

Performance Qualification for ADVIA CENTAUR CP

With reference to the Annexure 2 and studies carried out in the Laboratory have determined that the analyzer meets all performance criteria and has passed Performance Qualification.

The System is ready for specific usage.

Protocol performed by: Siemens Ltd.

Signature : 

Name : Pinki Das

Designation : Application Service

Customer Authorization : Impulse Diagnostics

Signature : 

Name : J.J Purkayastha

Designation : Lab In-Charge

Date:

Annexure 2.

ADVIA CENATUR Performance Evaluation.

Following Procedure was Carried out as part of the Performance Qualification for Advia Centaur CP bearing serial No. ROB30006116 Installed in Impulse Diagnostics, Silchar:-

1. Calibration of Assay

Checked and found all calibrations within the acceptable CV limits and in range.
See Print out Attached.

2. Internal Quality Control Performance

Three-Level Biorad Lyphocheck Immunoassays Control.
Checked and found all level Controls to be within the acceptable SD limits.
See print out Attached.

3. Precision Study

A Within Run Precision of 10 replicates were carried out for TSH, TT3, TT4 and CV % obtained are within the acceptable limit for the assay.

See print out attached.

Operational Qualification for ADVIA CENTAUR CP

With reference to the Installation Procedure and Checklist and the studies carried out in Impulse Diagnostics, Silchar, **ADVIA CENTAUR CP Serial No. ROB30006116** meets all criteria outlined for Operational Qualification

Exceptional conditions, if any, have been addressed.

a. The Flooring on which the analyzer has been placed is LEVEL. Yes No

Temperature and Humidity

b. Ambient Temperature Check Found Between 18 to 25 C Yes No

c. Humidity Found to be < 80 % Yes No

The Analyzer is ready for Performance Qualification

Protocol Performed By: Siemens Ltd.

Signature : *K Baishya*

Name : Mr. Kamal Kumar Baishya

Designation : Field Service Engineer

Customer Authorization: Impulse Diagnostics

Signature : *J.J Purkayastha*

Name : Mr. J.J Purkayastha

Designation : Lab In-Charge

Installation Certificate

This is to certify that the **ADVIA CENTAUR CP Immunoassay System**, Instrument Serial
ROB 300061116 has been successfully Installed and Commissioned at
Impulse Dagnostics, Silchar as per the Installation Procedure & Checklist.

Siemens Ltd.

Name: Kamal Kumar Baishya

Designation: Field Service Engineer

Signature : *K Baishya*

Date:

Impulse Diagnostics

Name: *J.J Purkayastha*

Designation: Lab In-Charge

Signature:

Date:

Installation Qualifications for ADVIA CENTAUR CP.

Carried out all the Installation Steps as well as the Necessary Checks and Alignments of all Robotics were done as per Installation Procedure and Checklist. (See Annexure 1).

Checked the Dark Counts with & without cuvettes and obtained values acceptable.

Performed all due maintenance activities such as Automated Daily Cleaning, Automated System Prime and Probe Bubble detector calibration.

Handed over the Instrument for Operations Training & Qualifications.

Enclosed:

- a. Quality Certificate duly signed by the Siemens Plant Quality Assurance Manager.
- b. ISO 9001:2000 / ISO 13485 : 2003
- c. Declaration of Conformity.
- d. QA INSTRUMENT RELEASE APPROVAL.

For Siemens Ltd.

Name : Mr. Kamal Kumar Baishya

Designation : Field Service Engineer

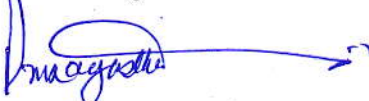
Signature : 

Date :

For Impulse Diagnostics

Name : J.J Purkayastha

Designation : Lab In-Charge

Signature : 

Date :

- c. Checked the Reagent Probe Dispense test.
- d. Checked the Tip Tray Loading and Tip Pick up.
- e. Checked the aspirate probe.
- f. Checked the Acid and Base Reagent Addition.
- g. Checked Dark Count

9. Verification of Water Requirement

- a. CLSI Type II or higher Water Used:

FSE Signature : K Baishya

Name : Kamal Kumar Baishya

Date :

Advia Centur CP

Installation Procedure and Checklist – ADVIA CENTAUR CP.

Models @ Serial No : ADVIA CENTAUR CP

Instrument Sr # : ROB30006116

Customer Name : Impulse Diagnostics

Doctor / In-Charge : Jagat Jyoti Purkayastha

Address : Hailakandi Road, Meherpur

City : Silchar

Phone : 9435213188

1. Inspect Shipper for physical damage, then Uncrate.

- a. Physical Damage to shipper : Yes No
- b. Accessories as per packing List : Yes No

2. Environmental Conditions.

- a. Air Conditioned Environment Available : Yes No
- b. Room free of Rodents/ Insects/ Pests : Yes No
- c. Humidity is less than 80 % : Yes No