



Calibration Certificate

This is to certify that the **Cobas E411** is a fully automated analyzer bearing the Serial Number **16HO – 21** at Likhitha's Diagnostics and Speciality Lab, H. No. 1-8-65/A ECIL, Hyderabad – 500062, has been calibrated on **19.08.2021**.

The calibration includes:

Adjustments: Checked and adjusted sample/Reagent Rotor, Incubator, Sample/Reagent probe, Bead Mixer and their respective home positions.

Incubation Disk: Range: 36.8°C to 37.2°C
Adjusted: 37°C

Detection Unit: Target: 28.0°C
Adjusted: 28.0°C

PC/CC: Target: 28°C
Adjusted: 28°C

Adding to this all the temperatures, PMT Voltage and volumes drawn by all pumps were checked and found they are OK.

Next calibration due on 18.08.2022

For Roche Diagnostics India Pvt Ltd.,

T R Siddardha,
Sr. Technical Service Specialist,
Hyderabad.

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cobas[®] e411 instrument

Qualification Service
Installation Qualification / Operation Qualification (v.1.0)





cobas[®] e411 instrument



General Information

Country: INDIA

Customer Name: LIKHITHA'S DIAGNOSTICS & SPECIALITY LAB

Customer Address: #1-8-65/A, North Kamala Nagar, Above Andhra Bank, ECIL, Hyderabad, Telangana, India 500062

Person Responsible for Quality Assurance: Mr. U Mehta

System Information

cobas e411 Disk

| | S/N | IP Address |
|------------|---------|---------------|
| cobas e411 | 16H0-21 | 172.18.38.230 |

cobas link: SCL NA

Host provider: NA

User Software Version: 02-08.

Installation Information

Installation Start Date: 10/24/2016

First Installation: YES

Relocation: From: To:

Roche Responsible Representative : Mr. Siddartha TR, Sr. Technical Service Engineer



Installation Qualification:

This document forms the basis of the Qualification Services Certificate. It certifies that the instrument is installed according to the manufacturer's specifications. The report presents and documents the test procedures, the documentation, reference and acceptance criteria used to verify that the system is installed according specifications. The report demonstrated that all installation qualification criteria have been met satisfactorily.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to confirm that the instrument was delivered undamaged and installed correctly.

| Test # | Test | Pass Fail | Signature Date |
|---------|--|----------------|-------------------|
| IQ.1.1 | Operator's Manual available | Pass | |
| IQ 1.2 | Environmental parameters met | Pass | |
| IQ 1.3 | Instrument delivered undamaged and complete | Pass | |
| IQ 1.4 | Transport locking successfully removed | Pass | |
| IQ 1.5 | All connections correctly installed | Pass | |
| IQ 1.6 | Instrument positioned according to Installation Manual | Pass | |
| IQ 1.7 | Instrument boot process successfully | Pass | |
| IQ 1.8 | Checksum according to specification | Pass | |
| IQ 1.9 | Mechanical adjustments complete | Pass | |
| IQ 1.10 | Auxiliary components positioned | Pass | |
| IQ 1.11 | Instrument installation check | Pass | |
| IQ 1.12 | Host communication settings checked | not applicable | |

| Test # | Test | Pass Fail | Signature Date |
|--------|---|--------------|-------------------|
| IQ.3 | Installation Qualification for all cobas <e411> | yes | |



Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

| | |
|---|---------|
| Deviation #1 | |
| NA | |
| Investigation | |
| | |
| Action taken | |
| | |
| Deviation resolved satisfactorily? | specify |

| | |
|---|---------|
| Deviation #2 | |
| NA | |
| Investigation | |
| | |
| Action taken | |
| | |
| Deviation resolved satisfactorily? | specify |

| | |
|---|---------|
| Deviation #3 | |
| NA | |
| Investigation | |
| | |
| Action taken | |
| | |
| Deviation resolved satisfactorily? | specify |



Operational Qualification:

