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

Roche Professional Services *(ISO 9001:2015 certified)*

Customer Support Center No: 1800-123-7599 /Toll No: +91-44-30413900

Case No.	CAS-0013498922	Instrument Model	cobas b 221 6 Roche OMNI S6 system
Order No.	ORD-0017419449	Instrument Serial No.	26369
Contract Type	IN-WARRANTY	Finance Status	CASH
Lab/Inst./hosp.Name		Abirami Kidney Care	
Customer No.		0052606946	
Contact Name :		Saravanan T	
Contact Number :		+914242269495	
Address :		No.582, Brough Road,	
City :		Erode	

Call Received Date/Time:	22.05.2021 16:30	Call Attended Date/Time:	13.08.2021 09:15

Job Type	PM Visit
Job Description	
Action Summary	Cause:PM Visit. Workdone:PM has been done as per the check list.Cleaned the instrument.Changed the PM Kit.Performed the calibration.Ran few samples. Verification:Machine working good. Customer Satisfaction Rating (1-5):5

Spare Part Replaced					
Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
05783461001(1)	KIT-PM cobas b 221 < 2/ 4/ 6 > (YEARLY)(1)			1	Free of charge

(1): Customer owned

Time Report	
Effective Visit Date : 04.08.2021	Complete Date : 04.08.2021

Date	Type	Time
2021.08.13	Travel Time--Standard	4.5
2021.08.13	Working Time--Standard	2.5
	Total:	7

Customer's Signature Name : T Saravanan	Service Engineer/Application Specialist Name : Thamaraiselvan Subramani
	
Date: 05.08.2021	Date: 05.08.2021

Disclaimer
1. This Service report has been signed by the authorized representative of your organization.

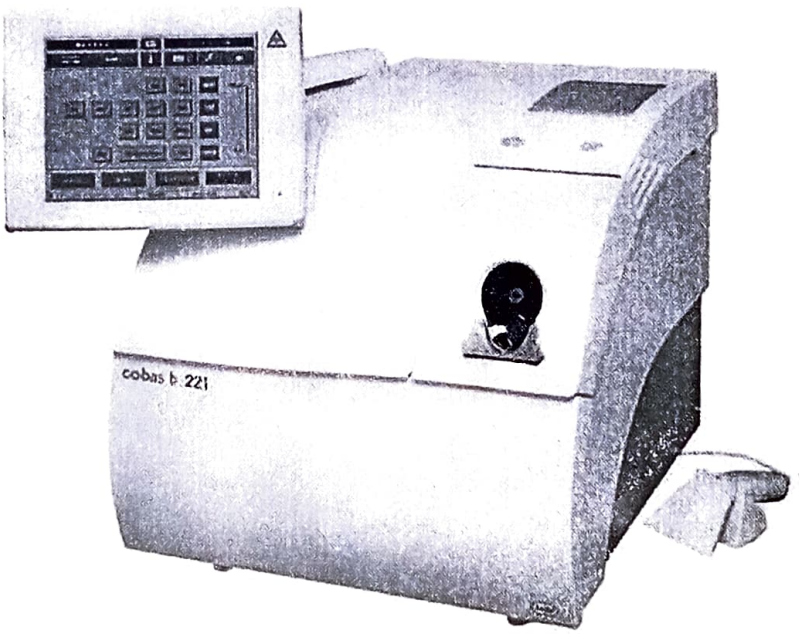
2. Discrepancies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive.
3. This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

Roche

Roche Diagnostics

cobas b221

Analyzer for measuring blood gases



INSTRUMENT QUALIFICATION DOCUMENT

IQ-OQ-PQ

MARKETED BY:

Roche Diagnostics India Pvt. Ltd,

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093.

Roche Diagnostics

cobas b221

Analyzer for measuring blood gases

INSTALLATION QUALIFICATION

for

ABIRAMI KIDNEY CARE

ERODE

MARKETED BY:

Roche Diagnostics India Pvt. Ltd,

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093.

