

cobas e411

Fully Automated Immunoassay Analyzer

Installation Qualification

Operation Qualification

For

Muljibhai Patel Urological Hospital

Nadiad

The Roche Diagnostics cobas e411 Immunoassay System is a fully automated, random access, software controlled, multichannel analyzer for immunological tests, intended for in vitro quantitative or qualitative determination of a wide range of analytes.

The analyzer is specially designed for performing assays utilizing electrochemiluminescent (ECL) technology & is marketed by Roche Diagnostics.

Analyzer Characteristics

The advantages of the system include:

- _ Easy operation via touchscreen, very few manual entries required.
- _ Both disk and rack systems have a throughput per hour of approximately 86 tests.
- _ Integrated bar code concept improves convenience and workflow. Manual entry of individual sample identifications is not required, if bar code-labeled tubes are used.
- _ Sample racks (on the rack system), reagent packs, calibrator and control vials (also bar code-labeled) are also read automatically.
- _ Automatic entry of test applications. Transfer of test parameters to the system via the reagent bar code label speeds installation of new assays.
- _ Real time monitoring of the analyzer allows the system to run unattended.
- _ Continuous access to samples avoids interruption of routine testing while ensuring that results will be available as quickly as possible.
- _ STAT samples are prioritized and processed first.
- _ Reagents are kept at a constant temperature (20 ± 3 °C) on the analyzer, allowing on-analyzer storage.

The cobas e411 analyzer at:

Facility : Muljibhai Patel Urological Hospital

Location: Nadiad

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1.0

(IQ)

Installation Qualification

1.1. Pre-site Installation and Installation checklist

cobas e411 analyzer specifications	N/A	<input type="checkbox"/>	Complete	<input checked="" type="checkbox"/>
Pre-site installation checklist	N/A	<input type="checkbox"/>	Complete	<input checked="" type="checkbox"/>
Installation report	N/A	<input type="checkbox"/>	Complete	<input checked="" type="checkbox"/>

cobas e411
IQ / OQ

Muljibhai Patel Urological Hospital
Serial No. 6257-16

1.2. System Components

Instrument :


(Immuno assays) cobas e411 instrument

: SI.No : 6257-16

Software installed in the Control Unit:

:Version: 02-04

Date: 17th March 2016

FSE Signature: 

FSE Name: Tejas Panchal

Comments

1.3. Installation checklist

cobas e411 Instrument installation

N/A

Complete



Electrical power lines from
UPS system installation

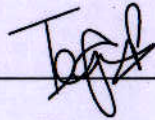
N/A

Complete



Date: 17th March 2016

FSE Signature: _____



Comments

1.4. System Initialization check list

- Perform Cell blank Measurements.
- Perform Assay Performance Checks.
- configuration of all the required tests, calibrators and controls.
- configuration of all system related parameters.
- Load all required reagents, consumables, reconstituted calibrators and controls.
- Select calibration for all the parameters on the system.
- Verify the calibration status and perform QC runs.

Date: 17th March 2016

Signature:  _____

<p>Comments</p>

1.5. Installation Qualification

After the satisfactory system performance checks the cobas e411 analyzer can be approved for Commissioning

Analyzer Released for Commissioning

N/A

Complete

Date: 17th March 2016

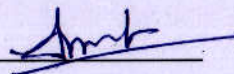
Signature: _____



Field Service Engineer

Date: 17/03/2016

Signature: _____



Customer

Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

Comments

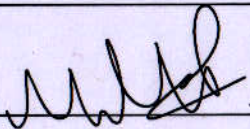
2.0 (O Q) Operation Qualification

2.1. Operation verification

Verify the test calibration & QC results in the respective results generation screens.

