



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

My Laboratory Name

My Laboratory Address 1

Calibration Monitor

MULTI
CALIBRATION
DATA

No.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
1	GLHK	Linear	BLANK	BLANK DW	111	0.000	0.0944	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	200.000	0.5918	402.1313	0	15
2	SGOTD	Linear	BLANK	BLANK DW	111	0.000	-0.0003	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	100.000	-0.0393	-2567.3940	0	15
3	SGPTD	Linear	BLANK	BLANK DW	111	0.000	-0.0001	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	88.800	-0.0345	-2581.3953	0	15
4	BIT	Linear	BLANK	BLANK DW	111	0.000	0.0005	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	4.540	0.1924	23.6705	0	15
5	GPTHL	Linear	BLANK	BLANK DW	111	0.000	-0.0010	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	88.800	-0.0243	-3811.1589	0	15
6	BIDD	Linear	BLANK	BLANK DW	111	0.000	0.0003	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	2.130	0.1060	20.1609	0	15
7	CRENZ	Linear	BLANK	BLANK DW	111	0.000	0.0080	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	3.840	0.0877	48.1807	0	15
8	UREA	Linear	BLANK	BLANK DW	111	0.000	-0.0030	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	100.000	-0.1617	-629.9212	0	15
9	ALBD	Linear	BLANK	BLANK DW	111	0.000	0.0799	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	3.520	0.7672	5.1215	0	15

My Laboratory Name

My Laboratory Address1

Calibration Monitor

MULTI
CALIBRATION
DATA

No.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
10	PRO	Linear	BLANK	BLANK DW	111	0.000	0.0668	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	5.040	0.3931	15.4483	0	15
11	ALPU	Linear	BLANK	BLANK DW	111	0.000	0.0004	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	262.000	0.0737	3574.3518	0	15
12	CA	Linear	BLANK	BLANK DW	111	0.000	0.1795	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	10.300	0.5616	26.9563	0	15
13	PHOS	Linear	BLANK	BLANK DW	111	0.000	0.2727	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	5.490	0.5862	17.5092	0	15
14	UA	Linear	BLANK	BLANK DW	111	0.000	0.0047	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	5.430	0.0843	68.1733	0	15
15	HDLC	Linear	BLANK	BLANK DW	111	0.000	0.0048	0.0000	0	15
		Linear	STD1	HDL S012343	S012343	72.600	0.1155	655.8265	0	15
16	TRIG	Linear	BLANK	BLANK DW	111	0.000	0.0272	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	140.000	0.2642	590.7173	0	15
17	CHOL	Linear	BLANK	BLANK DW	111	0.000	0.0479	0.0000	0	15
		Linear	STD1	MULTICAL 2206133A	2206133A	155.000	0.3217	566.1067	0	15

AFTER CALIBRATION IQC DATA

Result Reprint

Report Type : Controls

15-Mar-2023 To 17-Mar-2023

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	89711	BIORAD 1	SGPTD	25.8 U/L		7	17-Mar-2023 13:17:25	26.300	2.700	18.2 - 34.4
2	89712	BIORAD 2	SGPTD	93.2 U/L		8	17-Mar-2023 13:17:43	94.600	9.570	65.89 - 123.31
3	89711	BIORAD 1	SGOTD	42.0 U/L		15	17-Mar-2023 13:19:49	44.700	4.500	31.2 - 58.2
4	89712	BIORAD 2	SGOTD	205.4 U/L		16	17-Mar-2023 13:20:07	205.000	21.000	142 - 268
5	89711	BIORAD 1	ALPU	116 U/L		23	17-Mar-2023 13:22:14	128.000	13.500	87.5 - 168.5
6	89711	BIORAD 1	BIDD	0.40 mg/dL		31	17-Mar-2023 13:24:38	0.400	0.040	0.28 - 0.52
7	89712	BIORAD 2	BIDD	1.09 mg/dL		32	17-Mar-2023 13:24:56	1.120	0.130	0.73 - 1.51
8	89711	BIORAD 1	BIT	1.02 mg/dL		39	17-Mar-2023 13:27:03	1.010	0.120	0.65 - 1.37
9	89712	BIORAD 2	BIT	4.44 mg/dL		40	17-Mar-2023 13:27:21	4.480	0.550	2.83 - 6.13
10	89711	BIORAD 1	UREA	34.8 mg/dL		47	17-Mar-2023 13:29:27	33.500	2.550	25.85 - 41.15
11	89712	BIORAD 2	UREA	97.2 mg/dL		48	17-Mar-2023 13:29:45	103.000	7.500	80.5 - 125.5
12	89711	BIORAD 1	CRENZ	1.79 mg/dL		55	17-Mar-2023 13:31:51	1.800	0.180	1.26 - 2.34
13	89712	BIORAD 2	CRENZ	5.31 mg/dL		56	17-Mar-2023 13:32:10	5.390	0.540	3.77 - 7.01
14	89711	BIORAD 1	GLHK	87.6 mg/dL		63	17-Mar-2023 13:34:16	87.300	6.720	67.14 - 107.46
15	89712	BIORAD 2	GLHK	274.7 mg/dL		64	17-Mar-2023 13:34:34	280.000	21.000	217 - 343
16	89711	BIORAD 1	CA	10.0 mg/dL		71	17-Mar-2023 13:37:16	10.400	0.750	8.15 - 12.65
17	89712	BIORAD 2	CA	13.1 mg/dL		72	17-Mar-2023 13:37:34	14.000	1.020	10.94 - 17.06