Roche

Validation Protocol # **US-01** **Installation Qualification**

System/ Equipment: **cobas b221**
Analyzer for measuring blood gases

Protocol written by: **Roche Diagnostics Pvt Ltd.**

ABIRAMI KIDNEY CARE
Approval by: **Dr.Saravanan T**

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg.No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011

Sign & Date:

QA Approval by: Thamaraiselvan S
Service Engineer
Roche professional services

Sign & Date: 29/07/17

Objective

To ensure that the system/equipment installed confirms to the purchase specifications and the manufacturers literature, and to document the information that the equipment meets specifications.

Scope

To be performed at time of installation, modification, or relocation.

Responsibility

Person overseeing the installation from Roche Diagnostics India .Pvt will perform the installation qualification and record the information.
He will verify the records and write the IQ report.

Biochemistry Division Head will review the IQ results.

System/Equipment: cobas b221 Instrument ID: _26369_

a.) Description of the System/Equipment being installed:

The cobas b 221 system is a modular analyzer for measuring blood gases, electrolytes ,Metabolites and Hematocrit in whole blood, serum, plasma, acetate and Bicarbonate containing dialysis solutions, and QC materials.

The instrument is designed to measure BG/ISE /Metabolites and Hematocrit in whole blood. The accuracy of measurement values is checked accordingly.

Analyzer Characteristics

The advantages of the system include:

_ Analyzer : Measuring, QC, system, calibration, commonly used functions.

_Database: data about patients, measurement, calibration, commonly used functions.

_ Setup;- instrument settings.

_ Info: Roche info, version number, fill levels, helps, sensor report.

_ A new fluid calibration system eliminates the need for expensive calibration gases

_This change results in easier handling, a smaller foot print, and reduced costs.

_ An easily understood "Touch Screen " interface facilitates easy operation and saves costly and time-consuming user training.

_Patented electrodes are completely maintenance-free, only require a very small sample volume.

_ In this system complete database procedures or to make adjustment is possible during measurement or calibration.

b.) **List of the main components**

The analytical unit includes:

- PC Tower
- Printer
- Measuring chamber
- Pump
- Flap
- Bottle compartment
- Power supply

Packaging with your analyzer, includes:

- Barcode scanner (option)
- Auto QC module (option)
- Accessory kit
- User Manual & short Guide

Procedure

Prepare a checklist for all components and parts, including spare parts according to the purchase order and manufacturers specifications.

Record the information for each actual part, component, auxiliary equipment, supporting facilities, and compare to the manufacturers specifications.

Perform -Installation of Hardware,
(Guided by the system during installation)

-Software set up,
(See chapter 7 Software set up of the Reference Guide)

-Installation Checks

Record any deviations to the system/equipment.

Prepare a Deviation Report including the justification of acceptance and impact on the function.

Prepare an Installation Qualification Report:

This should include:

Date study initiated;
Date completed;
Observations made;
Problems encountered;
Completeness of information collected;
Results of any tests;
Sample data if appropriate;
Other information relevant to the study;
and conclusions on the validity of the installation.

Checklist _____
System: cobas b221 | Instrument ID: ____26369_____

	Required/Ordered	Actual	Deviations
Model	**Cobas b221**	**Cobas b221**	
System Description	Analyzer to measure blood gases and electrolytes from serum and plasma.	Analyzer to measure blood gases and electrolytes from serum and plasma.	*-NIL-*
Dimensions Analyzer Unit with monitor Width Depth Height Weight	 51.0 cm 59.0 cm 60.0 cm 45 kg	 51.0 cm 59.0 cm 60.0 cm 45 kg	*-NIL-*
Electrical Power requirements Mains voltage range: Frequency: Required power:	 100 to 240 VAC (±10% permissible tolerance) 50/60 Hz 200W	 100 to 240 VAC (±10% permissible tolerance) 50/60 Hz 200 W	*-NIL-*

