



CC-2725

**CERTIFICATE OF CALIBRATION**

Page No: 1 of 1

Certificate No: CC-22-23-L-495/13

Customer Name & Address M/s. MEDLINE DIAGNOSTICS (PVT) LTD. No. 23-A, Thennur High Road, Tiruchirappalli, Tamil Nadu - 620 017.	ULR No.	CC272522000008192F
	SRF No.	VCI-22-23-L-495
	Date of Receipt	28.11.2022
	Date of Calibration	28.11.2022
	Due Date for Calibration	27.11.2023
	Date of Issue	29.11.2022

Details of Unit Under Calibration

Description	Digital Tachometer	Make / Model	Lutron /DT-2234C
Range	2.5 to 99999 rpm	Type	Non-Contact
Resolution	0.1 rpm/ 1 rpm	Condition of UUC	Good
Serial Number	S320247	Instrument Location	-
ID Number	--	Cal. At	At Lab

Environmental Condition		Calibration Method Used	
Temperature (°C)	23±2	National / International Standard	TR 45
Humidity (%RH)	40-70	Cal Procedure No	VCI-L03-WI-SPE-001

Standard Used

Sl. No.	Description	ID.No. / SI. No.	Certificate No.	Make/Model	Traceability	Valid till
1	Digital Tachometer	VCI-M-TM-012 / S016271	2021-22/EQN/2202129-01	Mextech / DT-2236C	National Standards	28.02.2023

Results of Calibration

Sl. No.	UUC Reading (rpm)	Standard Reading (rpm)	Error (rpm)	Measurement Uncertainty (±) (%)
01	100.4	100.6	-0.2	3.50
02	500.3	500.6	-0.3	0.60
03	1016	1020	-4	0.67
04	50149	50155	-6	0.60
05	89865	89873	-8	0.60

Remarks:

- UUC is Defined as the Unit Under Calibration.
- This Calibration Certificate Results relates only to the above UUC & This report shall not be reproduced except in full/ part without approval of the Venus Calibration and Instruments.
- The reported results are valid at the time of under stated condition of measurement.
- Calibration of the UUC are traceable to National / International Standards.
- The recalibration interval shall be decided by the user.
- Nabl-133 guidelines are adopted for use of NABL symbol.
- The Measurement uncertainty is expressed at 95.45% confidence level with coverage factor $k=2$.

Checked & Issued by:

R. Bhuvaneshwari
R. Bhuvaneshwari
(Engineer - Calibration)



Authorised by:

C. Dhinakaran
(Technical / Quality Manager)

No.16, 6th Street, Annai Sathya Nagar, Poothapedu Ramapuram, Chennai - 89.

Ph: +91 44 2476 0533 /0633, Mob: 90031 20649, 9789893643, 8807402558

e: venuscallab@gmail.com, info@venuscal.com | www.venuscal.com



Thrissur Office:

Thattil Nadakalan Complex, Kuriachira P.O.,

Thrissur - 680 006, INDIA.

Tel.: (0487) 2250793, 6544048. Mobile No.: 9645084048.

E-mail: tulipkerala@gmail.com

10.07.2022

CALIBRATION CERTIFICATE

This is to certify that, **EVOLUTION 3000** Semi-Automatic Analyzer bearing Serial No **42229**

Installed at, M/S **MEDLINE DIAGNOSTICS P LTD, NO 23-A, THENNUR HIGH ROAD, TIRUCHIRAPPALLI, TAMILNADU-620017** is performing satisfactorily.

