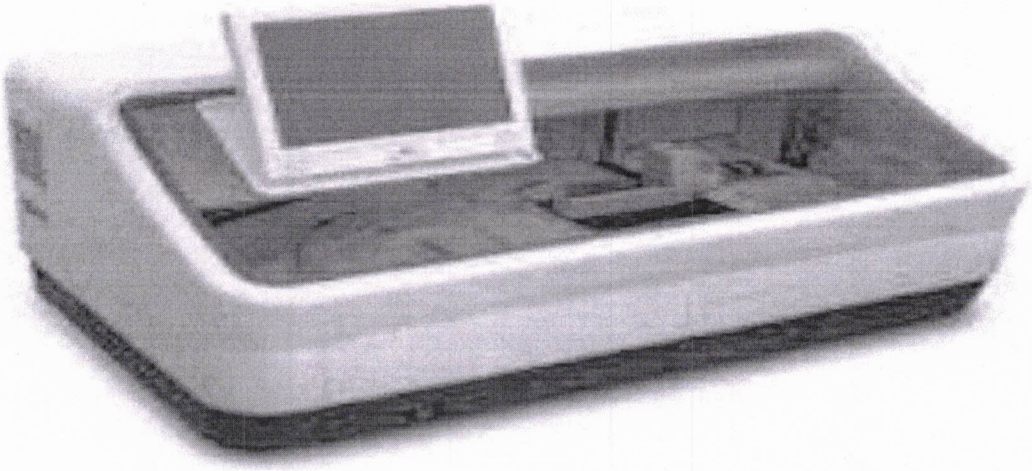
Roche



e 411

INSTALLATION QUALIFICATION,

OPERATIONAL QUALIFICATION

&

PERFORMANCE QUALIFICATION

VALIDATION REPORT

Equipment Name: Cobas e411

Equipment Make: Roche/Hitachi

Equipment Model No.: Cobas e411

Equipment Serial No.: 1198-19

Supplier: Roche Diagnostics India

Contact Name & Address: **Mr. Manoj Vishwakarma**

Roche Diagnostics India Pvt. Ltd.

Roche Professional Service,

New Delhi, Saket, 110062

I. APPROVAL OF THE IQ\OQ\PQ PROCEDURE:

Both Medicentre Clinical Lab, Chittorgarh and Roche Diagnostic India Pvt. LTD jointly responsible for the installation of cobas e-411 S.N0: 1198-19 in the Clinical Laboratory.

Validation Team from (Vendor):

Name: 1. Mr. Manoj Vishwakarma.

Designation: 1. Technical Service Specialist

Company: Roche Diagnostics India Pvt.Ltd.

Customer Authorizations:

Name: Mr. Kamlesh Jaiswal

Designation: Lab supervisor

Signature:

Date: 25/3

Site: Medicentre Clinical Lab, 7A- Ground Floor, Samrat Plaza, Main road- 05, Chittorgarh, Rajasthan, 312001.

II. INSTRUCTIONS:

1. This document is to be completed at the time the system is shifted to its current location (Clinical Laboratory) and setup for operation.

2. An authorized (Company) representative will check the system and enter the specific data related to installation, operational and performance qualification.

3. Employees of (customer) Clinical Laboratory will verify each result and sign the results. The members of the validation will carry this out.

4. All deviation from the normal specification to include any problems with installation will be noted under COMMENTS.

II. SCOPE

This installation Qualification protocol is performed on the **cobas e-411 Serial NO.: 1198-19** located at **Medicentre Clinical Lab, 7A- Ground Floor, Samrat Plaza, Main road- 05, Chittorgarh, Rajasthan, 312001.**
This protocol defines the documentation that is used to evaluate the instrument Installation in accordance with the manufacturer's specifications and intended use.
Successful completion of this protocol verifies that this instrument has been installed, operated in accordance with the intended usage.
Installation checks are performed to verify that the instrument has been installed with proper connections and utilities.

Operational qualification will evaluate that the instrument has operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument.

IV. Certificate of Purchase Order compliance

I certify to the best of my knowledge, the instrument **cobas e-411 Sl NO.1198-19** installed on **20/03/2011** is in compliance with the specifications of the purchase order

V. Equipment Description

	Instrument Identification	Verified by	Date
1	**Equipment name: Cobas e411**	**Mr. Manoj Vishwakarma**	**22/03/2011**
2	**Model: Cobas e411**	**-do-**	**22/03/2011**
3	**Marketed By:**	**Roche Diagnostics India Private Limited**	**22/03/2011**
4	**Equipment ID** (If two or more Instruments of the same category are available, first three characters of the ID should be same with different serial No. e.g. c501(1020-11),e601-(2268-08)	**e-411**	**22/03/2011**
5	**Serial No: 1198-19**	**Mr. Manoj Vishwakarma**	**22/03/2011**