N/A Complete

Date: 18th March 2016

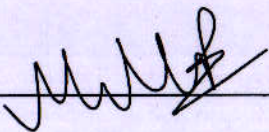
Signature: 

Comments

2.2. Documentation available

Operator Manual Ver:	N/A <input type="checkbox"/>	Complete <input checked="" type="checkbox"/>
Short Guide Ver:	N/A <input type="checkbox"/>	Complete <input checked="" type="checkbox"/>

Date: 18th March 2016

Signature: 

Comments

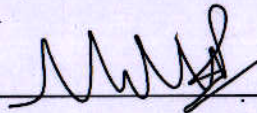
2.3. Routine Operator Training

Operator training certificates

N/A

Complete

Date: 18th March 2016

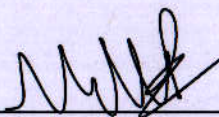
Signature: 

Comments

2.4. Maintenance Schedules

- 2.4.1. Daily Maintenance
- 2.4.2. Weekly Maintenance
- 2.4.3. Bi-Weekly Maintenance
- 2.4.4. Maintenance as required
- 2.4.5. Preventive maintenance

Date: 18th March 2016

Signature: 

Comments

2.5. Operational Qualification

After the satisfactory Operator Training and Operational Performance the cobas e411 analyzer can be approved for customer evaluation.

Analyzer Released for evaluation

N/A

Complete

Date: 18th March 2016

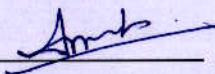
Signature: _____



Consultant – Application Support

Date: 18-03-2016

Signature: _____



Customer

Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

Comments



Case No.	CAS-0014519189	Instrument Model	cobas e411 disk
Order No.	ORD-0018747265	Instrument Serial No.	6257-16
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name	Muljibhai Patel Urological Hospital		
Customer No.	0052011546		
Contact Name :	Banibrata Mukhopadhyay		
Contact Number :	+919771425514		
Address :	DR. V V DESAI ROAD		
City :	Nadiad		
Call Received Date/Time:	28.11.2021 17:45	Call Attended Date/Time:	15.02.2022 10:00

Job Type	PM Visit
Job Description	
Action Summary	Cause:Need to do PM Workdone:Done PM as per procedure carried out all checks run blank cell calibration run qc found ok. Verification:Done Customer Satisfaction Rating (1-5):5

Spare Part Replaced

Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
07938071001 ⁽¹⁾	KIT MAINTENANCE E2010 / E411 6 MONTHS ⁽¹⁾			1	Free of charge
08153094001 ⁽¹⁾	KIT SERVICE E411 12 MONTH ⁽¹⁾			1	Free of charge

⁽¹⁾: Customer owned

Time Report

Effective Visit Date : 15.02.2022	Complete Date : 15.02.2022	
Date	Type	Time
2022.02.15	Travel Time--Standard	2
2022.02.15	Working Time--Standard	3.75
Total:		5.75

Customer's Signature Name : Dr.Shailesh Soni	Service Engineer/Application Specialist Name : Tejas Panchal
Date: 15.02.2022	Date: 15.02.2022

Dr. Shailesh Soni
Consultant Pathologist
M.R.U. No. 724
Reg. No. 10011



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.

Dr. S. Nilesh S. Sarda
Consultant Pathologist
M.D. (C), F.I.C.C. (C), F.I.C.C. (P)
Roche Diagnostics India Pvt. Ltd.

Instrument Information

Operator-ID: bmserv

2022/02/15, 11:31

System Volume : 4
 Last LFC date : 2022/02/05
 Overall Test Counter : 92387
 Cell Exchange Counter : 29000

Adjustment data

Reagent disk	Pos.1	R1	Beads	Beads	Mixing
	0	2	2		6
Beads mixer	Wash	Mixing	U/D		
Pipetter X	1 P1	2 Wash	-2 Beads		R1
	-2 R2	0 S.Disk	0 VB		-1
Pipetter Z	1 T/V Buffer	0 T/V Bottom	-1 Beads Bottom		S.Cup Bottom
Cap opener	-18 F/B Cap	-2 U/D Home	-20 U/D Cap		-20
BCR	0 R.Disk	-12 S.Disk	12		
Sample Disk	0 BC scan	-7 Pipetting			
Sipper X	0 CC2	7 Wash	Sipping		
Sipper Z	5 Incubator	1 Inc Bottom	6 AB1 Bottom		CC2 Bottom
Gripper X	-8 TM Front	-5 TM Back	7 Sipping	2 Tip pos.1	V.Buffer
Gripper Y	5 TM Front	3 VM Left	7 Sipping	-1	-2
Gripper Z	-4 Incubator	-2 Tip Pos.1	-1 V.Buffer		
	1 Sipping	0 V.Buffer	0		
A line	3 Loading Pos.	9			
B line	0 Sampling	Unloading	Sample ID		Rack ID
Turn Table	0 Home	0 End	0		0
	0	0			


