

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

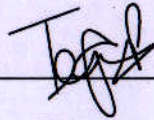
N/A

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

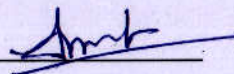
Signature: _____



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

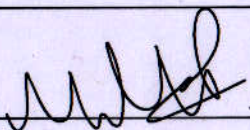
2.0 (O Q) Operation Qualification

2.1. Operation verification

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

N/A Complete

Date: 18th March 2016

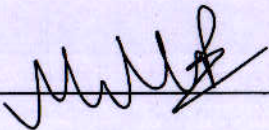
Signature: 

<p>Comments</p>

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

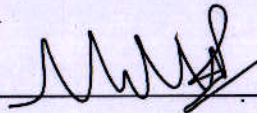
2.3. Routine Operator Training

Operator training certificates

N/A

Complete

Date: 18th March 2016

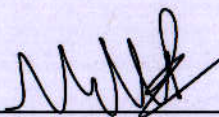
Signature: 

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: 

<p>Comments</p>

2.5. Operational Qualification

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

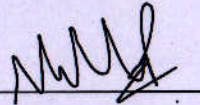
Analyzer Released for evaluation

N/A

Complete

Date: 18th March 2016

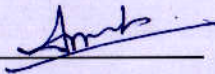
Signature: _____



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