This document is the basis of the Qualification Service Certificate. It certifies that the instrument is operating according to the manufacture's specifications. This report presents and documents the test procedures, documentation, references and acceptance criteria used to verify that the specified system is operating according the specifications. The report demonstrates that all operational qualification criteria have been met satisfactorily.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to check that the modules are operating in accordance with the

| Test # | Test | Pass Fail | Signature Date |
|--------|------------------------------|-----------|----------------|
| OQ.1 | Calibration successfully | Pass | |
| OQ.2 | Quality Control successfully | Pass | |
| OQ.3 | Accuracy check successfully | Pass | |

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

| |
|---|
| Deviation #1 |
| NA |
| Investigation |
| |
| Action taken |
| |
| Deviation resolved satisfactorily? specify |

| |
|---|
| Deviation #2 |
| NA |
| Investigation |
| |
| Action taken |
| |
| Deviation resolved satisfactorily? specify |



Conclusion

All test results are acceptable. yes

Any deviation or non-conformances observed have been recorded as a deviation and the relevant forms completed. no

All acceptance criteria have been met. This equipment is deemed acceptable and the unit is approved for its intended use. yes

Comments

All available parameter calibrations were passed. QC values were within the range.

Completed by Roche Representative Date 10/24/2016

Print Name Mr. Bhavani Prasad Varupula Signature 

Reviewed by Customer Contact Date 24/10/2016

Print Name Mr. U MEHTA Signature 

Reviewed by Customer Quality Assurance Date 24/10/2016

Print Name Mr. U MEHTA Signature 

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cobas[®] e411 instrument

Qualification Service
Installation Qualification





Installation Qualification for cobas e411®

Description

| | | |
|---------------|---|------|
| IQ.3.1 | Function check of e411 according to specifications | |
| | The e411 is installed according to the installation manual and using official tools | Pass |
| IQ.3.2 | Mechanical adjustments complete | |
| | All mechanical adjustments for the different e411 mechanical parts are carried out | Pass |
| | Adjustment check during mechanical check function | Pass |
| | Sample LLD adjusted to spec. | Pass |
| IQ.3.3 | Auxiliary components positioned | |
| | Sample probe, reagent probe, beads mixer paddle and measuring cell installed | yes |
| | Waste liner, CC/PC cups, CleanCell, ProCell positioned | yes |
| | System prime and system air purge for syringes and reagents | Pass |
| IQ 3.4 | Instrument installation check | |
| | Incubator temperature 37°C ± 0.3°C | Pass |
| | No alarms during check | Pass |
| | System Volume Check (attached printout) | Pass |
| | PMT HV adjustment (attached printout) | Pass |
| | Assay Performance Check (AM+TSH, attached printout) | Pass |
| | Blank Cell calibration (attached printout) | Pass |
| | Mechanical adjustments parameter backed up | Pass |



Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

| | |
|---|---------|
| Deviation #1 | |
| NA | |
| Investigation | |
| | |
| Action taken | |
| | |
| Deviation resolved satisfactorily? | specify |

| | |
|---|---------|
| Deviation #2 | |
| NA | |
| Investigation | |
| | |
| Action taken | |
| | |
| Deviation resolved satisfactorily? | specify |

| | |
|---|---------|
| Deviation #3 | |
| NA | |
| Investigation | |
| | |
| Action taken | |
| | |
| Deviation resolved satisfactorily? | specify |

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Qualification Service
Operation Qualification (v.1.0)





Operational Qualification:

Notice:

The steps described in OQ.1 have to be carried out after a new system installation and after any repair action which requires additional calibration.

If the service action does not affect the measurement performance, only apply steps OQ.2 and OQ.3 of the Operation Qualification.