 Dr. Shailesh Soni
 Consultant Pathologist
 M.P.M.H. Hospital, Bhopal
 Bhopal, India

Workplace Reagent Calibration QC Utility

System Maintenance Application Calc. Test

Instrument Check


PMT High Voltage Adjustment

Pos.	Effective Signal	Dark Level
1	89340	627
2	85922	627
3	88971	627

Buttons: Running Test, LH Check, Close, Start, HBQ Test, Restore Parameter, Close

Vertical Buttons: Stop, Logoff, S.Stop, Stat Mode, Alarm, Print, Start, Print Screen, Remove USB

Bottom Left: ? Help


Dr. Shailesh Soni
Consultant Pathologist
M.F.U.H. Emp. No.- 724
Reg. No. 19943

Blank Cell

Operator-ID: bmserv

2022/02/15, 11:46

BlankCell was generated

BlankCell Date : 2022/02/15
 RackPack-No. : 8460
 Lot-No. : 551821
 Expiry-Date : 2023/04

Calibration Quality Criteria


Missing values -----

Deviation of replicate measurements OK

Achievement of Targets OK

Comparison to last valid BlankCell -----

	Last valid BlankCell	Actual BlankCell
	Lot : 503897	Lot : 551821
BCR1-1	162	203
BCR1-2	169	207
BCR1-3	171	207
Median	169	207
Target	300	300
Lower	90	90
Upper	400	400
Repl. limit	20 %	20 %
BCR2-1	87947	86242
BCR2-2	87959	86698
BCR2-3	88472	86865
Median	87959	86698
Target	87000	86000
Lower	81000	80000
Upper	93000	92000
Repl. limit	10 %	10 %


 Dr. Shailesh Soni
 Consultant Pathologist
 M.P.C.H. Emp. No.: 724
 Reg. No. 19841

Host E Stop

Workplace Reagent Calibration QC Utility

System Maintenance Application Calc. Test

Initial BlankCell

BlankCell Date	2022/02/15
RP No. for BlankCell	6460
Lot No. of BlankCell	681821
BlankCell Parameter (a)	-66.40
BlankCell Parameter (b)	1.01
BlankCell Option	<input type="radio"/> On <input checked="" type="radio"/> Off

Buttons: Cancel, BlankCell Data Print, OK, Select

- Stop
- Logout
- S.Stop
- Stat Mode
- Alarm
- Print
- Start
- Remove USB

3 Help


Dr. Shailesh Soni
Consultant Pathologist
M.P.U.H. Emp. No.: 724
Reg. No. 19841

Workplace	Reagent	Calibration	QC	Utility
System	Maintenance	Application	Calc. Test	

Stop

Logout

S.Stop

Stat Mode

Alarm

Print

Start

Print Screen

Remove USB

Voltage Monitor

S/R Probe LLD

0.76 V

Pressure Sensor

Sipper LLD

Monitoring Stop

1: Touch the button for which you want to display the voltage.

2: To see another voltage touch the Monitoring Stop button.

3: To Exit the Voltage Monitor Screen, touch the Monitoring Stop button and then Close button.

Close

? Help


Dr. Shailesh Soni
 Consultant Pathologist
 M.P.U.H. Emp. No.:- 724
 Reg. No. 19841

Workplace	Reagent	Calibration	QC	Utility
System	Maintenance	Application	Calc. Test	

Voltage Monitor

S/R Probe LLD	Pressure Sensor	Sipper LLD	Monitoring Stop
---------------	-----------------	------------	-----------------

1.80 V

- 1: Touch the button for which you want to display the voltage.
- 2: To see another voltage touch the Monitoring Stop button.
- 3: To Exit the Voltage Monitor Screen, touch the Monitoring Stop button and then Close button.

Close

? Help

Print Screen

Remove USB

Stop

Logoff

S.Stop

Stat Mode

Alarm

Print

Start

Dr. Shailesh Soni
Consultant Pathologist
M.P.U.H. Emp. No.:- 724
Reg. No. 19841

Host E sipper LLD Volt.

