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CIN No.: U24232GJ1990PTC013764

## **Calibration Certificate**

Calibration of the **B AUTO 400** (Fully Automatic chemistry Analyzer) has been carried out as per the recommendations of the principle company.

Customer Name: ST. PIOUS HEALTHCARE PVT. LTD. BHAGALPUR, BIHAR

Date of Installation: 28/11/2022.

Calibration Date :24/09/2024.

Next Calibration Due On: 23/03/2025.

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## **Performance Qualification**

**MODEL: B AUTO 400** SR.NO: AES2K1KH10040A Version: V4.8.3.7 Date: 24-09-2024

#### PQ is performed at

ST. PIOUS HEALTHCARE PVT. LTD. BHAGALPUR, BIHAR.

According to the assay results that are comprised in this document the B AUTO 400 systems can be approved for the routine operation.

PERFORMANCE CALIBRATION					
LOT No: LP10-017					
TEST	TARGET	RANGE	RESULT		
GLU	279.03	238.00 ~ 320.00	278.29		
ALT	137.00	110.00 ~ 164.00	113.30		
TBIL	6.06	4.00 ~ 6.12	5.05		
ALB	2.45	2.51 ~ 3.39	3.14		
UREA	120.00	102.00 ~ 138.00	121.77		





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СНО	290.00	262.00 ~ 328.00	302.85
CREA-E	4.59	3.67 ~ 5.51	4.64
UA	9.31	8.09 ~ 10.53	9.42
TG	255.00	214.00 ~ 296.00	260.00

Note: Performance of the parameters are subject to traceability of Reagents, Manufacturer or Supplier.





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# **Operational Qualification**

MODEL: B AUTO 400 | Sr. No: AES2K1KH10040A | Version: V4.8.3.7 | Date: 24-09-2024

Operational Qualification Protocol run at ST. PIOUS HEALTHCARE PVT. LTD. BHAGALPUR, BIHAR.

#	Description	Status
1	Blank/Optics	ОК
2	Assays(Parameter) Calibration	ОК
3	Assay (Parameter) Control – BEACON	ОК
4	Assays(Parameter) Samples(Patient)	ОК
5	Programming and operational training completed	ОК
6	Instrument operating training complected	ОК

• Error msg. list in case of hardware issue: Refer Operational Manual page no. 75

I confirm that the above specified analyzer B AUTO 400 (Fully Automatic chemistry Analyzer) is installed properly and its performance is within the specification.







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CIN No.: U24232GJ1990PTC013764

## **Installation Qualification**

MODEL: BEACONIC B 400 | Sr. No: AES2K1KH10040A | Version: V4.8.3.7 | Date: 28-11-2022

Installation of the BEACONIC B 400 (Fully auto Chemistry Analyzer) at ST. PIOUS HEALTHCARE PVT. LTD. BHAGALPUR, BIHAR.

#### The Installation Checklist is as given below:-

#	Position	Action	Status
1	Unpacking	Unpack the Complete System	ОК
2	Inventory	<b>Check Accessories With packing list</b>	ОК
3	Installation	Connection Of Pipeline Connection Of the Equipment Installation Of Software	ОК
4	Service	Executing Air Purge Checking Syringe Sample and Reagent Probe Reaction Disk	ОК
5	User	Start Work Procedure Check Reagent & DDW Cell blank Test Run QC Run Samples/Check Reproducibility Stop Work Procedure	ОК