

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 pe	rformed by	<i>!</i> :
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Siemens Ltd.

Signature

Pinki Das.

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. ROB30006116Installed inImpulse Daignostics, 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 Precisionof10 replicates were carried out for TSH, TT3, TT4 andCV % 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 ☐ **Temperature and Humidity** ☐ Yes ☐ No b. Ambient Temperature Check Found Between 18 to 25 C ☐ Yes ☐ No c. Humidity Found to be < 80 % The Analyzer is ready for Performance Qualification Protocol Performed By: Siemens Ltd. (Baishyer Signature : Mr. Kamal Kumar Baishya Name Designation : Field Service Engineer Customer Authorization: Impulse Diagnostics Signature : Mr. J.J Purkayastha

Name

Designation :Lab In-Charge



Installation Certificate

This is to certify that the ADVIA CENTAUR CP Immunoassay System, Instrument Serial

ROB 30006116 has been successfully Installed and Commissioned at

Impulse Daignostics, Silchar as per the Installation Procedure Checklist.

Siemens Ltd.	Impulse Diagnostics
Name: Kamal Kumar Baishya	Name: J.J Purkayastha
Designation: Field Service Engineer	Designation: Lab In-Charge
Signature: KBeishyer	Signature:
Date:	Date:



Installation Qualifications for ADVIA CENTAUR CP.

Carried out all the InstallationSteps 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 RELÉASE 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	
4		
9. Verific	cation of Water Requirement	
	*	
a.	CLSI Type II or higher Water Used:	
	as a second of the second of t	
FSE Signature	e: KBaeshya	
Name	: Kamal Kumar Baishya	
Date	SI CONTRACTOR OF THE PROPERTY	



3.	Power Requirements.
	a. Uninterrupted Power Supply Available.
20	 UPS Rating2 _KVA UPS Make Type of batteries Back Up Time0.5Hours Incoming AC Power: V AC. Earth VoltageV.
4.	General Cleanliness Around Site : Acceptable ☐ Not Acceptable ☐
5.	Verified all Instruments Components and Accessories :
6.	Installed all Accessories as per the Instrument Set - Up Procedure Below : Removed all shipping screws from the System Assembled the User Interface Modules – PC, Keyboard &Mouse Installed the Printer & Bar Code Scanner Installed the Top Cover Installed the Syringe Assembly Checked all cable connections; Checked all Electronic Boards are properly plugged in Checked the Dispense Test for Probes Installed the Current Software Version 6.1 Installed Test Definition Version 1.0.X
7.	
	a. Make: b. Installed: □ OK
8.	System Calibration and Inspection.
	a. Verified All Mechanical Configuration Adjustment of the Site and Back up in Disc
	(Instrument Calibration Diskette provided to the User Department) b. Checked the Thermal Operations of Reagent and Ancillary Compartment.



Advia Centur CP

Installation Procedure and Checklist – ADVIA CENTAUR CP.

Models @ Serial No	: ADVIA CENTAUR CP				
Instrument Sr # :ROB30	0006116				
Customer Name	: Impulse Diagnostics				08
Doctor / In-Charge	: Jagat Jyoti Purkayastha				
Address	: Hailakandi Road, Meherpur				
City	: Silchar				
Phone	: 9435213188				
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Inspect Shipper for	physical damage, then Uncrate.				
	a contract of the contract of			20	
a. Physical Dar	mage to shipper	:	☐ Yes		No
b. Accessories	as per packing List		☐ Yes		No
Environmental Cond	ditions				
2. Environmental Cont	AIGO13.				
a. Air Condition	ned Environment Available	:	☐ Yes		No
	f Rodents/ Insects/ Pests	-	_ · Yes		No
	ess than 80 %	* * 1	☐ Yes	. 🗆	No
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