Description

| | |
|-------------|--|
| OQ 1 | Calibration |
| | Calibration of all Immuno parameters successful (attached printout) yes |
| OQ.2 | Quality Control |
| | Specify the type of control used: 3rd Party control (Bio-Rad) |
| | QC of Immuno parameters within acceptable range (attached printout) yes |
| OQ.3 | Accuracy check for Immunology Assays |
| | Perform test with analytical reagents |
| | Any non-infectious disease assay (e.g. TSH) Number of det. 21 |
| | Sample solution: Applicable control material Fill 21 Hitachi cups with control material and perform 21 determinations of each |
| | Accuracy check for immunoassays was within acceptable range yes |

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

| | |
|---|---------|
| Deviation #1 | NA |
| Investigation | |
| Action taken | |
| Deviation resolved satisfactorily? | specify |



Attachments

1. Calibration Printout
2. QC Printout
3. Precision Data

cobas[®] e411 instrument

Qualification Service
Attachments



Result Report

Operator-ID: NELIMA

09/02/2022, 18:03

| Sample/Control ID | Seq. | Pos. | Test | Dil | RPos | Result | Flag |
|-------------------|------|------|-----------------------|-----|-------------|----------------------|------|
| 000015142304 | 3523 | 0-21 | TSH 0 | | 3 | 5.55 | H |
| 000015142304 | 3522 | 0-20 | TSH 0 | | 3 | 5.59 | H |
| 000015142304 | 3521 | 0-19 | TSH 0 | | 3 | 5.63 | H |
| 000015142304 | 3520 | 0-18 | TSH 0 | | 3 | 5.76 | H |
| 000015142304 | 3519 | 0-17 | TSH 0 | | 3 | 5.67 | H |
| 000015142304 | 3518 | 0-16 | TSH 0 | | 3 | 5.58 | H |
| 000015142304 | 3517 | 0-15 | TSH 0 | | 3 | 5.44 | H |
| 000015142304 | 3516 | 0-14 | TSH 0 | | 3 | 5.66 | H |
| 000015142304 | 3515 | 0-13 | TSH 0 | | 3 | 5.78 | H |
| 000015142304 | 3514 | 0-12 | TSH 0 | | 3 | 5.52 | H |
| 000015142304 | 3513 | 0-11 | TSH 0 | | 3 | 5.63 | H |
| 000015142304 | 3512 | 0-10 | TSH 0 | | 3 | 5.51 | H |
| 000015142304 | 3511 | 0-9 | TSH 0 | | 3 | 5.53 | H |
| 000015142304 | 3510 | 0-8 | TSH 0 | | 3 | 5.35 | H |
| 000015142304 | 3509 | 0-7 | TSH 0 | | 3 | 5.51 | H |
| 000015142304 | 3508 | 0-6 | TSH 0 | | 3 | 5.69 | H |
| 000015142304 | 3507 | 0-5 | TSH 0 | | 3 | 5.69 | H |
| 000015142304 | 3506 | 0-4 | TSH 0 | | 3 | 5.65 | H |
| 000015142304 | 3505 | 0-3 | TSH 0 | | 3 | 5.67 | H |
| 000015142304 | 3504 | 0-2 | TSH 0 | | 3 | 5.72 | H |
| 000015142304 | 3503 | 0-1 | TSH 0 | | 3 | 5.40 | H |
| 000926896900 | 3502 | 0-4 | T3 0 T4 1 TSH 0 | | 1 2 3 | 1.09 6.43 2.45 | |
| 000926897000 | 3501 | 0-3 | TSH 0 | | 3 | 9.60 | H |
| 000910308103 | 3500 | 0-2 | A-HCVII 0 | | 14 | 0.050 | |
| 000014942704 | 3499 | 0-1 | IGE 0 | | 13 | 94.92 | |
| 000014942904 | 3498 | 0-20 | TSH 0 | | 3 | 1.72 | |
| 000910308503 | 3497 | 0-19 | TSH 0 | | 3 | 6.79 | H |


 7

Cobas E411 - Intrassay Precision Study

Date : 09.02.2022

Sample ID - Pooled Human Serum Sample

Analyte - Thyroid Stimulating Hormone

| Replicate No. | Results |
|---------------|-------------|
| 1 | 5.55 |
| 2 | 5.51 |
| 3 | 5.63 |
| 4 | 5.76 |
| 5 | 5.67 |
| 6 | 5.58 |
| 7 | 5.44 |
| 8 | 5.66 |
| 9 | 5.78 |
| 10 | 5.52 |
| 11 | 5.63 |
| 12 | 5.51 |
| 13 | 5.53 |
| 14 | 5.35 |
| 15 | 5.51 |
| 16 | 5.69 |
| 17 | 5.69 |
| 18 | 5.65 |
| 19 | 5.67 |
| 20 | 5.72 |
| 21 | 5.4 |
| Mean | 5.59 |
| SD | 0.11 |
| %CV | 2.03 |

