



## CALIBRATION CERTIFICATE

**SP Well Fort**  
**Trivandrum**

Model Name & Sr. No : . EM 200- 2002880  
Range of the instrument: Optical density Linear form 0-2.5 A  
Precision & Accuracy study on EM 200 done on 05.06.2023  
Calibration Due Date: 04.06.2024  
Calibration Done By : Mr. Jibin M T

Reagent/ Sample ratio -

Cup Position	Replicates	Absorbance (X)	SD	CV
Cup 1	20	1.5438 OD	0.0054	0.40%
Cup 2	20	1.5438 OD	0.0052	0.42 %
Cup 3	20	1.5449 OD	0.0047	0.38%

### Test of Potassium Dichromate ( $K_2Cr_2O_7$ ) on EM-200

Pipetted / Measured by Em200		Manually Pipettes Em200		Manually pipetted & read in Autospan	
Low	High	Low	High	Low	High
0.2005	1.8670	0.1975	1.8710	0.2025	1.7630





This instrument is manufactured in accordance with the European law in force, in particular to "Electricity Safety" EN 610101 and "Electromagnetic Compatibility" EN 61326 Standards.

	Ideal	Actual
Pressure	0.9 bar	0.90bar
Lamp Voltage	11.87 V	12.05V
Temperature	37 <sup>0</sup> C	37 <sup>0</sup> C

Photometer Calibration Check	Ok
Cuvette Blank Check	Ok

Wavelength	Off Set	Gain
340	255	540
405	255	525
505	255	520
546	255	487
578	255	535
600	255	470
660	255	485
700	255	475

The instrument does photometer check before each batch of tests is run. It will give an error message if the photometer test fails and it will not run any samples.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,  
For Transasia Bio- Medicals Ltd,

*For*  
*Sajin*  
**Sajin SNair**  
Regional Service Manager  
Cochin



**CERTIFICATE OF CALIBRATION**

Customer Name	SP WELL FORT HOSPITAL	Certificate No.	SPW001
Customer Address	THIRUVANANTHAPURAM KERALA-695010	Date of Calibration	03/02/2024
		Valid Upto	02/02/2025
		Date of Issue	04/02/2024

DUC* Details			
DUC* Name	CENTRIFUGE	S No.	19491
Make/Model No.	ROTEK PLUS/P8E	Location	LABORATORY
ID No.	NA	Visual Inspection	OK

Details of Reference Standards & Major Equipments Used		
Equipment Name	DIGITAL TACHO METER	THERMO HYGROMETER
Make	METRAVI	HTC-2
Model/SR No.	NCTM 1000/190518478	...
Equipment Id	CHPL/MT-KL/TAM/002	
Calibration certificate No	UCSL/07-23/202_05	UCSL/07-23/202_03
Calibration Validity	20/07/2024	20/07/2024
Calibration By	UNIQUE CALIBRATIONS	UNIQUE CALIBRATION SOLUTIONS

Environmental Condition			
Temperature	27°C	Relative Humidity	54%

Calibration Results				
SL NO	SET READING (RPM)	MEASURED READING (RPM)	TOLERANCE	STATUS
1	500	506	±5%	PASS
2	1000	1016	±5%	PASS
3	2500	2513	±5%	PASS

<b>CALIBRATION STATUS</b>	<b>PASS</b>	✓	<b>FAIL</b>	
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REMARKS:- \*DUC- DEVICE UNDER CALIBRATION

- ❖ This result of calibration refers to only to the particular items submitted for calibration.
- ❖ The above result is valid at the time of and under the stated conditions measurement.
- ❖ Calibration certificate issued for weight & measure parameters like mass, weighting balance, volumetric equipment, measuring scales/tapes etc. Are scientific purpose only and should not used for commercial.

