



INSTALLATION QUALIFICATION

INSTRUMENT NAME : CKK Lyte
SERIAL NUMBER : CKKL-944
CUSTOMER NAME : CLUE PATH DIAGNOSTICS
ADDRESS : #1 9A, NEW HIGH SCHOOL, VV PURAM,
BANGALORE

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

REQUIREMENTS	ACCEPTABLE RANGE	OBSERVED RANGE
Input Voltage	230 \pm 10AC	231 \pm 5V AC
Line Frequency	50/60 HZ	50HZ
Ambient Temperature	15-45 degree	21 degree

FOR ARK DIAGNOSTICS BANGALORE PVT. LTD.



MR. MANOHAR
(APPLICATION SPECIALIST)



**CKK Lyte
Electrolyte Analyzer**

OPERATIONAL QUALIFICATION

FOR

**CLUE PATH DIAGNOSTICS.
(BANGALORE)**

BY

Ark Diagnostics Bangalore Pvt. Ltd.



**CKK Lyte
Electrolyte Analyzer**

PERFORMANCE QUALIFICATION

FOR

**CLUE PATH DIAGNOSTICS.
(BANGALORE)**

BY

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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.NANDHU
Designation : APPLICATION SPECIALIST
Company : ARK DIAGNOSTICS BANGALORE PVT. LTD.

QUALITY MANAGER

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



QUALITY CONTROLS ANALYSIS

QC LOT: UQC2208A
EXPIRY: 30/JUL/2024.

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

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INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE VERSION 24SW5.5F.M023	INSTALLED
2	REAGENT PACK	INSTALLED
3	QUALITY CONTROL	TESTED

OPERATION INSPECTION

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

FOR ARK DIAGNOSTICS BANGALORE PVT. LTD.



MR. NANDHU

(APPLICATION SPECIALIST)




CERTIFICATION OF INSTALLATION


INSTRUMENT NAME : CKK Lyte
SERIAL NUMBER : CKKL-944
CUSTOMER NAME : CLUE PATH DIAGNOSTICS
**ADDRESS : #1 9A, NEW HIGH SCHOOL, VV PURAM,
BANGALORE**

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

ENGINEER

Signature : 
Name : Mr.NANDHU
Designation : APPLICATION SPECIALIST
Company : Ark Diagnostics Bangalore Pvt. Ltd.

QUALITY MANAGER

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


(AUTHORIZED SIGNATURE)



ARK Diagnostics Bangalore Pvt. Ltd.

CERTIFICATE of CALIBRATION

Manufacturer : ARK DIAGNOSTICS BANGALORE PVT. LTD.,

Instrument : ELECTROLYTE ANALYSER

Serial Number : CKK-LYTE#944

Customer : CLUE PATH DIAGNOSTICS- BANGALORE

Ark Diagnostics Bangalore Pvt. Ltd., certifies that the above listed instrument was calibrated on date noted at, #1 9a, new high school, vv puram, bangalore, 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:-5th JUL 2023

Calibrated by Mr.NANDU

Calibration Due:-4th JUL 2024.

For ark Diagnostics Bangalore Pvt. Ltd.,



(Authorized Signature)

*Subjected to AMC



ARK *Diagnostics Bangalore Pvt. Ltd.*

Ark Diagnostics Bangalore Pvt. Ltd.,

Electrolyte Analyzer (Ckklyte) – Sr.No.944.

INSTALLATION QUALIFICATION – IQ

OPERATIONAL QUALIFICATION – OQ

PERFORMANCE QUALIFICATION – PQ

FOR

**CLUE PATH DIAGNOSTICS.
(BANGALORE)**



ARK Diagnostics Bangalore Pvt. Ltd.

CERTIFICATE of CALIBRATION

Manufacturer : ARK DIAGNOSTICS BANGALORE PVT. LTD.,

Instrument : ELECTROLYTE ANALYSER

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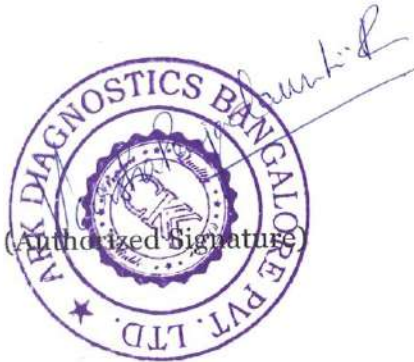
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For ark Diagnostics Bangalore Pvt. Ltd.,



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