Processed By : Lab Techn Mr. Vamshi



Verified By : Quality Manager



L-Calib. could not be generated!
Released as R-Calib. by System

Test : HIVCOMPT 0
Reagent pack Lot no. : 00564117
Reagent pack number : 004795
Reagent pack expiration date : 05/2022

— Data latest successful calibration —

L Calibration

L calibration Date :
Reagent pack no. for L Calib. :
Calibrator Lot no. :
Expiration date calibrator :
Recalibration recommended at :

RP Calibration

RP Calibration date : 21/01/2022
Reagent pack no. for RP Calib. : 004795
Calibrator Lot no. : 00564117
Expiration date calibrator : 05/2022
Recalibration recommended at : 28/01/2022

— Data current measurement —

Calibration Quality Criteria

Calibrator Lot no. : 00564117
Expiration date calibrator : 05/2022
Calibration date : 21/01/2022
Missing values : ----
Slope : OK
Min/Max signal : ----
Min. acceptable difference : OK
Deviation of duplicates : --
System errors : --

Calibrators 1. signal 2. signal
1 : 1883 1805
2 : 30676 31693

Cut off : 1409
Borderline area: 0.900 - 1.00

✓
12/2/22

Calibration Result

Operator-ID: NELIMA

12/02/2022, 11:54

This calib can not be released!
No valid calibration available

Test : HBSAGII 0
Reagent pack Lot no. : 00537075
Reagent pack number : 001694
Reagent pack expiration date : 12/2021

— Data latest successful calibration —

L Calibration

L calibration Date :
Reagent pack no. for L Calib. :
Calibrator Lot no. :
Expiration date calibrator :
Recalibration recommended at :

RP Calibration

RP Calibration date :
Reagent pack no. for RP Calib. :
Calibrator Lot no. :
Expiration date calibrator :
Recalibration recommended at :

— Data current measurement —

Calibration Quality Criteria

Calibrator Lot no. :
Expiration date calibrator :
Calibration date :
Missing values : ----
Slope : OK
Min/Max signal : ----
Min. acceptable difference : OK
Deviation of duplicates : --
System errors : --

Calibrators 1. signal 2. signal

Cut off : 0.000
Borderline area: 0.900 - 1.00

V. S. 12/2/22

Calibration Result

Operator-ID: NELIMA

12/02/2022, 11:55

L-Calib. could not be generated!
Released as R-Calib. by System

Test : A-HCVII 0
Reagent pack Lot no. : 00559159
Reagent pack number : 044282
Reagent pack expiration date : 04/2022

Data latest successful calibration

L Calibration

L calibration Date :
Reagent pack no. for L Calib. :
Calibrator Lot no. :
Expiration date calibrator :
Recalibration recommended at :

RP Calibration

RP Calibration date : 03/02/2022
Reagent pack no. for RP Calib. : 044282
Calibrator Lot no. : 00559159
Expiration date calibrator : 04/2022
Recalibration recommended at : 10/02/2022

Data current measurement

Calibration Quality Criteria

Calibrator Lot no. : 00559159
Expiration date calibrator : 04/2022
Calibration date : 03/02/2022
Missing values : ----
Slope : OK
Min/Max signal : ----
Min. acceptable difference : OK
Deviation of duplicates : --
System errors : --

| Calibrators | 1. signal | 2. signal |
|-------------|-----------|-----------|
| 1 | : 1416 | 1455 |
| 2 | : 121255 | 121490 |

Cut off : 19421
Borderline area: 0.900 - 1.00

V. S. 12/2/22

Control: HIV VIROTR Lot no.: 00119150 Test: HIVCOMPT 0 Unit: COI

| | | | | | |
|------|--|--|--|--|--|
| 3SD | | | | | |
| 2SD | | | | | |
| Mean | | | | | |
| -2SD | | | | | |
| -3SD | | | | | |