Calibrated By

  
ACHUTH P K



Issued and Approved By

  
PREJITH B  
TECHNICAL MANAGER



**CERTIFICATE OF CALIBRATION**

Customer Name	SP WELL FORT HOSPITAL	Certificate No.	SPW001
Address	THIRUVANANTHAPURAM KERALA-695010	Date of Calibration	03/02/2024
		Valid Upto	02/02/2025
		Date of Issue	04/02/2024

DUC* Details					
DUC* Name	Make/Model No	S No.	ASSET ID	LOCATION	Visual Inspection
CENTRIFUGE	ROTEK PLUS/P8E	19491	NA	LABORATORY	OK

Details of Reference Standards & Major Equipments Used		
Equipment Name	ELECTRICAL SAFETY ANALYZER	THERMO HYGROMETER
Make	FLUKE	HTC-2
Model/SR No.	ESA 612/2959012	...
Equipment Id	CHPL/MT-KL/ESA/002	
Calibration certificate No	ET/240123C/01	UCSL/07-23/202_03
Calibration Validity	23/01/2025	20/07/2024
Calibration By	STIC	UNIQUE CALIBRATION SOLUTIONS

\*\*STANDARD USED IS IEC 60601-1

ELECTRICAL SAFETY TEST VALUES

TEST NO.	NAME OF THE TEST	READING	HIGH LIMIT	LOW LIMIT	UNIT	STATUS
1	MAIN VOLTAGE -LIVE TO NEUTRAL	229	250	225	V	PASS
2	MAIN VOLTAGE -LIVE TO EARTH	228	240	220	V	PASS
3	MAIN VOLTAGE-NEUTRAL TO EARTH	0.3	3	0	V	PASS
4	EQUIPMENT CURRENT	0.4	16	0.1	mA	PASS
5	PROTECTIVE EARTH RESISTANCE	0.4	2	0	Ω	PASS
6	EARTH LEAKAGE CURRENT - NC	0.7	1	0.5	mA	PASS
7	EARTH LEAKAGE CURRENT - OC	0.6	1	0.5	mA	PASS
8	ENCLOSURE LEAKAGE CURRENT -NC	0.3	0.5	0.1	mA	PASS
9	ENCLOSURE LEAKAGE CURRENT -OC	0.2	0.5	0.1	mA	PASS
10	INSULATION RESITANCE					
	1.MAIN-PROTECTIVE EARTH	OL	100	0	MΩ	PASS
	2.APPLIED PART TO PROTECTIVE EARTH	NA	100	0	MΩ	PASS
	3.MAIN-TO APPLIED PART	NA	100	0	MΩ	PASS
	4.MAIN-TO NEUTRAL	OL	100	0	MΩ	PASS
	5.APPLIED PART TO NEUTRAL	NA	100	0	MΩ	PASS

\*NOTE ( NC -NORMAL CONDITION, OC-OPEN CONDTION), REMARKS- \*DUC- DEVICE UNDER CALIBRATION

**CALIBRATED BY**

ACHUTH P



**ISSUED AND APPROVED BY**

PREJITH B  
TECHNICAL MANAGER

**CERTIFICATE OF CALIBRATION**

CUSTOMER NAME	<b>SP WELFORT HOSPITAL</b>		
ADDRESS	ASHRMAM LN, SASTHAMANGALAM, THIRUVANANTHAPURAM , KERALA 695010	DATE OF CALIBRATION	08/02/2024
CERTIFICATE NO :	CHPL/PC/SPWH/001	VALID UP TO	07/02/2025
		DATE OF ISSUE	08/02/2024

INSTRUMENT DETAILS			
Instrument Name	MICRO PIPETTE	S.No.	---
Make / Model No.	THERMO SCIENTIFIC FINNPIPETTE F3	Visual Inspection	OK
LOCATION :	LAB	RANGE	100 µL
ASSET ID : NA			

DETAILS OF REFERENCE STANDARDS & MAJOR EQUIPMENTS USED		
Equipment Name	ANALYTICAL BALANCE	THERMO HYGROMETER
Make	WENSAR	HTC-1/-
Model / SR No.	MAB182/39736	....
Calibration Validity	27/07/2024	20/07/2024
Calibration By	UNIQUE	UNIQUE

ENVIRONMENTAL CONDITION			
Temperature	23.0 °C	Relative Humidity	45 %

Calibration Results							
SL NO	SET READING (µl)	MEASURED READING (µl)					STATUS
		I	II	III	IV	V	
1	100	100.00	100.01	100.02	99.99	99.98	PASS

REMARKS:-

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- ❖ Calibration certificate issued for weight & measure parameters like mass, weighting balance, volumetric equipment, measuring scales/tapes etc. Are scientific purpose only and should not used for commercial.

