LabX medical systems

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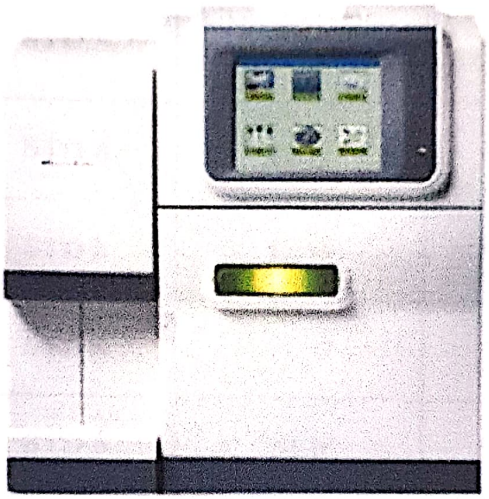
InnoLyte



Calibration Certificate

Hospital Name	:	Nirnaya Diagnostics Trivandrum
Address	:	Main Road,Kunnathukal,Karakonam P O Trivandrum
Instrument Name	:	Innolyte
Serial No.	:	0350911161486
Department	:	Laboratory
Calibration Date	:	17-11-2021
Next Calibration Due	:	17-11-2022
Appearance	:	Clean

Calibration Status:

Item	Reagent	Value (mV)	Range	Remarks
Empty Tube ADC	Air	323	0-500	OK
Calibration A ADC	STD A	1235	>800	OK
Valve to Sensor Steps	STD A	1286	<2000	OK
Sodium	STD A	77.21	Stable	Ok
Sodium	STD B	71.45	Stable	Ok
Potassium	STD A	70.43	Stable	Ok
Potassium	STD B	85.6	Stable	Ok

Item	Concentration		
	Sodium	Potassium	Remarks
STD A	140	4	OK
STD B	110	8	OK

This is to certify that above instrument is calibrated and validated as per specification by the manufacturer and instrument is ready to report the samples of the patients with daily quality controls validation.

Performed by,

Amal V K
Service Engineer
Ernakulam

1) INNOLYTE INSTALLATION QUALIFICATION

InnoLyte Electrolyte Analyzer

LABORATORY : Nirnaya Diagnostics Centre

ADDRESS : Main Road, Kunnathukal, Karakonam P.O. Thiruvananthapuram

COUNTRY : India.

SERIAL No : 0350911161486

Software Ver :

Installation Date : 10-10-2016

Objective:

This checklist applies to the installation for InnoLyte, allowing the completion of each stage to be verified.

Documents required:

The reference for this checklist is the user's guide Rev:A/0 and an installation Check List.

1. Installation (instrument powered OFF):

1.1. Primary unpacking:

Instrument and peripherals inspection.	☐ OK	☐ NOK
Remove the instrument protective packing.	☐ OK	☐ NOK
Checking the display,electrodes,tubing and probe.	☐ OK	☐ NOK

Comments:
Instrument received in good condition.

1.2. Installation auxiliary materials and disposables:

Install the probe.	☐ OK	☐ NOK
Install the peristaltic tube	☐ OK	☐ NOK
Install the reagent.	☐ OK	☐ NOK
Install the printer paper.	☐ OK	☐ NOK
Install the waste bottle.	☐ OK	☐ NOK

Comments:
Successfully completed auxiliary installation.

1.3.Inspection of tubing connection and electrodes :

Physical inspection of tubing connection and electrodes.	☐ OK	☐ NOK

Comments:
Inspected tubings, firmly connected & Electrodes found bubble free and adequately filled.

2. Switching on the instrument...

2.1. Language configuration:

Selected language.	☐ OK	☐ NOK

2.2. Self Check:

Initiated self check.	☐ OK	☐ NOK
Self check completed successfully.	☐ OK	☐ NOK

Comments: Software is configured and checked, completed successfully.