Reagent Lot No : 00564117

| Date | Time | OP.ID | Result | Flag | Date | Time | OP.ID | Result | Flag |
|------|-------|-------|--------|------|------|------|-------|--------|------|
| 1 | 02/06 | 07:18 | NELIMA | 2.59 | | | | | |

| Test | Control | Contr.LOT | T.Mean | T.SD | N | Mean | SD | CV(%) |
|------------|------------|-----------|--------|-------|---|------|-------|-------|
| HIVCOMPT 0 | HIV VIROTR | 00119150 | 2.81 | 0.196 | 5 | 2.88 | 0.377 | 13.10 |

Marks in the chart and list:

- * = included data (chart)
- @ = excluded data
- ! = reagent lot number change (chart)
- * left to date = accumulated data (list)
- * right to result = out of 3 SD range (list)

Nelima
06/02/2022

Roche Diagnostics

Immunoanalyzer cobas e 411

S/N 16H021

Individual QC Chart

Operator-ID: NELIMA

12/02/2022, 16:18

Control: HIV VIROCL

Lot no.: 00107770

Test: HIVCOMPT 0

Unit: COI

| | | | | | |
|------|--|--|--|--|--|
| 3SD | | | | | |
| 2SD | | | | | |
| Mean | | | | | |
| -2SD | | | | | |
| -3SD | | | | | |

Reagent Lot No : 00564117

| Date | Time | OP.ID | Result | Flag | Date | Time | OP.ID | Result | Flag |
|------|-------|-------|--------|-------|------|------|-------|--------|------|
| 1 | 02/06 | 07:19 | NELIMA | 0.542 | | | | | |

| Test | Control | Contr.LOT | T.Mean | T.SD | N | Mean | SD | CV(%) |
|------------|------------|-----------|--------|-------|---|-------|-------|-------|
| HIVCOMPT 0 | HIV VIROCL | 00107770 | 0.550 | 0.107 | 6 | 0.699 | 0.363 | 52.01 |

Naveen
06/02/2022

Individual QC Chart

Operator-ID: NELIMA

14/02/2022, 09:55

Control: hbsa VIROT

Lot no.: 00119150

Test: HBSAGII 0

Unit: COI

| | | | | |
|------|--|--|--|--|
| 3SD | | | | |
| 2SD | | | | |
| Mean | | | | |
| -2SD | | | | |
| -3SD | | | | |

Reagent Lot No : 00537075

| | Date | Time | OP.ID | Result | Flag | Date | Time | OP.ID | Result | Flag |
|---|-------|-------|--------|--------|--------|------|------|-------|--------|------|
| 1 | 01/20 | 12:58 | NELIMA | 2.23 | ReagEx | | | | | |

| Test | Control | Contr.LOT | T.Mean | T.SD | N | Mean | SD | CV(%) |
|-----------|------------|-----------|--------|-------|---|------|-------|-------|
| HBSAGII 0 | hbsa VIROT | 00119150 | 3.16 | 0.485 | 2 | 2.09 | 0.198 | 9.47 |

Flags: ReagEx = Expired RackPack

Marks in the chart and list:

- * = included data (chart)
- @ = excluded data
- ! = reagent lot number change (chart)
- * left to date = accumulated data (list)
- * right to result = out of 3 SD range (list)