AFTER CALIBRATION IQC DATA

Result Reprint

Report Type : Controls

15-Mar-2023 To 17-Mar-2023

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	89711	BIORAD 1	ALBD	4.12 g/dL		79	17-Mar-2023 13:41:47	3.940	0.300	3.04 - 4.84
19	89712	BIORAD 2	ALBD	2.77 g/dL		80	17-Mar-2023 13:42:05	2.680	0.190	2.11 - 3.25
20	89711	BIORAD 1	PRO	6.58 g/dL		87	17-Mar-2023 13:44:11	6.890	0.510	5.36 - 8.42
21	89712	BIORAD 2	PRO	4.66 g/dL		88	17-Mar-2023 13:44:30	4.780	0.360	3.7 - 5.86
22	89712	BIORAD 2	ALPU	493 U/L		89	17-Mar-2023 14:27:50	522.000	52.500	364.5 - 679.5
23	89711	BIORAD 1	PHOS	4.20 mg/dL		216	17-Mar-2023 16:32:38	4.110	0.310	3.18 - 5.04
24	89712	BIORAD 2	PHOS	8.45 mg/dL	+1SD	217	17-Mar-2023 16:32:56	7.450	0.550	5.8 - 9.1
25	89711	BIORAD 1	TRIG	200.5 mg/dL		224	17-Mar-2023 16:35:02	198.000	15.000	153 - 243
26	89712	BIORAD 2	TRIG	88.3 mg/dL		225	17-Mar-2023 16:35:20	84.600	6.300	65.7 - 103.5
27	89711	BIORAD 1	HDLC	74.7 mg/dL	+1SD	232	17-Mar-2023 16:37:27	67.500	6.750	47.25 - 87.75
28	89712	BIORAD 2	HDLC	24.1 mg/dL		233	17-Mar-2023 16:37:45	23.200	2.250	16.45 - 29.95
29	89711	BIORAD 1	UA	5.4 mg/dL		240	17-Mar-2023 16:39:51	5.320	0.400	4.12 - 6.52
30	89712	BIORAD 2	UA	10.0 mg/dL		241	17-Mar-2023 16:40:10	10.700	0.750	8.45 - 12.95

AFTER CALIBRATION IQC DATA

Result Reprint

Report Type : Controls

25-Mar-2023 To 30-Mar-2023

Test: CHOL

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	89711	BIORAD 1	CHOL	268 mg/dL		749	27-Mar-2023 10:56:23	258.000	19.500	199.5 - 316.5
2	89712	BIORAD 2	CHOL	101 mg/dL		750	27-Mar-2023 10:56:42	99.400	7.400	77.2 - 121.6

TECHNICAL RESOURCES

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A MSME Registered Unit, NSIC-CRISIL Rated SE 3C

A NABL Accredited Laboratory

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SERVICE CENTRE : OFFICE NO. 2, TONES PARADISE, OPP. NEW PEDESTRAIN BRIDGE, NAVAGAON, DAHISAR (W), MUMBAI - 400 068.

Calibration Certificate

Calibration field:	Mechanical-Mass-Volume	NABL Accreditation no:	CC-2112
Accreditation valid up to:	11.04.2024	Certificate No:	TR/2023/PIP/747
Requisition no:	Apr2023-IW-109	URL No:	CC211223000001086
Date of receipt:	07.04.2023	Date of calibration:	07.04.2023
Calibration Done:	At lab	Agreed Next Calibration on:	06.04.2024
		Page no:	1 of 2

Customer details:		Location:	Lab
Name:	Intense Diagnostics		
Address:	Shop No 21 Building No 37 Shanti Plaza Chs Ltd Shanti Park Layout Opp Shanti Nagar Sector VI Mira Road (E) Thane - 401107		

Details of DUC:		Reference used:	Mettler Toledo, PM 011
Type:	Micropipette Variable (Single Channel)	Balance ID	C147032536
Make:	Erba	Balance Ser. No.	CC/M&V/1697/22-23
Condition of item:	Good	Traceable Certificate	27.12.2023
Pipette volume:	5-50µl	Valid up to	IDEMI CC2287
Serial no:	AB09151	Calibrated at	
ID No:	INT/VP/01		