Workplace	Reagent	Calibration	QC	Utility
System	Maintenance	Application	Calc. Test	

Voltage Monitor

S/R Probe LLD	Pressure Sensor	Sipper LLD	Monitoring Stop
---------------	-----------------	------------	-----------------

2.02 V

- 1: Touch the button for which you want to display the voltage.
- 2: To see another voltage touch the Monitoring Stop button.
- 3: To Exit the Voltage Monitor Screen, touch the Monitoring Stop button and then Close button.

Close

Stop

Logout

S.Stop

Stat Mode

Alarm

Print

Start

Print Screen

Remove USB

? Help

Dr. Shailesh Soni
 Dr. Shailesh Soni
 Consultant Pathologist
 M.P.U.M. Emp. No.: 724
 Reg. No. 11041

Host E Stand-by

Workplace Reagent Calibration QC Utility

System Maintenance Application Calc. Test


Temperature Monitor

	Ambient Temp.	Temperature	Target Temp.	Control Param.
Detection Unit	-----	28.0 °C	28.0 °C	0.1
Incubator	-----	37.0 °C	37.0 °C	1.9
Reagent	23.5 °C	18.2 °C	17.7 °C	-0.7
PC/CC	25.2 °C	27.7 °C	28.0 °C	0.3

Close

- Stop
- Logoff
- S.Stop
- Stat Mode
- Alarm
- Print
- Start
- Print Screen
- Remove USB

7 Help


Dr. Shallesh Soni
 Consultant Pathologist
 M.P.U.H. Emp. No.:- 724
 Reg. No. 19841

Result Report

Operator-ID: bmserv

2022/02/15, 12:41

Sample : Control
 Control ID : PC HIV3
 Disk-Position: 0-8

Type : Ser/Pl
 Sequence Number: 311
 Pipetting Time : 2022/02/15 12:05

Test	Result	Unit	Flags	Dil.	Exp. Range	Ready ResultMsg
HIVCOMPT 0	4.27	COI			[2.09 - 6.27]	12:33 reac.

Test Signal Lot No. RP No.
 HIVCOMPT 0 00564117 032175

Sample : Control
 Control ID : PC HBSAG2
 Disk-Position: 0-6

Type : Ser/Pl
 Sequence Number: 309
 Pipetting Time : 2022/02/15 12:04

Test	Result	Unit	Flags	Dil.	Exp. Range	Ready ResultMsg
HBSAGII 0	3.24	COI			[2.27 - 4.21]	12:22 reac.

Test Signal Lot No. RP No.
 HBSAGII 0 00559215 003599

Sample : Control
 Control ID : PC HIV2
 Disk-Position: 0-5

Type : Ser/Pl
 Sequence Number: 308
 Pipetting Time : 2022/02/15 12:03

Test	Result	Unit	Flags	Dil.	Exp. Range	Ready ResultMsg
HIVCOMPT 0	4.67	COI			[2.65 - 7.97]	12:31 reac.

Test Signal Lot No. RP No.
 HIVCOMPT 0 00564117 032175

Sample : Control
 Control ID : PC HBSAG1
 Disk-Position: 0-3

Type : Ser/Pl
 Sequence Number: 305
 Pipetting Time : 2022/02/15 12:02

Test	Result	Unit	Flags	Dil.	Exp. Range	Ready ResultMsg
HBSAGII 0	0.568	COI			[0.000 - 0.800]	12:20 n-reac.

Test Signal Lot No. RP No.
 HBSAGII 0 00559215 003599

Dr. Shallesh Sonik
 Consultant Pathologist
 M.P.U. (I. Em.) No: 724
 Reg. No. 13841

Sample : Control
Control ID : PC HIV1
Disk-Position: 0-2

Type : Ser/Pl
Sequence Number: 304
Pipetting Time : 2022/02/15 12:01

Test	Result	Unit	Flags	Dil.	Exp. Range	Ready ResultMsg
HIVCOMPT 0	0.386	COI			[0.005 - 0.495]	12:28 n-reac.

Test	Signal	Lot No.	RP No.
HIVCOMPT 0		00564117	032175

Dr. Shailish Soni
 Consultant Pathologist
 M.P.U.H. Emp. No: 724
 Reg. No. 19841