Naveen
 20/01/2022

Individual QC Chart

Operator-ID: NELIMA

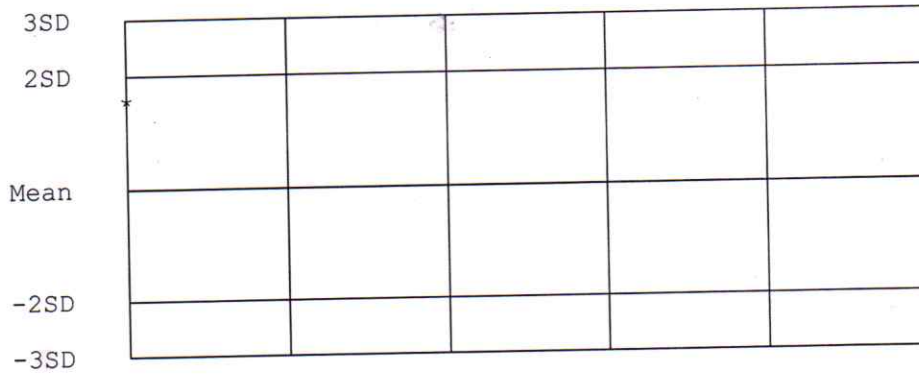
14/02/2022, 09:55

Control: hbsa VIROC

Lot no.: 00107770

Test: HBSAGII 0

Unit: COI



Reagent Lot No : 00537075

| Date | Time | OP.ID | Result | Flag | Date | Time | OP.ID | Result | Flag |
|------|-------|-------|--------|-------|--------|------|-------|--------|------|
| 1 | 01/20 | 12:58 | NELIMA | 0.706 | ReagEx | | | | |

| Test | Control | Contr.LOT | T.Mean | T.SD | N | Mean | SD | CV(%) |
|-----------|------------|-----------|--------|-------|---|-------|-------|-------|
| HBSAGII 0 | hbsa VIROC | 00107770 | 0.581 | 0.080 | 2 | 0.609 | 0.137 | 22.53 |

Flags: ReagEx = Expired RackPack

Marks in the chart and list:

- * = included data (chart)
- @ = excluded data
- ! = reagent lot number change (chart)
- * left to date = accumulated data (list)
- * right to result = out of 3 SD range (list)

Naureen
20/01/2022

Control: HCV VIROTR Lot no.: 00119150 Test: A-HCVII 0 Unit: COI

| | | | | | |
|------|---|--|--|--|--|
| 3SD | | | | | |
| 2SD | | | | | |
| Mean | * | | | | |
| -2SD | | | | | |
| -3SD | | | | | |

Reagent Lot No : 00559159

| Date | Time | OP.ID | Result | Flag | Date | Time | OP.ID | Result | Flag |
|------|-------|-------|--------|-------|------|------|-------|--------|------|
| 1 | 02/05 | 07:12 | NELIMA | 80.85 | | | | | |

| Test | Control | Contr.LOT | T.Mean | T.SD | N | Mean | SD | CV(%) |
|-----------|------------|-----------|--------|------|---|-------|------|-------|
| A-HCVII 0 | HCV VIROTR | 00119150 | 85.60 | 7.98 | 6 | 63.46 | 8.78 | 13.83 |

Marks in the chart and list:

- * = included data (chart)
- @ = excluded data
- ! = reagent lot number change (chart)
- * left to date = accumulated data (list)
- * right to result = out of 3 SD range (list)

Nelima
05/02/22

Individual QC Chart

Operator-ID: NELIMA

12/02/2022, 16:15

Control: HCV VIROCL

Lot no.: 00107770

Test: A-HCVII 0

Unit: COI

| | | | | | |
|------|--|--|--|--|--|
| 3SD | | | | | |
| 2SD | | | | | |
| Mean | | | | | |
| -2SD | | | | | |
| -3SD | | | | | |

Reagent Lot No : 00559159

| Date | Time | OP.ID | Result | Flag | Date | Time | OP.ID | Result | Flag |
|------|-------|-------|--------|-------|------|------|-------|--------|------|
| 1 | 02/05 | 07:13 | NELIMA | 0.064 | | | | | |

| Test | Control | Contr.LOT | T.Mean | T.SD | N | Mean | SD | CV(%) |
|-----------|------------|-----------|--------|-------|---|-------|-------|-------|
| A-HCVII 0 | HCV VIROCL | 00107770 | 0.072 | 0.018 | 5 | 0.086 | 0.025 | 28.97 |

Marks in the chart and list:

- * = included data (chart)
- @ = excluded data
- ! = reagent lot number change (chart)
- * left to date = accumulated data (list)
- * right to result = out of 3 SD range (list)

Navceq
 05/02/22