Ambient Temp(°C):	25.5	Humidity(%Rh):	56	Conversion Factor Z:	1.0045
Air Pressure (hPa):	1013	Evaporation loss(mg):	0.02		

- Remark:
1. Calibration procedure used: LAB SOP/09, 10 as per ISO 8655-6 & ISO/TR 20461 and NABL 129
 2. The Reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $K=2$, providing a level of confidence of approx. 95%.
 3. The observations reported represent values at the time of measurement. They do not convey any long term stability information.
 4. The reported results are calculated for 27°C
 5. The standards maintained are traceable to National / International Standards through accredited laboratories.
 6. Sticker affixed on the unit
 7. Term Good indicates without any broken or missing parts.
 8. Please check the values of SD weather in permissible limit

- Note:
1. This certificate refer only to particular instrument submitted for calibration.
 2. This certificate shall not be reproduced.
 3. Technical Resources shall not be responsible for any change in calibration date and performance specification on account of malfunctioning of the instrument due to damage caused to it after handing over it to the customer.
 4. Any queries for the calibration certificate will be clarified only if raised with in 30days from date of issue. The reissue of certificate after 30 days will be chargeable.

Authorised Signatory
Sr Technical Manager
N Srinivas Rao

F.7.8.3.1

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Calibration data:

Requisition no:	Apr2023-IW-109	Certificate No:	TR/2023/PIP/747
Serial no:	AB09151	URL No:	CC211223000001086
ID. No.:	INT/VP/01	Date of calibration:	07.04.2023
		Page no:	2 of 2

RUN DETAILS

Set Vol in μ l	Weight in mg									
	1	2	3	4	5	6	7	8	9	10
Vol 1										
5.00	5.041	5.069	5.074	5.011	5.069	5.024	5.089	4.996	4.991	4.993
Vol 2										
25.00	25.116	25.107	25.089	25.072	25.066	25.052	25.082	25.092	25.113	25.052
Vol 3										
50.00	50.069	50.071	50.082	50.092	50.071	50.085	50.084	50.099	50.091	50.056

SUMMARY STATISTICS

	Vol 1	Vol 2	Vol 3
Set Vol in μl	5.00	25.00	50.00
Mean μl	5.078	25.217	50.325
Random Error μl	0.038	0.024	0.013
Systematic Error μl	0.078	0.217	0.325
Exp Uncertainty $\pm\mu$l	0.09	0.09	0.09

Status Of pipette (according to ISO 8655-2 & 6 :2002 permissible limits):- Within limits Not Within limits

END OF RESULT

08.04.2023

Certificate Issue Date

[Signature]
Checked By

[Signature]
Authorised signatory
Sr Technical Manager
N Srinivas Rao

TECHNICAL RESOURCES

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Calibration Certificate

Calibration field:	Mechanical-Mass-Volume	NABL Accreditation no:	CC-2112
Accreditation valid up to:	11.04.2024	Certificate No:	TR/2023/PIP/748
Requisition no:	Apr2023-IW-109	URL No:	CC21122300001087
Date of receipt:	07.04.2023	Date of calibration:	07.04.2023
Calibration Done:	At lab	Agreed Next Calibration on:	06.04.2024
		Page no:	1 of 2

Customer details:			
Name:	Intense Diagnostics	Location:	Lab
Address:	Shop No 21 Building No 37 Shanti Plaza Chs Ltd Shanti Park Layout Opp Shanti Nagar Sector VI Mira Road (E) Thane - 401107		

Details of DUC:		Reference used:	
Type:	Micropipette Variable (Single Channel)	Balance ID	METTLER AE 163
Make:	Erba	Balance Ser. No.	LC046257
Condition of item:	Good	Traceable Certificate	CC/M&V/1696/22-23
Pipette volume:	100-1000 μ l	Valid up to	27.12.2023
Serial no:	AB158608	Calibrated at	IDEMI CC2287
ID No:	INT/VP/02		

Ambient Temp($^{\circ}$ C):	25.5	Humidity(%Rh):	56	Conversion Factor Z:	1.0045
Air Pressure (hPa):	1013	Evaporation loss(mg):	0		

Remark:

1. Calibration procedure used: LAB SOP/09, 10 as per ISO 8655-6 & ISO/TR 20461 and NABL 122-04
2. The Reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor K=2, providing a level of confidence of approx. 95%.
3. The observations reported represent values at the time of measurement. They do not convey any long term stability information.
4. The reported results are calculated for 27 $^{\circ}$ C
5. The standards maintained are traceable to National / International Standards through accredited laboratories.
6. Sticker affixed on the unit
7. Term Good indicates without any broken or missing parts.
8. Please check the values of SD weather in permissible limit

Note:

1. This certificate refer only to particular instrument submitted for calibration.
2. This certificate shall not be reproduced.
3. Technical Resources shall not be responsible for any change in calibration date and performance specification on account of malfunctioning of the instrument due to damage caused to it after handing over it to the customer.
4. Any queries for the calibration certificate will be clarified only if raised with in 30days from date of issue. The reissue of certificate after 30 days will be chargeable.


