



CKK Diagnostics Bangalore Pvt. Ltd.

CERTIFICATE of CALIBRATION

MANUFACTURER : CKK Diagnostics Bangalore Pvt. Ltd.,

INSTRUMENT : ELECTROLYTE ANALYSER

SERIAL NUMBER : CKK-LYTE # 1007

CUSTOMER : BGS MEDICAL COLLEGE & HOSPITAL - NELAMANGALA

CKK Diagnostics Bangalore Pvt. Ltd., certifies that the above listed instrument was calibrated on date noted at, **BGS VIJNATHAM SOUTH CAMPUS, NAGARUR, DASANAPURA, BANGALORE NORTH-562123** .in accordance with the specifications set forth by the manufacturer using the certified control material as per the provided assay values and expected ranges from the manufacturer.

Calibration Date:-**18 MAR 2024**

Calibrated by **MR.LITHIN**

Calibration Due:-**17 MAR 2025.**

For CKK Diagnostics Bangalore Pvt.Ltd.,



(Authorized Signature)

*Subjected to AMC



CKK *Diagnosics Bangalore Pvt. Ltd.*

INSTALLATION QUALIFICATION - IQ
OPERATIONAL QUALIFICATION - OQ
&
PERFORMANCE QUALIFICATION – PQ
Of
Electrolyte Analyzer (CKKLyte)

CKKLyte
Electrolyte Analyzer



CKK *Diagnostics Bangalore Pvt. Ltd.*

INSTALLATION QUALIFICATION

FOR

BGS MEDICAL COLLEGE & HOSPITAL

BY

CKK Diagnostics Bangalore Pvt. Ltd.,



CKK *Diagnostics Bangalore Pvt. Ltd.*

INSTALLATION QUALIFICATION

INSTRUMENT NAME : CKK LYTE
SERIAL NUMBER : CKKL-1007
CUSTOMER NAME : BGS MEDICAL COLLEGE & HOSPITAL – NELAMANGALA
**ADDRESS : BGS Vijnatham south campus, Nagarur, Dasanapura,
Bangalore North – 562123.**

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

REQUIREMENTS	ACCEPTABLE RANGE	OBSERVED RANGE
Input Voltage	230 \pm 10AC	232 \pm 5V AC
Line Frequency	50/60 HZ	50HZ
Ambient Temperature	15-45 degree	21 degree

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.,

MR. LITHIN.K

(SALES & SERVICE ENGINEER)



CKK *Diagnostics Bangalore Pvt. Ltd.*

INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE VERSION 24SW5.5USF.3R.M029	INSTALLED
2	REAGENT PACK	INSTALLED
3	QUALITY CONTROL	TESTED

OPERATION INSPECTION

- POWER SUPPLY CHECKED.
- NO UNUSUAL NOISE PRODUCED IN THE SYSTEM.

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.

MR. LITHIN.K

(SALES & SERVICE ENGINEER)



CKK *Diagnostics Bangalore Pvt. Ltd.*

INSTALLATION REPORT

CUSTOMER NAME : BGS MEDICAL COLLEGE & HOSPITAL.
PLACE : BGS VIJNATHAM SOUTH CAMPUS, NAGARUR,
DASANAPURA, BANGALORE NORTH – 562123.
DEPARTMENT : BIOCHEMISTRY
CONTACT PERSON : MR. RAMKRISHNA
INSTRUMENT NAME : CKK LYTE
SERIAL NUMBER : CKKL-1007
INSTALLATION DATE : 18/03/2024
WARRANTY EXPIRY : 1 Year

THE ELECTROLYTE ANALYZER WAS INSTALLED ALONG WITH THE NECESSARY STANDARD ACCESSORIES, ALL BASIC REQUIREMENTS AND ADJUSTMENTS WERE CHECKED AND FOUND TO BE SATISFACTORY. THE PRELIMINARY STANDARDIZATION OF THE ELECTROLYTE ANALYZER AND THE TRAINING WERE PROVIDED TO THE COMPLETE SATISFACTION OF THE CUSTOMER. THE ELECTROLYTE ANALYZER IS FOUND TO BE WORKING SATISFACTORILY.

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.

MR. LITHIN.K

(SALES & SERVICE ENGINEER)



CKK *Diagnostics Bangalore Pvt. Ltd.*

CERTIFICATION OF INSTALLATION

INSTRUMENT NAME : CKK LYTE
SERIAL NUMBER : CKKL-1007
CUSTOMER NAME : BGS MEDICAL COLLEGE & HOSPITAL – NELAMANGALA
**ADDRESS : BGS Vijnatham south campus, Nagarur, Dasanapura,
Bangalore North – 562123.**

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER

Signature :
Name : MR. LITHIN.K
Designation : SALES & SERVICE ENGINEER
Company : CKK Diagnostics Bangalore Pvt. Ltd.,

QUALITY MANAGER

Signature :
Name : MR. JAGADEESH
Designation : QA/QC TEAM LEADER
Company : CKK Diagnostics Bangalore Pvt. Ltd.,



CKK *Diagnostics Bangalore Pvt. Ltd.*

OPERATIONAL QUALIFICATION

FOR

BGS MEDICAL COLLEGE & HOSPITAL

BY

CKK Diagnostics Bangalore Pvt. Ltd.,

**CKK Lyte
Electrolyte Analyzer**



CKK *Diagnostics Bangalore Pvt. Ltd.*

OPERATIONAL QUALIFICATION OF THE INSTRUMENT:

DESCRIPTION	STATUS	REMARKS
POWER SUPPLY	SELF CHECK	PASSED
ELECTRONICS	SELF CHECK	PASSED
REAGENT PACK	SELF CHECK	PASSED
HARDWARE	SELF CHECK	PASSED
FLOW PATH	SELF CHECK	PASSED

For CKK Diagnostics Bangalore Pvt. Ltd.

(AUTHORISED SIGNATURE)



CKK *Diagnostics Bangalore Pvt. Ltd.*

CERTIFICATION OF OPERATION

INSTRUMENT NAME : CKK LYTE

SERIAL NUMBER : CKKL-1007

CUSTOMER NAME : BGS MEDICAL COLLEGE & HOSPITAL – NELAMANGALA

**ADDRESS : BGS VIJNATHAM SOUTH CAMPUS, NAGARUR, DASANAPURA,
BANGALORE NORTH – 562123.**

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE OPERATIONAL
QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR
THE INSTRUMENT STATED ABOVE.

ENGINEER

Signature :
Name : Mr. LITHIN
Designation : SALES & SERVICE ENGINEER
Company : CKK Diagnostics Bangalore Pvt. Ltd.

QUALITY MANAGER

Signature :
Name : Mr. Jagadeesh
Designation : QA/QC TEAM LEADER
Company : CKK Diagnostics Bangalore Pvt. Ltd.



CKK *Diagnostics Bangalore Pvt. Ltd.*

PERFORMANCE QUALIFICATION

FOR

BGS MEDICAL COLLEGE & HOSPITAL

BY

CKK Diagnostics Bangalore Pvt. Ltd.

**CKK Lyte
Electrolyte Analyzer**



CKK Diagnostics Bangalore Pvt. Ltd.

PERFORMANCE ANALYSIS

The performance of the system has been verified by the following process.

Five replicates of the control Level 1 & Level 2 & Level 3 have been run and the statistical analysis of the data is performed. The results should be within control range with following precision limits.

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE PERFORMANCE QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

A separate annexure has been attached along with this document

ENGINEER

Signature :
Name : MR. LITHIN.K
Designation : SALES & SERVICE ENGINEER
Company : CKK DIAGNOSTICS BANGALORE PVT. LTD.

QUALITY MANAGER

Signature :
Name : MR. JAGADEESH
Designation : QA/QC TEAM LEADER
Company : CKK DIAGNOSTICS BANGALORE PVT. LTD.



QUALITY CONTROLS ANALYSIS

QC LOT: UQC2312A
EXPIRY: NOV 2025

QUALITY CONTROL ASSIGNMENT FOR CKK LYTE

QC TYPE		MEAN (mmol/L)	MIN(mmol/L)	MAX(mmol/L)
LEVEL 1	Na+	121	112	130
	K+	1.91	1.41	2.38
	Cl-	83	74	92
LEVEL 2	Na+	141	134	148
	K+	4.04	3.54	4.54
	Cl-	100	93	107
LEVEL 3	Na+	159	150	168
	K+	5.75	5.25	6.25
	Cl-	122	113	131

CONTROLS RUN IN CKK LYTE

NO	LEVEL 1 (mmol/L)			LEVEL 2 (mmol/L)			LEVEL 3 (mmol/L)		
	Na+	K+	Cl-	Na+	K+	Cl-	Na	K+	Cl-
1	119.2	1.89	110	140	3.98	99	157.3	5.64	121
2	119.1	1.87	111	140.5	3.99	98.9	157.6	5.63	120
3	119.1	1.89	110	140.3	3.98	99	157.6	5.64	121
4	119.3	1.86	111	140.6	3.99	98.7	157	5.62	121
5	119.1	1.89	110	140.9	4.00	98.8	158	5.63	120

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.

MR. LITHIN.K
(SERVICE ENGINEER)



CKK *Diagnostics Bangalore Pvt. Ltd.*

📍 "Ark House", Plot No.92 & 93, Opp. Nimhans Hospital, Sakalavara Village, Jigani Hobli, Bangalore - 560 083. India.

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CKK *Diagnostics Bangalore Pvt. Ltd.*