EVOLUTION 3000 is calibrated last on **10.07.2022** by our Service Engineer,

Mr. S. JAWAHAR

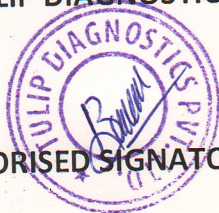
Following checks have been performed:

1. Peristaltic Pump Cleaned
2. Cleaned flowcell & Tubings
3. Adjusted Lamp Gain.
4. Checked all the Voltage.

Next Calibration Due on **09.07.2023**

For **TULIP DIAGNOSTICS (P) LTD**

AUTHORISED SIGNATORY



IQ/OQ/PQ Protocol

Installation Qualification
Operational Qualification
Performance Qualification

Instrument name: Csense 200^{CD}

Serial No.: 0532401014 IEC

D.O.I. : 28/06/2022

Customer Details

MEDLINE DIAGNOSTICS PVT. LTD

NO. 23-A, NEAR THENNUR BRIDGE

TRICHY-700083, TAMIL NADU

CONTACT NO- 7421857777



Medsource Ozone Biomedical Pvt. Ltd.

Corporate office: Plot No109, HSIIDC, Sector-31,
Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612
Email mail@ozonebio.com, Website: www.ozonebio.com.

Installation Qualification

To verify that the facilities provided for the installation of fully automated Biochemistry analyzer meets the requirements for the system and that all components of the system have been delivered, ready for installation in accordance with the standard for the system and other appropriate regulations.

Purpose: The purpose of the installation qualification (IQ) is to confirm that the instrument is installed as per the requirement.

S.No.	Parameter	Expected Result	Observed	Remarks
1	Ground voltage (voltage between neutral and earth)	< 3V	1V	OK.
2	Line voltage (voltage between line and neutral)	180V to 245V	232V	OK.
3	Capacity of online ups	>2 KVA	5 KVA	OK
4	Installation space	The gap between the analyzer and wall must not be less than 0.5m		OK
Unpacking				
Caution: Unpacking and lifting is 2 persons job				
4	Package inspection	No damage and sealed		OK
		Inspection of accessory supplied		OK
		Accessory box included computer		OK

- The analyzer passed the installation qualification
- The analyzer didn't pass the installation qualification

Special Note: Installation report attached.

Engineer name and signature



Customer name and signature



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Csense 200^{CD} IQ/OQ/PQ

Operational Qualification

Purpose: The purpose of the operational qualification (OQ) is to ensure that the system can be operated as expected and to devise the standard operating procedure.

S no	Parameter	Expected result	Result
1	Switch ON the instrument and Run self check	Software started with no error message	OK
2	Check the reagent cooling	Reagent components starts cooling	OK
3	Position of Probe	Probe should be in the wash station	OK
4	Functionality of Probe level sensor	Responding with green LED ON/OFF	OK
5	Functionality check of mixer motor.	Judge whether the mixer is in the centre of the test cuvette/cleaning pool and whether you can hear the sound of rubbing up against the wall at the time of rotation	OK
6	Installation of all system pack reagents, Calibration and QC data	Installed	OK
7	Place any of three reagent bottle and test volume	All volumes have to be recognized.	OK
8	Training	Have all users been properly trained on the safety, theory of operation and maintenance of the Csense 200 ^{CD} ?	OK

- The analyzer passed the operational qualification
- The analyzer didn't pass the operational qualification

Special note:

Engineer name and signature



Customer name and signature



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Performance Qualification


Purpose: The purpose of the performance qualification (PQ) is to confirm that the instrument is installed and performed as per requirement.

S no	Parameter	Expected result	Obtained value	Result
1	AD Values of 340nm	20,000 to 60,000	52400	OK
2	AD Values of 405nm	20,000 to 60,000	53300	OK
3	AD Values of 510nm	20,000 to 60,000	54700	OK
4	AD Values of 546nm	20,000 to 60,000	51700	OK
5	AD Values of 578nm	20,000 to 60,000	53400	OK
6	AD Values of 630nm	20,000 to 60,000	52900	OK
7	AD Values of 670nm	20,000 to 60,000	51700	OK
8	Accuracy study	The results of both QC samples should be in the specified range		OK
9	Precision study	The CV in % should be lesser than 5% for each test		OK

Reports Print out	Expected	Remarks
Reports of both QC performed	Attached printout/ Saved file name and location	✓
Reports of precision study done	Attached printout/ Saved file name and location	✓

- The analyzer passed the performance qualification
- The analyzer didn't pass the performance qualification

Special note:



 Engineer name and signature



Medsource Ozone Biomedicals Pvt. Ltd.

