITROS 250



Manufactured by:
Ortho Clinical Diagnostics, Inc., US

Table of Contents

I. Approval of the PQ procedure

Both **Lupin Health Care Ltd.** and Ortho Clinical Diagnostics are jointly responsible for conducting the Performance Check of the Biochemistry Analyzer, Model – VITROS 250, **Serial. No. 27001093** in the Central lab Department of c/o: **Jeevan Surakha Hospital** as per the attached protocol.

Protocol Performed By: Ortho Clinical Diagnostics Representative

Name : Mr. SUMAN OJHA Signature:

Designation : Application Date: 27-10-2021

Company : Ortho clinical Diagnostics

Validation Team from:

Name : AMIT LAHA Signature:

Designation : Lab Technician Date: 27-10-2021

Department : Bio chemistry

Name : Mousumi Ghee Signature :

Designation : Lab Technician Date : 27/10/2021

Department : Biochemistry

Customer Authorizations:

Name : Sewarup Saini

Designation : Sr. Lab Tech.

Site : Lupin diagnostics.

LUPIN DIAGNOSTICS
Katjuridanga, Chhatna Road
Bankura, Pin- 722102
Signature:

Date: 27-10-2021

II. Instructions.

1. An authorized Ortho Clinical Diagnostics representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.

2. Performance checks on a regular basis described in the Further Performance Checks will be the responsibility of customer's personnel.

3. Employees of **Lupin Health Care Ltd.** will verify each result and sign in the last page.

4. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the PQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

5. Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.

6. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by **Lupin Health Care Ltd.** and Ortho-Clinical Diagnostics.

III. Scope

This Performance Qualification protocol will be performed on the VITROS 250 **Serial No. 27001093** located in Central lab Department of **Jeevan Surakha Hospital** located in **Bankura**. This Performance qualification protocol will define the documentation that will be used to evaluate the instrument operation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the Performance qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All data will be documented.

IV. Performance Qualification

A. Instrument Identification

Verified Date

1. Model Name: VITROS 250 — 27/10/2021
2. Serial Number: 27001093

B. Following is a list of tests to be performed and verified:

Sr.No	Test Name	Test Purpose	Initial / Date
01	QC Run	To see the performance of quality control material on the equipment on selected assay parameters as per the specifications given	SUMAN OJHA 27/10/2021
02	Accuracy Study	To compare the obtained value with true values of processed control.	,,
03	Precision Study	To check the precision performance of the equipment	,,

C. Performance Testing:

Test I

Test Name : **QC Run**

Purpose : To see the performance of quality control material on the equipment as per the specifications given

Method : Microslide – Rate Chemistry
Microslide - Endpoint Chemistry
Microslide – Potentiometric Chemistry;
Microslide – Immunorate Chemistry;

Analysis of controls:

Note: Analyze controls for: ALT (Microslide Rate Chemistry);
Amylase (Microslide – Two point rate Chemistry);
Sodium (Potentiometric Chemistry);
Potassium (Potentiometric Chemistry);
Phenytoin (Microslide – Immunorate Chemistry)

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 250 Chemistry System Operator's manual – Quality Control	Remarks Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	"Instructions for use" of QC material	Pass	27/10/2021
02	Creating QC file	Quality Control – Define control fluids	Pass	"
03	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	"

Test II

Test Name : **Accuracy**

Purpose : To see the accuracy of obtained quality control value in comparison with the expected mean values.

Method : Microslide method as mentioned above

Analysis of controls:

Note: Analyze controls as mentioned above.

Sr. No.	Activity	Procedure done as per the protocol defined in VITROS 250 System Operator's manual - Quality Control	Remarks Pass/Fail	Done By Date
01	Preparing Liquid or Lyophilized control fluids	'Instructions for use' of QC material	Pass	27/10/2021
02	QC sample programming and analysis	Quality Control – Process Control fluid samples & Review the Control sample results.	Pass	,,
03	Accuracy Analysis	Compare the obtained Q.C value with mean of expected value as mentioned in the Performance verifier / QC Value chart.	Pass	,,

Test III:

Test Name : Precision Study (As per criteria attached)

Purpose : To estimate the imprecision or random error of the analytical method

Procedure:

Analyze Performance Verifier Level 1 control for all Parameters (1 x 5 times).

Calculate the Mean, SD and CV%.

Acceptance Criteria:

Sr. No.	Analyte	Control Level	Precision Limit
01	ALT	PV I	≤ 2.3 SD
02	Amylase	PV I	≤ 3.9 SD
03	Sodium	PV I	≤ 0.8% CV
04	Potassium	PV I	≤ 1.0% CV
05	CRBM	TDM	≤ 4 % CV

COMMENTS:

V. System Certification

Study data has determined that the VITROS 250 Dry Chemistry system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: Ortho Clinical Diagnostics Representative

Name : SUMAN OJHA
Designation : Application
Company : Ortho Clinical Diagnostics

Signature:
Date: 27-10-2021

Validation Team from:

Name : Amit Lohar
Designation : Lab Tech.
Department : Bio chemistry

Signature:
Date: 27.10.2021

Name : Mousumi Ghosh
Designation : Lab Technician
Department : Biochemistry

Signature :
Date : 27/10/2021

Customer Authorizations:

Name : Swaraj saini
Designation : Sr. Lab Tech.
Site : Lupin Diagnostics

LUPIN DIAGNOSTICS
Katjuridanga, Chhatna Road
Bankura, Pin- 722102

Signature:
Date: 27-10-2021

Ortho Clinical Diagnostics

PM & CALIBRATION CERTIFICATE

This is to certify that the System Maintenance & Calibration (Preventive Maintenance) was performed on **6th June ,2022** for the machine, **Vitros 250** (S/N-**27001093**) installed at **Lupin Diagnostics Jeeban Suraksha Hospital Bankura.**

The system's calibration includes checking the performance of the instrument as per the guidelines provided by the manufacturer. The next System's calibration is due on December 2022.

Dipankar Majumdar

Area Service Manager- Ortho Care

Date: 07.06.2022

Ortho Clinical Diagnostics India Private Limited
Office : 3A, Auckland Place, Suite 6B, 6th Floor, Kolkata - 700017.
CIN: U51397MH2015FTC262650
Email ID: connectood@orthoclinicaldiagnostics.com
Website: www.orthoclinicaldiagnostics.com

Ortho Clinical Diagnostics

PM & CALIBRATION CERTIFICATE

This is to certify that the System Maintenance & Calibration (Preventive Maintenance) was performed on **5th December ,2022** for the machine, **Vitros 250** (S/N-**27001093**) installed at **Lupin Diagnostics Jeeban Suraksha Hospital Bankura.**

The system's calibration includes checking the performance of the instrument as per the guidelines provided by the manufacturer. The next System's calibration is due on June 2023.

Dipankar Majumdar

Area Service Manager- Ortho Care

Date: 5.12.2022

Ortho Clinical Diagnostics India Private Limited
Office : 3A, Auckland Place, Suite 6B, 6th Floor, Kolkata - 700017.
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Website: www.orthoclinicaldiagnostics.com