6	**Size:1200mm(w);730mm(D);560mm(H)**	**Mr. Manoj Vishwakarma**	**22/03/2011**
7	**Power: AC 220 V+/-10%;60Hz Single Phase**	**Mr. Manoj Vishwakarma**	**22/03/2011**

VI. Utilities

Sno.	Utility	Verified by	Date
1	**Environmental conditions as required.** (Free from dust, electrical and magnetic interference), Yes **Yes/No** Temperature: 25°C Humidity: 45-85%	**Mr. Manoj Vishwakarma**	**22/03/2011**
2	**Adequate space for installation: Yes / No:** Yes	**Mr. Manoj Vishwakarma**	**22/03/2011**
3	**Electrical Outlets:** Actual voltage on site: 230 V	**Mr. Manoj Vishwakarma**	**22/03/2011**
4	**Grounded** Yes **Yes / No**	**Mr. Manoj Vishwakarma**	**22/03/2011**
5	**Connected through UPS** Yes **Yes / No**	**Mr. Manoj Vishwakarma**	**22/03/2011**
6	**Stabilizer** No **Yes / No**	**Mr. Manoj Vishwakarma**	**22/03/2011**

VII. The instrument has been checked for the following:

Sno.	Verification	Verified by	Date
1	Instrument is identified **Yes / No:** Yes	**Mr. Manoj Vishwakarma**	**22/03/2011**
2	Manufacturer's specifications are included **Yes / No:** Yes	**Mr. Manoj Vishwakarma**	**22/03/2011**
3	Accessories /consumables are listed **Yes / No:** Yes	**Mr. Manoj Vishwakarma**	**22/03/2011**
4	Equipment manual from the manufacturer **Yes / No:** Yes	**Mr. Manoj Vishwakarma**	**22/03/2011**

VIII. Accessories *I* Consumables

The following accessories were supplied with the instrument. Check 'verified by" in case they are found to be in order. **Separate list included**.

SNo.	Description	Quantity	Verified bv	Date
01	As Specified	As per	**Mr. Manoj Vishwakarma**	**22/03/2011**
		The List		

VIII. List of Manuals and Certificates.

Supplier provides the following with the instrument.

1	Operating Manual	Available - Yes / No
2	Purchase order	Available - Yes / No
3	Software validation certificate	Available - Yes / No
4	Safety Instructions	Available - Yes / No
5	Training Records	Available - Yes / No
6	Certificate of Authorization/Training of the engineer If any other	Available - Yes / No Available - Yes / No

IX. Maintenance:

The instrument listed within this document will be placed under the control of purchasing institution with respect to proper maintenance procedures as detailed in the operator's manual. The maintenance procedures will be filed separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period vendor will offer several level of maintenance agreements and performance testing services to assist you in maintaining GLP/GMP compliance.

Contacting your local representative and requesting the additional service agreement can supply additional information.

X. INSTALLATION PROCEDURE

a- Installation of Hardware and software

Follow the instructions mentioned in the Installation guide.

b- Installation of Printer

Follow the instructions mentioned in the Installation guide.

XI. OPERATIONAL QUALIFICATION

a) Following features/ functions are available in the instrument as per manufacturer's specification and verified e.g. self-test, washer assays, quality control, test assay, maintenance checks.

Test No.	Test Name	Test Purpose	Verified	Date
1	Self-test	To get results in range	**Mr. Manoj Vishwakarma**	**22/03/2011**
2	Quality Control	To check the accuracy of results	**Mr. Manoj Vishwakarma**	**22/03/2011**
3	Maintenance	To maintain the system	**Mr. Manoj Vishwakarma**	**22/03/2011**
4	Calibration feature	Auto Calibration	**Mr. Manoj Vishwakarma**	**22/03/2011**
5	Test Assay	All Immunoassays available with Roche	**Mr. Manoj Vishwakarma**	**22/03/2011**

Certificate of Training:

1. Technician Training

This certifies that the technicians listed below have received basic user training for the system described.

Sl No.	Training Program	Initials	Date
1	Instrument Setup	All technicians are trained.	**22/03/2011**
2	System Operation	All technicians are trained.	**22/03/2011**
3	Basic Troubleshooting	All technicians are trained.	**22/03/2011**

2. Training given by: Mr. Manoj Vishwakarma

XII. PERFORMANCE QUALIFICATION

Performance qualification validates the test procedure performed on the new instrument.

Performance qualification not only validates instrument performance but also test procedure.

QC Results - Pass/ Fail: PASS

Precision Check- Pass/ Fail: PASS

Validation Team from (Vendor):

Name: 1. **Mr. Manoj Vishwakarma**

2. **Mr. Kamlesh Jaiswal**

Designation: 1. Technical specialist

2. Lab Supervisor

Company: Roche Diagnostics India Pvt.Ltd.

Customer Authorizations:

Name: Mr. Kamlesh Jaiswal

Designation: Lab Supervisor

Signature:

Date: 25/3

Site: Medicentre Clinical Lab, 7A- Ground Floor, Samrat Plaza, Main road- 05, Chittorgarh, Rajasthan, 312001.