	Required/Ordered	Actual	Deviations
Model	**cobas b221**	**cobas b221**	
Environmental Conditions Ambient temperature	+15 °C to +33 °C	+15 °C to +33 °C	*-NIL-*
Ambient air pressure	462 - 800 mmHg 61.63 - 106.60 kPa	462 - 800 mmHg 61.63 - 106.60 kPa	
Sea level	-400 m to +4000 m	-400 m to +4000 m	
Measurement chamber temp.	37°C ± 0.2 °C	37°C ± 0.2 °C	
Sample Throughput			
BG	25 Samples/25 Sample	25 Samples/25 Sample	**-Nil-**
BG-ISE	25 Samples/25 Sample	25 Samples/25 Sample	
Screen			
Type	TFT LCD Screen	TFT LCD Screen	**-Nil-**
Format	10.4 inch	10.4 inch	
Resolution	320 x 240 pixel	320 x 240 pixel	
Sample Port Module	Flap	Flap	**-Nil-**
	Fill port holder (including fill port)	Fill port holder (including fill port)	
	Needle	Needle	
	Drip tray	Drip tray	

	Required/Ordered	Actual	Deviations
Model	**cobas b221**	**cobas b221**	
Barcode Scanner (Optional)			*-NIL-*
Type	PS2 hand-held scanner with integrated decoder	PS2 hand-held scanner with integrated decoder	
Reading Speed	Up to 45 scans/ Sec	Up to 45 scans/ Sec	
Measuring Chamber	Electrical ground contact	Electrical ground contact	*IL-*
	Sample pre-heating module	Sample pre-heating module	
	Valves, SD Input V22,VBI, VBO,VII,VIO, VSI	Valves, SD Input V22,VBI, VBO,VII,VIO, VSI	
	Sample sensors SS6, SS2, SS1, SS3, SS4	Sample sensors SS6, SS2, SS3, SS1, SS4	
	Tubing	Tubing	
	Measuring chamber trough	Measuring chamber trough	
	Measuring chamber cover	Measuring chamber cover	
	Contact bank	Contact bank	
	Left retainer	Left retainer	
	Locking lever	Locking lever	

These have been performed at the time of original installation at the initial location

Checklist _____ **Instrument Installation**

System: cobas b221 Instrument ID: ___26369____

Installation Procedure	Protocol Location	Performed Yes/No	Sign/Date
Installation of Hardware	Guided by the system during installation	*-Yes-*	
Software set up	See chapter 7 Software set up of the Reference Guide	*-Yes-*	

Conclusion : *Do the results meet the specified Acceptance Criteria?*

Yes: ☑ *No:* ☐ *Signature & Date:*

Performed by: Roche Diagnostics Pvt. Ltd. ***Signature & Date:*** 29/07/21

Reviewed by **:Dr.T.Saravanan** ***Sign & Date:***

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Deviation Report

Deviation(s):

No Deviation Observed

Justification for acceptance:

All Installation Specification matching as per manufacturer recommendations.

Impact on operation:

Instrument can be used for its Operational Qualification test.

Report Written by: Roche Diagnostics Pvt. Ltd.

Signature & Date : 29/07/19

Installation Qualification Report

Date study initiated: 28/07/2017

Date study completed: 29/07/2017

Observation Made:

Instrument Qualification complies as per manufacturer recommendations.

Problems encountered: *Nil*

Completeness of information collected:

All information registered was found complete. Refer to the checklist.

Results: *All results under acceptable norms.*

For Report refer to the attachment

Conclusions on the validity of the installation :

Study data has determined that the system described in this document meets/ does not meet all criteria outlined in this Installation Qualification protocol.

Installation Qualification completed/ not completed successfully.

The system is ready for its Operational Qualification.

