NUTECH CALIBRATORS & ENGINEERS

(An NABL Accredited Calibration Laboratory in the field of Mechanical, Electro-Technical & Thermal)
Vide Certificate Nos.: CC-2271 (C-0421, C-0295 & C-0296)
Regd. Office & Lab. : 28/6 & 7, TOLLYGUNGE CIRCULAR ROAD, KOLKATA- 700 053
PHONE : (033) 2400 2182 (O), TELEFAX : 033 2400 2182
e-mail : nutech_cali2006@rediffmail.com, nutech.calibration700053@gmail.com
info@nutechcalibrators.com, Website : www.nutechcalibrators.com

NABL ACCREDITED LABORATORY CC-2271

Issued To:
M/s: Oncquest Laboratories Ltd. Kolkata
BF 2, Sushma Castle, Rajarhat Main Road,
Beside Arati Cinema Hall, P.O.: Jyangra,
Kolkata-700059, West Bengal.

Form No.- NCE/FM/03.
Certificate No.: NCE/CF-01854/20-21
ULR-CC227120000001099F
Date : 26/09/2020

CALIBRATION REPORT

CALIBRATED ON:	NEXT DUE DATE :	PAGE 1 OF 1
23/09/2020	22/09/2021	

1)	Reference Standard (Traceability No.& Date)	:	TSC/18-19/9948-4 Dt. 01/01/2019 and Valid up to 01/01/2021
2)	Description Of Instrument	:	**Centrifuge**
	a) Make : Remi	b) Model : R-8C	c) Range : 5250 rpm (Max) d) L/c : 10 rpm
3)	Identification No	:	Sr. No.: ZDJN-27326
4)	Receipt of Instrument	:	23/09/2020
5)	End User	:	Lab
6)	Ambient condition during Calibration	:	a) Temp : 25°C ± 5°C b) Humidity : < 70 % RH
7)	Basis of Calibration	:	Comparison Method
8)	Standard/ Equipment used for Calibration	:	Digital Tachometer (NCE/DTM/01)
9)	Measurement Uncertainty (of 95% C.L. at k = 2)	:	± 0.15 % rpm (for the maximum reported range)
10)	Laboratory Identification	:	Sticker is affixed for authentication of calibration.

CALIBRATION RESULTS

Sl No.	DUC Set in rpm	Reading Observed through Ref. Std. in rpm
1	2040	2046.2
2.	2760	2768.7
3.	3380	3389.5
4.	3820	3831.2
5.	4350	4364.6

REMARKS :The above DUC* has been calibrated over its range & the readings observed are tabulated above. The reference standard is traceable to National Standard. * DUC : Device Under Calibration

Calibrated By : S. Banik
Calibration Engineer

Approved By : S. GHOSH (QM) CUM TM
Authorised Signatory

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Form No.- NCE/FM/03.
Certificate No.: NCE/MP-01858/20-21
ULR-CC227120000001103F
Date : 26/09/2020

CALIBRATION REPORT

CALIBRATED ON:	NEXT DUE DATE :	PAGE 1 OF 1
23/09/2020	22/09/2021	

1) Reference Standard (Traceability No.& Date) : TSC/19-20/9490-6 dt.31/10/2019 & valid upto 31/10/2020
2) Description Of Instrument : **Micro Pipette**
   a) Make : CE b) Model : Finnpipette F3 c) Range : (5-50) µl d) L/c : 0.1 µl
3) Identification No : ONC/KOL/PIPE/02 (Sr.No.: OW07658)
4) Receipt of Instrument : 23/09/2020
5) End User : Lab
6) Ambient condition during Calibration : a) Temp : 25°C ± 5°C b) Humidity : < 70 % RH
   Temp. during Calibration at DUC including liquid : 27 °C
7) Basis of Calibration : Gravimetric Method
8) Standard/ Equipment used for Calibration : Electronic Balance (NCE/DWM/01)
9) Measurement Uncertainty (of 95% C.L. at k = 2) : ± 5.92 µl (for the maximum reported range)
10) Laboratory Identification : Sticker is affixed for authentication of calibration.

CALIBRATION RESULTS

Sl. No.	DUC Set in µl	Corresponding Reading Observed through Ref. Std. in µl (Avg.of five reading)
1.	10	9.91
2.	25	24.86
3.	50	49.79

REMARKS :The above DUC* has been calibrated over its range & the readings observed are tabulated above. The reference standard is traceable to National Standard. * DUC : Device Under Calibration

Calibrated By : S. Banik
Calibration Engineer

S. GHOSH (QM) CUM TM
Approved By :
Authorised Signatory

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Kolkata-700059, West Bengal.

Form No.- NCE/FM/03.
***Certificate No.:** NCE/DT-01847/20-21*
ULR-CC227120000001092F
***Date :** 26/09/2020*

CALIBRATION REPORT

CALIBRATED ON:	NEXT DUE DATE :	PAGE 1 OF 1
23/09/2020	22/09/2021	

1) Reference Standard (Traceability No.& Date) : TSC/18-19/9951-3 Dt. 01/01/2019 and Valid up to 01/01/2021
2) Description Of Instrument : **Digital Thermometer**
   a) Range : (-50 to 300)°C c) L/c : 0.1 °C e) Model/Type : ST 9283B
   b) Identification No : ONC/KOL/DTHER/03 d) Make : Multi
3) Receipt of Instrument : 23/09/2020
4) End User : Lab
5) a) Ambient condition during Calibration : 25°C ± 4°C (b) Humidity : [50 ± 20]% RH.
6) Basis of Calibration : Comparison Method
7) Standard/ Equipment used for Calibration : Dig Thermometer with Sensor (YD13006356) & Low Temp. bath & Heat Source.
8) Laboratory Identification : Sticker is affixed for authentication of calibration.
9) Measurement Uncertainty of 95% confidence level k=2 : ± 0.4 °C (For the maximum reported range)

CALIBRATION RESULTS

Sl No.	Temprature set at DUC in °C	Reading Observed through in Ref. Std.in °C
1.	(-) 25	(-) 24.53
2.	(-) 20	(-) 20.61
3.	(-) 15	(-) 15.68
4.	(-) 10	(-) 9.73
5.	5	5.27

REMARKS :The above DUC has been calibrated for its range & readings observed are tabulated above. The reference standard used is traceable to National Standard.
DUC: Device Under Calibration

Calibrated By : S. Banik
Calibration Engineer

Approved By : S. GHOSH (QM) CUM TM
Authorised Signatory

To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories – requirements regarding "Calibration & Verification Procedures" [1]

All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

The In-Vitro-Diagnostics Directive of the European Union [2] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro Diagnostics Directive. This means that all processes in development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2012 [3] + AC:2012 and 21 CFR Part 820 [4].

The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required of the user in order to assure the specified performance of every system of Roche Diagnostics GmbH. Only if a user deviates from these manufacturer's recommendations, the user have to establish site-specific calibration and verification procedures as part of his accreditation process.

Mannheim, 18 December 2017

Roche Diagnostics GmbH

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

i.V. Andrea Weber
Project Manager Regulatory Affairs

ppa. Dr. Beate Bonefeld
Head of Quality Assurance Mannheim, CPS Quality

[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories – Requirements for quality and competence
[2] Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices
[3] EN ISO 13485:2012 + AC:2012 Medical devices – Quality management systems-Requirements for regulatory purposes
[4] CFR Part 820, Quality System regulations 21 Requirements on medical devices