Authorised signatory
Sr Technical Manager
N Srinivas Rao

TECHNICAL RESOURCES

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Calibration data:

Requisition no:	Apr2023-IW-109	Certificate No:	TR/2023/PIP/748
Serial no:	AB158608	URL No:	CC211223000001087
Id. No.:	INT/VP/02	Date of calibration:	07.04.2023
		Page no:	2 of 2

RUN DETAILS

Set Vol in µl	Weight in mg									
	1	2	3	4	5	6	7	8	9	10
Vol 1										
100.00	100.11	100.18	100.09	100.14	100.22	100.29	100.18	100.25	100.16	100.12
Vol 2										
500.00	500.34	500.48	500.41	500.49	500.33	500.35	500.49	500.41	500.36	500.34
Vol 3										
1000.00	1001.18	1001.12	1001.24	1001.29	1001.38	1001.37	1001.29	1001.25	1001.36	1001.32

SUMMARY STATISTICS

	Vol 1	Vol 2	Vol 3
Set Vol in µl	100.00	500.00	1000.00
Mean µl	100.62	502.54	1005.79
Random error µl	0.06	0.07	0.08
Systematic Error µl	0.62	2.54	5.79
Exp Uncertainty+/-µl	0.27	0.27	0.27

Status Of pipette (according to ISO 8655-2 & 6 :2002 permissible limits): Within limits Not Within limits

END OF RESULT

08.04.2023

Certificate Issue Date:

Checked By

Authorised signatory
 Sr Technical Manager
 N Srinivas Rao

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Calibration Certificate

Calibration field:	Mechanical-RPM	NABL Accreditation no:	CC-2112
Accreditation valid upto:	11.04.2024	Certificate no:	TR/2023/RPM/75
Requestion no:	Apr2023-47	ULR no:	CC211223000001088
Calibration done at	At Site	Date of calibration:	07.04.2023
		Agreed Next Callb On:	06.04.2024
		Page no:	1 of 2

Customer details:		Reference used:	
Name:	Intense Diagnostics	Master:	Tachometer DT-2001B
Address:	Shop No 21 Building No 37 Shanti Plaza, Chs Ltd Shanti Park Layout Opp Shanti, Nagar Sector VI Mira Road (E) Thane - 401107	Master Ser. No.:	O33442 ID No. RMOO2
		Traceable Certificate:	C-220728-15-1 Godrej CC-2634
		Valid upto:	29.07.2023

Details of DUC:		Condition of item:	Good
Equipment:	Centrifuge	Range RPM:	Not Specified
Make:	Remi	Accuracy:	Not Specified
Model:	R-303	Resolution (RPM):	Not Specified
Serial No.	ZIHN-33887		
ID No.	INT/CF/01		
Location	Lab		

Ambient Temp(°C):	25+/- 2	Humidity Rh(%):	50 +/-20
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Remark:

1. Calibration procedure used: LAB-SOP/08
2. The Reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $K=2$, providing a level of confidence of approx. 95%.
3. The observations reported represent values at the time of measurement. They donot convey any long term stability information.
4. The standards maintained are traceable to National / International Standards through accredited laboratories.
5. Sticker affixed on the unit

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Mumbai
Authorised signatory
Sr Technical Manager
N Srinivas Rao

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SERVICE CENTRE : OFFICE NO. 2, TONES PARADISE, OPP. NEW PEDESTRAIN BRIDGE, NAVAGAON, DAHISAR (W), MUMBAI - 400 068.

Calibration data:

Equipment:	Centrifuge	Certificate no:	TR/2023/RPM/75
Serial no:	ZIHN-33887	ULR no:	CC21122300001088
ID no.	INT/CF/01	Date of calibration:	06.04.2023
		Page No:	2 of 2

RUN DETAILS

Set RPM Display	Avg. Reading on UUC Display RPM	Avg. Reading On Ref. RPM	Deviation in RPM (+/-)	Expanded Uncertainty in RPM (+/-)
Step 1	NA	1629.8	NA	7.5
Step 3	NA	3079.2	NA	7.5
Step 5	NA	3985.6	NA	7.5

END OF RESULT

10.04.2023

Certificate Issue Date:

Checked By 



Authorized signatory
Sr Technical Manager
N Srinivas Rao