2.3. Instrument setup:

Set up test parameter.	☐ OK	☐ NOK
Set up unit.	☐ OK	☐ NOK
Set up std values.	☐ OK	☐ NOK
Set up the time.	☐ OK	☐ NOK
Set up aspiration volume.	☐ OK	☐ NOK
Set up empty tube ADC.	☐ OK	☐ NOK
Set up std A ADC.	☐ OK	☐ NOK
Set up deproteinization frequency.	☐ OK	☐ NOK
Set up calibration frequency.	☐ OK	☐ NOK
Set up revise function if necessary..	☐ OK	☐ NOK

Comments:
Checked and verified all installation qualification with reference to manufacturer recommendatio

.....END OF INSTALLATION.....

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
YES NO			
Customer's comments		Installer's comments	
		Installation was successful and is well followed the a Recommendation by Manufacturer.	
Customer (name and position)	Signature	Installer (name and position)	Signature
		Amal V K FSE LabX.	
This document is prepared and signed in duplicate. Each page must be initialled by the installer.			

2) INNOLYTE OPERATIONAL QUALIFICATION

InnoLyte Electrolyte Analyzer

LABORATORY : Nirnaya Diagnostics Centre

ADDRESS : Main Road, Kunnathukal, Karakonam P.O. Thiruvananthapuram

COUNTRY : India.

SERIAL No : 0350911161486

Software Ver :

Installation Date : 10-10-2016

Objective:

Verify that the instrument is operating within established limits and tolerances.

This procedure must be carried out during the installation after a successful installation qualification (IQ).

Reference documents:

Refer to the user's manual REV: A/0.

1. Choice of parameters for acceptance testing:

The final QC procedure after production of a IVD analyser is to focus on the different measurement components. Thus the final phase tests will be performed with the following parameters: Na,K,Cl,Ca,Li,pH.

These tests will check the performance of the analyser:

During these operations, the following modules are equally covered:

- Aspiration needle.
- ADC sensor.
- Electrode Packing.
- Tubing connections.
- Reagent sensor.
- Aspiration pump.
- Allot rotary valve.
- And all Electrodes.

A close look in to the calibration screen:

Empty tube ADC:	
Std A ADC:	
Valve to sensor step:	

	Na	K	Cl	Ca/Li/pH
B				
A				
B				
A				
B				
A				
Slope				

2. Data analysis:

Procedure:

This procedure consists of running quality control, third party(.....).

Products status:

Product name	Lot Number	Expiry date
Reagent(DS-I).		
QC Level 1		
QC Level 2		

2.3. QC acceptance ranges (lot:.....).

	Na (unit:mmol)		K (unit:mmol)		Cl/Ca/Li (unit:mmol)	
	min	max	min	max	min	max
Level-1						
Level-2						

*(please find attached value sheet for ref)

1. QC data:

(refer to 2.3. for acceptance ranges)

	Na (unit:mmol)		K (unit:mmol)		Cl/Ca/Li (unit:mmol)	
	1	2	1	2	1	2
Level 1						
Level 2						
acceptance (OK /NOK/ n/a)						

Comments: Successfully completed operational qualification verification

1.Repeatability Check:

With pool normal serum prepared from more than three samples.

Sr. No.	Na+	K+	Cl-/Ca+/Li+
1			
2			
3			
4			
5			

……..END OF OPERATIONAL QUALIFICATION……..

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.			
☐ ☐YES NO			
Customer's comments		Installer's comments	
		Successfully verified all operational criteria as per manufacturer recommendation.	
Customer (name and position)	Signature	Installer (name and position)	Signature
		Amal V K FSE LabX.	
This document is prepared and signed in duplicate. Each page must be initialled by the installer.			

PERFORMENCE QUALIFICATION

Qc Results :-

Level [26481] - I		Mean	Ref. Range
Na^+	: 144.2	144	139 - 149
K^+	: 3.81	3.89	3.69 - 4.09

Level [26482] - II			
Na^+	: 126	125	120 - 130
K^+	: 6.1	6.09	5.59 - 6.59

Repeatability :-

Na^+	:	144 ,	144.2 ,	144.1,	144.5
K^+	:	4.21 ,	4.21 ,	4.22,	4.0