Report Written by: Roche Diagnostics Pvt. Ltd. *Signature & Date:* 29/07/17

QA approved by: Thamaraiselvan S
Service Engineer
Roche professional services
Signature & Date: 29/07/17

Roche Diagnostics

cobas b 221

Analyzer for measuring blood gases

OPERATIONAL QUALIFICATION

for

ABIRAMI KIDNEY CARE

Erode

MARKETED BY:

Roche Diagnostics India Pvt. Ltd.

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093.

Roche

System/ Equipment: **Cobas b221**
Analyzer for Measuring Blood Gases

Protocol written by: **Roche Diagnostics Pvt Ltd.**

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Abirami Kidney Care, Erode - 638 011.

Approval by: **Dr. T.Saravanan** *Sign & Date:* Director

QA Approval by: Thamaraiselvan S
Service Engineer
Roche professional services

Signature & Date:

Objective

To determine that the system/equipment operates according to specifications, and to record all relevant information and data to demonstrate it functions as expected.

Scope

To be performed after installation, modification or relocation, after the Installation Qualification has been completed.

Responsibility

Person responsible for operating the system/equipment from Roche Diagnostics India Pvt Ltd will perform the qualification and record the information.

He will supervise the study, verify the completion of the records, write the deviation report and the Operational Qualification Report.
Biochemistry Division Head will review the results.

Materials, SOPs, Documents

Following are the topics course needed to perform the Operational Qualification

1.) Daily operating procedures in step-by-step format (Chapter B, Instruction for use)

2.) Maintenance procedures (Chapter C, cobas b221 Instruction for use)

3.) Special Operation –Troubleshooting (How To ...Chapter D, Instruction for use)

Procedure

Provide SOPs and datasheets for normal operations of the system.

Provide basic operational training and documenting that operators have been trained.

Ensure adequate practice with general maintenance and some tips to troubleshooting.

Test and record calibration data with QC reports.

Test and record outputs.

Record any deviations to the procedures performed.

Prepare a Deviation Report including the justification of acceptance and impact on the operation.

Prepare an Operational Qualification Report:

This should include date study initiated; date completed; observations made; problems encountered; completeness of information collected; results of control/alarm tests; sample data if appropriate; other information relevant to the study; and conclusions on the validity of the equipment/system operations.

Submit the reports to QA for review and approval.

Preparation
Document check

SOP Title and number	File Location	QA/QC approval date
Operation	Chapter B- Instruction for use	_____
Maintenance	Chapter C- Instruction for use	_____
Troubleshooting	Chapter D- Instruction for use	_____

Training Records

Staff name	Designation	Sign
1. Dr. T.Saravanan	Managing Director	
2. Mrs.V.Rajeshwari	Technical Supervisor	
3. Mrs.K.Prema	Biochemist	
4. Mr.T.Muraliprasath	Biochemist	

Given By: **Roche Diagnostics Pvt. Ltd.**
Name: Thamaraiselvan S

Designation: Service Engineer

Date & Signature:

For training certificates refer to the attachment.

Equipment Make and Model

Roche cobas b221

Manual Available

Y [✓] N [ ]

Performed by: Roche Diagnostics Pvt. Ltd

Signature & Date:

Reviewed by: **Dr.T.Saravanan**

Sign & Date:

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Results

Calibration and Control data

Calibration Data

Parameters	Expected millivolt value				Measured Millivolt Value	
	1Pmin-mv	1P max-mv	Slope Min-mv	Slope Max-mv	1P pot mv	Slope Mv
PCO2	-1300	2000	-160	-110	- 726.51	-134.11
PO2	250	550	-10	15	341.33	5.91
Ph	-2100	1600	-340	-250	144.02	- 305.99
K	-1700	2100	90	140	308.09	128.90
Ca	-2000	2200	-105	-65	310.11	-84.20
Cl	-2300	1700	-120	-90	586.36	-103.91
Na	-1700	2300	110	140	832.45	129.55
Conductivity of BGA	A Pot. 55	A Pot. 105	B Pot. 1320	B pot. 1710	A=70.98	B=1452.33
Conductivity of ISE	A Pot. 14	A Pot. 70	B Pot. 930	B pot. 1250	A=51.51	B=1040.30

Performed by: Roche Diagnostics Pvt. Ltd.
Deviations: NIL.

