



CKK Diagnostics Bangalore Pvt. Ltd.

CERTIFICATE of CALIBRATION

MANUFACTURER : CKK Diagnostics Bangalore Pvt. Ltd.,

INSTRUMENT : HPLC ANALYSER

SERIAL NUMBER : CKK-A1C#123-061

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 *Diagnostics Bangalore Pvt. Ltd.*

INSTALLATION QUALIFICATION – IQ

OPERATIONAL QUALIFICATION – OQ

&

PERFORMANCE QUALIFICATION – PQ

Of

HbA1cAnalyser (CKKA1c)

**CKKA1c
HbA1c Analyzer**



CKK *Diagnostics Bangalore Pvt. Ltd.*

INSTALLATION QUALIFICATON

FOR

BGS MEDICAL COLLEGE & HOSPITAL

BY

CKK Diagnostics Bangalore Pvt. Ltd.



CKK Diagnostics Bangalore Pvt. Ltd.

INSTALLATION QUALIFICATION

INSTRUMENT NAME : CKKA1c
SERIAL NUMBER : 123-061
CUSTOMER NAME : BGS Medical College and Hospital – Nelamanagala.
**ADDRESS : BGS Vijnatham South Campus, Nagarur, Dasanpura,
Bangalore North - 562123**

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

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

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.

MR. LITHIN

(SALES & SERVICE ENGINEER)



CKK *Diagnostics Bangalore Pvt. Ltd.*

INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE VERSION 1.3.A.8	INSTALLED
2	REAGENT SET	INSTALLED
3	QUALITY CONTROL L1&L2	TESTED

OPERATION INSPECTION

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

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.

MR. LITHIN

(SALES & SERVICE ENGINEER)



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INSTALLATION REPORT

CUSTOMER NAME : BGS Medical College & Hospital.
ADDRESS : BGS Vijnatham south Campus, Nagarur, Dasanapura,
Bangalore North - 562123
DEPARTMENT : BIO-CHEMISTRY
CONTACT PERSON : MR. RAMKRISHNA
INSTRUMENT NAME : CKKA1c
SERIAL NUMBER : 123-061
INSTALLATION DATE : 18/MAR/2024
WARRANTY EXPIRY : 1 year

THE HbA1c 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 HbA1c ANALYZER AND THE TRAINING WERE PROVIDED TO THE COMPLETE SATISFACTION OF THE CUSTOMER. THE HbA1c ANALYZER IS FOUND TO BE WORKING SATISFACTORILY.

FOR CKK DIAGNOSTICS BANGALORE PVT. LTD.

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CERTIFICATION OF INSTALLATION

INSTRUMENT NAME : CKKA1c

SERIAL NUMBER : 123-061

CUSTOMER NAME : BGS Medical College and 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

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.

**CKKA1c
HbA1c 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 SIGNATORY)



CKK Diagnostics Bangalore Pvt. Ltd.

CERTIFICATION OF OPERATION

INSTRUMENT NAME : CKKA1c
SERIAL NUMBER : 123-061
CUSTOMER NAME : BGS Medical College and 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 AND 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.

**CKKA1c
HbA1c Analyzer**



PERFORMANCE ANALYSIS

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

Five replicates of the control Level 1 & Level 2 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
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.,



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QUALITY CONTROLS ANALYSIS

QC LOT: 20230718
EXPIRY: 17 JUL 2025.

QUALITY CONTROL ASSIGNMENT FOR CKK LYTE

	QC TYPE	MEAN (%)	MIN (%)	MAX (%)
1	LEVEL 1(QC1)	5.5	4.9	6.1
2	LEVEL 2(QC2)	9.9	8.7	11.1

CONTROLS RUN IN CKK A1c

	QC 1	QC 2
1	5.7	10.1
2	5.7	10
3	5.8	10
4	5.7	10
5	5.7	10.1

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