Calibrated By  
( CALIBRATION ENGINEER )

Approved By  
( TECHNICAL MANAGER )  
PREJITH T





**CERTIFICATE OF CALIBRATION**

CUSTOMER NAME	<b>SP WELLFORT HOSPITAL</b>		
ADDRESS	ASHRMAM LN, SASTHAMANGALAM, THIRUVANANTHAPURAM , KERALA 695010	DATE OF CALIBRATION	08/02/2024
CERTIFICATE NO :	CHPL/PC/SPWH/002	VALID UP TO	07/02/2025
		DATE OF ISSUE	08/02/2024

INSTRUMENT DETAILS			
Instrument Name	<b>MICRO PIPETTE</b>	S.No.	---
Make / Model No.	<b>THERMO SCIENTIFIC FINNPIPETTE F3</b>	Visual Inspection	OK
LOCATION :	<b>LAB</b>	RANGE	<b>500 µL</b>
ASSET ID : NA			

DETAILS OF REFERENCE STANDARDS & MAJOR EQUIPMENTS USED		
Equipment Name	ANALYTICAL BALANCE	THERMO HYGROMETER
Make	WENSAR	HTC-1/-
Model / SR No.	MAB182/39736	....
Calibration Validity	27/07/2024	20/07/2024
Calibration By	UNIQUE	UNIQUE

ENVIRONMENTAL CONDITION			
Temperature	23.0 °C	Relative Humidity	45 %

Calibration Results							
SL NO	SET READING (µl)	MEASURED READING (µl)					STATUS
		I	II	III	IV	V	
1	500	500.00	500.01	500.02	499.99	499.98	PASS

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PREJITH T B



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CUSTOMER NAME	<b>SP WELLFORT HOSPITAL</b>		
ADDRESS	ASHRMAM LN, SASTHAMANGALAM, THIRUVANANTHAPURAM, KERALA 695010	DATE OF CALIBRATION	08/02/2024
CERTIFICATE NO :	CHPL/PC/SPWH/003	VALID UP TO	07/02/2025
		DATE OF ISSUE	08/02/2024

INSTRUMENT DETAILS			
Instrument Name	MICRO PIPETTE	S.No.	---
Make / Model No.	THERMO SCIENTIFIC FINNPIPETTE F3	Visual Inspection	OK
LOCATION :	LAB	RANGE	1000 µL
ASSET ID : NA			


DETAILS OF REFERENCE STANDARDS & MAJOR EQUIPMENTS USED		
Equipment Name	ANALYTICAL BALANCE	THERMO HYGROMETER
Make	WENSAR	HTC-1/-
Model / SR No.	MAB182/39736	....
Calibration Validity	27/07/2024	20/07/2024
Calibration By	UNIQUE	UNIQUE


ENVIRONMENTAL CONDITION			
Temperature	23.0 °C	Relative Humidity	45 %

Calibration Results							
SL NO	SET READING (µl)	MEASURED READING (µl)					STATUS
		I	II	III	IV	V	
1	1000	1000.00	1000.01	1000.02	999.99	999.98	PASS

REMARKS:-

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Calibrated By   
( CALIBRATION ENGINEER )

Approved By  
( TECHNICAL MANAGER )  
PREJITH YB 







## ***Certificate of Conformity and Calibration***

**TO WHOMSOEVER IT MAY CONCERN**

### **ISO 15189:2012 REQUIREMENTS REGARDING, "CALIBRATION AND VERIFICATION PROCEDURE"**

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Date:-26/04/2021

**Manish Airan**

**Head Of Quality Department & Regulatory**