Signature & Date: 29/02/12

Reviewed by: Dr. T.Saravanan

Sign & Date:

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

QC Data- Material -BIORAD

Level -1

Test	Result	Range	Acceptance (Yes/No)
Na+	117.3	111-121	Yes
K+	2.02	1.4-2.4	Yes
Cl-	85.6	78-88	Yes
Ca++	5.98	5.41-6.61	Yes
Ph	7.162	7.13-7.19	Yes
Pc02	71.3	63-79	Yes
Po2	51.2	48-72	Yes

Level-2

Test	Result	Range	Acceptance (Yes/No)
Na+	135.1	128 138	Yes
K+	4.42	04-05	Yes
Cl-	99.4	93-103	Yes
Ca++	4.54	4.17-4.97	Yes
Ph	7.402	7.37-7.43	Yes
Pc02	45.3	41-51	Yes
Po2	101.4	93-117	Yes

Level-3

Test	Result	Range	Acceptance (Yes/No)
Na+	162.6	153-163	Yes
K+	6.37	5.7-6.7	Yes
Cl-	130.7	126-136	Yes
Ca++	2.14	1.44-2.24	Yes
Ph	7.586	7.58-7.64	Yes
Pc02	22.8	19-27	Yes
Po2	142.5	132-156	Yes

Maintenance procedures of the equipment or system

Daily

-Check Liquid Fill

-Check Printer paper

Weekly

-Check needle and fill port

Semi Annual

-Replace Peristaltic tubing

As Needed

-Changing Solutions, Empty liquid waste container, Changing fill port holder

Clean bottle compartment, Clean dip tray and waste plate, Replacing electrode and

Mcon, Cleaning Measuring chamber, Removing Obstructions, Decontamination tube path.

For Protocols refer to cobas b221 Operator manual Chapter C

Performed by: Roche Diagnostics Pvt. Ltd.

Signature & Date:

Deviations: NIL .

Reviewed by: Dr.T.Saravanan

Sign & Date:

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Deviation Report

Deviation(s):

NIL

Justification for acceptance:

All Operational Requirements Qualified

Impact on operation:

Instrument Ready for its Performance Qualification & routine operation.

Written by: Roche Diagnostics Pvt. Ltd

Signature &Date: 29/07/19

Operational Qualification Report

Date study initiated: 28/07/2017

Date study completed:29/07/2017

Observations made:

Operational Qualification complies as per manufacturer recommendations

Problems encountered:

Nil

Completeness of information collected:

All information found to be complete.

Results of the tests:

Acceptable results. For Cal and QC Results refer to the attachment.

Conclusions on the validity of the system operations:

Study data has determined that the system described in this document meets all criteria outlined in this Operational Qualification protocol.

Operational Qualification completed

The system is ready for its Performance Qualification.

Report Written by: Roche Diagnostics Pvt. Ltd.
QA approved by: **Dr.T.Saravanan**

Signature & Date: 29/07/17
Sign & Date:

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director

Roche Diagnostics

cobas b221

Analyzer for measuring blood gases

PERFORMANCE QUALIFICATION

for

ABIRAMI KIDNEY CARE

ERODE

MARKETED BY:

Roche Diagnostics India Pvt. Ltd,

Roche House, Plot No. 114 Road No. 15, MIDC, Andheri (E) , Mumbai - 400 093.