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 Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612
 Email mail@ozonebio.com, Website: www.ozonebio.com.



Certificate Of Calibration

- INSTRUMENT NAME : ADAMS 8380 V
- INSTRUMENT SERIAL NO. : 61909001
- CALIBRATION DATE : 07-09-2022
- DUE DATE OF CALIBRATION : 06-09-2023

CALIBRATION STATUS

Calibrator Lot : C1L0M52

Calibration Error Range : 3.0%

	Value Obtained (mmol/mol)	Mean (mmol/mol)	Target Value(mmol/mol)
Low Calibrator	30.0	30.1	34
	30.2		
	30.1		
High Calibrator	88.2	88.3	93
	88.4		
	88.3		

This is to Certify that ADAMS-8380V installed at Medline Diagnostics (Trichy , Tamilnadu) has been calibrated successfully.

**The results obtained are satisfactory within acceptable range.
The supporting documents attached with this certificate.**

For, Arkray Healthcare Pvt Ltd. <i>P. Sulthan Ahmed</i> Sulthan Ahmed P, (Application specialist, Chennai)	Customer's Signature and Stamp
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CC-2725

**CERTIFICATE OF CALIBRATION**

Page No : 1 of 1

Certificate No: CC-22-23-L-495/03		ULR No.	CC27252200008182F
Customer Name & Address M/s. MEDLINE DIAGNOSTICS (PVT) LTD. No. 23-A, Thennur High Road, Tiruchirappalli, Tamil Nadu - 620 017.		SRF No.	VCI-22-23-L-495
		Date of Receipt	28.11.2022
		Date of Calibration	28.11.2022
		Due Date for Calibration	27.11.2023
		Date of Issue	29.11.2022

Details of Unit Under Calibration

Description	Micro Pipette	Make	ThermoScientific
Range	100 - 1000 µl	Model	Finnpipette F3
Resolution	1 µl	Material	pvc
Serial Number	PW04233	Operating Range	100 - 1000 µl
ID Number	MLD/TRY/MOLBIO/EQP/22	Condition of UUC	Good
Cal. At	Mechanical Lab	Instrument Location	--

Environmental Condition

Calibration Method Used

Temperature (°C)	23±2	Humidity (%RH)	55±15	National / International Standard	ISO 8655-6:2002, ISO 8655-2:2002
Atmospheric Pressure (mbar)	1006	Water Temperature (°C)	21.6	Cal Procedure No	VCI-L03-WI-MASS-003

Standard Used

SI. No.	Description	ID.No. / SI. No.	Certificate No.	Make/Model	Traceability	Valid till
1	Electronic Semi Micro Balance	VCI-M-WB-017 / 55492	CC-22-23-S-852/01	Wensar / MAB 250	National Standards	12.10.2023

Result of Calibration in µl

Sl. No.	Nominal Value	Observed Readings					Mean Value	Systematic Error	Random Error	Measurement Uncertainty (±)
1	100	99.92	99.77	99.91	99.90	99.82	99.87	-0.13	0.05	0.88
		99.94	99.88	99.85	99.84	99.87				
2	500	499.66	499.64	499.52	499.61	499.62	499.59	-0.41	0.07	0.88
		499.58	499.59	499.44	499.57	499.67				
3	1000	999.33	999.36	999.48	999.47	999.37	999.42	-0.58	0.07	0.88
		999.46	999.55	999.44	999.35	999.37				

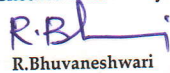
Note: Conformity Statement

Pass: Fail:

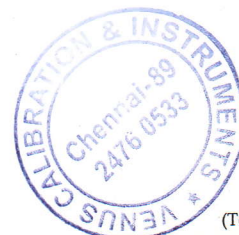
Remarks

- UUC is Defined as the Unit Under Calibration.
- The Measurement uncertainty is expressed at 95.45% confidence level with coverage factor $k=2$.
- This Calibration Certificate relates only to the above UUC & Reported results are valid at the time of and under the stated conditions of measurements.
- Calibration of the UUC are traceable to National / International Standards.
- This report shall not be reproduced in full/ part without prior permission of Venus Calibration and Instruments.
- The recalibration interval shall be determined on the user requirements.
- Nabl-133 guidelines are adopted for use of NABL symbol.
- Calibration Liquid Used: Distilled or Deionized water conforming Grade3 as specified in ISO 3696.
- Our Nabl Scope is Upto 10µl to 10ml.

Checked & Issued by:


 R. Bhuvaneshwari

(Engineer - Calibration)



Authorised by:


 C. Dhinakaran

(Technical / Quality Manager)

No.16, 6th Street, Annai Sathya Nagar, Poothapedu Ramapuram, Chennai - 89.

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e: venuscallab@gmail.com, info@venuscal.com | www.venuscal.com



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**CERTIFICATE OF CALIBRATION**

Certificate No: CC-22-23-L-499/01

Page No: 1 of 1

Customer Name & Address M/s. MEDLINE DIAGNOSTICS (PVT) LTD. No. 23-A, Thennur High Road, Tiruchirappalli, Tamil Nadu - 620 017.	ULR No.	CC27252200008203P
	SRF No.	VCI-22-23-L-499
	Date of Receipt	06.12.2022
	Date of Calibration	06.12.2022
	Due Date for Calibration	05.12.2023
	Date of Issue	07.12.2022

Details of Unit Under Calibration

Description	Micro Pipette	Make	ThermoScientific
Range	2-20µl	Model	Finnpipette F3
Resolution	0.02 µl	Material	pvc
Serial Number	MW19717	Operating Range	2-20µl
ID Number	--	Condition of UUC	Good
Cal. At	Mechanical Lab	Instrument Location	--

Environmental Condition				Calibration Method Used	
Temperature (°C)	23±2	Humidity (%RH)	55±15	National / International Standard	ISO 8655-6:2002, ISO 8655-2:2002
Atmospheric Pressure (mbar)	1006	Water Temperature (°C)	21.4	Cal Procedure No	VCI-L03-WI-MASS-003

Standard Used

SI. No.	Description	ID.No. / SI. No.	Certificate No.	Make/Model	Traceability	Valid till
1	Electronic Semi Micro Balance	VCI-M-WB-017 / 55492	CC-22-23-S-852/01	Wensar / MAB 250	National Standards	12.10.2023

Z Factor: 1.00319

Result of Calibration in µl											
Sl. No.	Nominal Value	Observed Readings					Mean Value	Systematic Error	Random Error	Measurement Uncertainty (±)	
1	2	2.02	2.08	2.09	2.13	2.17	2.11	0.11	0.05	0.20	
		2.05	2.07	2.11	2.15	2.19					
2	10	10.23	10.27	10.31	10.33	10.35	10.31	0.31	0.05	0.20	
		10.25	10.29	10.32	10.34	10.37					
3	20	20.39	20.42	20.45	20.49	20.53	20.47	0.47	0.05	0.20	
		20.41	20.44	20.47	20.51	20.55					

Note: Conformity Statement

Pass: Fail:

Remarks

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- Calibration Liquid Used: Distilled or Deionized water conforming Grade3 as specified in ISO 3696.
- Our Nabl Scope is Upto 10µl to 10ml.
- The Deviation is within MPE, So after calibration is not required.

Checked & Issued by:

R. Bhuvaneshwari

(Engineer - Calibration)



Authorised by:

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