Roche

System/ Equipment: **cobas b221**
Analyzer for measuring blood gases

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Departmental Approval by: **Dr.T.Sraravanan** *Sign & Date:*

QA Approval by: Thamariselvan S
Service Engineer
Roche professional services
Signature & Date: 29/07/17

Objective

To determine that the systems/equipment perform as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets pre-determined specifications under normal conditions, and where appropriate for worst case situations.

Scope

To be performed after the Installation and Operational Qualification have been completed and approved. To be performed after installation, modification or relocation and for re-validation at appropriate intervals. The performance Qualification protocol includes: Precision study, Control recovery study, Linearity study, Method Correlation study, & Ref range Study.

Responsibility

Person responsible for operating the system or equipment will perform the qualification and record the information. The supervisor will supervise the study, verify the completion of the records and write the Deviation Report and the Performance Qualification Report.

Procedure:

Equipment: Run normal procedure for self-test and record all required data and any deviations to the procedure.

*Precision study: Pooled samples were taken and run 5 times in analyzer to check reproducibility of all parameters.

1)Intra Assay Study 2) Inter Assay Study.

*Correlation Study: Samples run in existing Radiometer analyzer was run parallelly in Roche Cobas b 221 Analyzer to Check the correlation of the assay.

Result

Results:

Instrument ID: __26369__

Chart 1: Summary Data Record – **Precision – Within Run**

Test	Na	K	Ca	CL	pH
Rep 1	137.4	3.95	4.23	100.4	7.62
Rep 2	138	3.98	4.22	100.3	7.64
Rep 3	137.4	3.99	4.21	100.2	7.63
Rep 4	138.9	4.03	4.14	101	7.68
Rep 5	139.5	4.06	4.1	101.4	7.74
Mean	138.24	4.00	4.18	100.66	7.66
SD	0.93	0.04	0.05	0.51	0.04
CV%	0.67	1.08	1.36	0.51	0.64

Results: **Instrument ID: ____26369____**

Chart 2: Data Record – **Precision- Inter assay/ Between run**

Test	Na	K	Ca	CL	pH
Interval-1	143.3	4.24	4.61	103.3	7.53
Interval -2	144.4	4.28	4.51	103.5	7.59
Interval -3	144.6	4.27	4.54	102.5	7.60
Interval -4	144.9	4.24	4.41	102.3	7.62
Mean	144.3	4.25	4.51	102.9	7.59
SD	0.69	0.02	0.08	0.58	0.03

Conclusion : *Do the results meet the specified Acceptance Criteria?*

Yes: ☑ *No:* ☐

Performed by: **ABIRAMI KIDNEY CARE_** *Signature & Date* 29.07.2017

Verified by: **Dr.T.Saravanan** *Sign & Date:*

Dr.T.Saravanan, M.D.,D.M.,(Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638

Deviation Report

Deviation(s):

No Deviation observed.

Justification for acceptance:

Results found to be satisfactory.

Impact on operation, function or process:

Precision CV% found within acceptable criterion..

Instrument functioning satisfactorily

Report written by: **ABIRAMI KIDNEY CARE**

Signature & Date

Dr. T. Saravanan, M.D., D.M. (Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Performance Qualification Report

Date study initiated: 28/07/20217

Date study completed: 29/07/2017

Observations made:

Performance Qualification complies as per manufacturer Recommendations

Problems encountered:

Nil

Completeness of information collected:

All information found to be complete.

Results of the tests:

All Acceptable results. For Results refer to the attachment.

Conclusions:

Study data has determined that the system described in this document meets all criteria outlined in this Performance Qualification protocol.

Performance Qualification completed / not completed successfully.

The system is ready for its Routine Use.

Dr.T.Saravanan, M.D., D.M., (Nephrology)
Consultant Nephrologist & Transplant Physician
Reg. No.:76095
Medical Director
Abirami Kidney Care, Erode - 638 011.

Report written by: **ABIRAMI KIDNEY CARE** *Signature & Date:*

QA approved by: Thamaraiselvan S
Service Engineer
Roche professional services

Signature & Date: