



Calibration Certificate, Semi Automatic BioChemistry Analyzer

Name	STAR – 20 (SEMIAUTO BIOCHEMISTRY ANALYZER)
Hospital	YASH DIAGNOSTIC CENTER , VISHESHARPUR PACHAHATIYA U.P. – (222001)
Date	20 July 2021

This is certify that STAR-20 (SEMIAUTO BIOCHEMISTRY ANALYZER) have calibrated & produced following data..

Action Details:-

- AD VALUE - (49200 To 51550) Limits – 35000 to 55000
- OFFSET VALUE- (34 To 126) Limits- 0.0 to 4000
- Water Blank Abs - 0.005 Limits- < 0.01
- Temp Value - < 5% Variation Limits - < 5%

Instrument Identification				QC Passed	
Serial no.		Date of Calibration	20.07.2021	Yes	Yes
Model	STAR-20	Due Date of Calibration	19.07.2022	Yes	Yes

After calibration Q.C. Test for all level passed successfully.

Test results is coming ok	✓	Remarks	Done
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Service Engineer

Boyan

GSTIN: 09CKLPS0218M1Z0

9452769367



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Ref. :

Date : 01-10-2021

Performance Qualification for Semy Automatic Bio Chemistry Analyser Star 20 ES1001905P9004

Calibration Parameters

Checked and found all the control [parameters to be with in the acceptable CV limits and in range.

Checked and found all controls to be within The acceptable SD.

System Certification:

Study data has determined that the system described in this document either meets thenecessary criteria outlined inthis Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The system is ready for Specific Usage.

Protocol Performed By:

Name : SAURAJ SINGH

Designation : Application



PERFORMANCE QUALIFICATION DONE BY

Name : SAURAJ SINGH Designation : Application



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External Requirement for Installation:

1. Input voltage of 220V-240V/50Hz or 60 Hz.
2. Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% and Atmospheric pressure 70-106kPa.

Installation Qualification for Semy Automatic Biochemistry Analyser STAR 20 Sr. ES1001905P9004

Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Handover the Instrument for operatos Training And Qualifications

For Pragma Enterprises

Technical Services Department



Name : Sauraj Singh

Designation : Area Manager Sales & Service



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Date : 01.10.2021

Operational Qualification:

System Certification:

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

The System is ready for specific usage.

Protocol Performed by : For Pragya Enterprises

Name: Sauraj Singh

Designation: Area Manager Sales & Service



Customer Authorization : : YASH DIAGNOSTIC CENTER

VISHESHARPUR PACHAHATIYA JAUNPUR 222001

Name:

Designation:

Company Representative Name And Sign

Date:

Sauraj Singh
01-10-21

Customer Name And Sign

Date:

Yash Diagnostic Center

GSTIN: 09CKLPS0218M1ZO

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Date : 01-10-2021

Operation Qualification for Semy Automatic Bio Chemstry Analyzer Star 20

1. Verified all the Mechanical Movements : Done
2. Verifeied Hydraulics : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents Systems : Done

For Pragya Enterprises

Technical Services Department

Name : SAURAJ SINGH

Designation : Area Manager Sales & Service

Date : 01-10-2021





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Ref. :

Date : 01-10-2021

Installation Qualification for Semy Automatic Bio Chemistry Analyzer

This is to certify that the instrument Star 20 Sr. No:- ES 100195P9004 is successfully installed the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : October 2018

For Pragma Enterprises

Technical Services Department

Name : Sauraj Singh

Designation : Area Manager Sales & Service





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Ref. :

Date :

Operational Inspection:

1. Checked and found Mechanical Movements OK.
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with Controls And Samples, Results Are found OK.

For Pragya Enterprises

Technical Services Department



Name : SAURAJ SINGH

Designation : Area Manager Sales & Service



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Email : pragyaenterprises@gmail.com

Ref. :

Date : 01-10-2021

Installation Qualification for Semy Automatic BioChemistry Analyzer

Customer Name : YASH DIAGNOSTIC CENTER
 Address : VISHESHARPUR PACHAHATIYA JAUNPUR – U.P.
 Contact Person : Mr. DHARMENDRA JI
 Instrument Model : STAR 20
 Serial No. : ES 1001905P9004
 Date Of installation : OCTOBER 2018

The instrument was installed And was found to be working satisfactory. Preliminary Customer Training was provided And standardization of the parameters Were done. The results were found to be within the expected range and system found to be working satisfactorily.

For Pragya Enterprises

Customer: Yash Diagnostic Center

. Technical Services Department

Name : Sauraj Singh Contact Person : Mr. Anil Singh
 Designation : Area Manager Sales & Service Designation : Lab Incharge

Signature :



Signature :

Anil Singh

GSTIN: 09CKLPS0218M1Z0



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Email : pragmaenterprises@gmail.com

Date : 01.10.2021

Ref. :

Installation Qualification for Semy Automatic Biochemistry Analyser Star 20 No:-

ES1001905P9004

Customer Name : YASH DIAGNOSTIC

Address : VISHESHARPUR JAUNPUR 222001 – U.P.

Instrument Name : STAR 20

Serial No : ES1001905P9004

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the system to have been delivered in satisfactory condition and no external physical damaged observed on the same, Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Intallation Procedure And Checklist Attached for the records.



S.NO.	UHID NO	TEST NAME	TEST VALUE	TEST RANGE	SIGNATURE/ date
1	Control	ALBUMIN	3.25	2.88 - 3.52	MONU / 1-17-2022
2	Control	SGPT	53.28	42.99 - 60.59	MONU / 1-17-2022
3	Control	SGOT	49.51	39.84 - 56.16	MONU / 1-17-2022
4	Control	BILIRUBIN TOTAL	1.68	1.09 - 2.02	MONU / 1-17-2022
5	Control	BILIRUBIN DIRECT	0.91	0.59 - 0.19	MONU / 1-17-2022
6	Control	ALKALINE PHOSPHATE	64.29	49.80 - 70.20	MONU / 1-17-2022
7	Control	CALCIUM	7.92	6.93 - 8.47	MONU / 1-17-2022
8	Control	CHOLESTROL	127.32	104.17 - 146.84	MONU / 1-17-2022
9	Control	HDL CHOLESTROL	39.73	30.89 - 46.33	MONU / 1-17-2022
10	Control	CREATININE	1.52	1.20 - 1.70	MONU / 1-17-2022
11	Control	GLUCOSE	93	75.53 - 106.47	MONU / 1-17-2022
12	Control	TRIGLYCERIDE	94.11	74.7 - 105.3	MONU / 1-17-2022
13	Control	TOTAL PROTIEN	5.06	4.46 - 5.46	MONU / 1-17-2022
14	Control	UREA	43.9	35.47 - 50.00	MONU / 1-17-2022
15	Control	URIC ACID	5.08	4.00 - 5.64	MONU / 1-17-2022
16	Control	LDL CHOLESTROL	75.22	58.40 - 87.60	MONU / 1-17-2022
17	Control	CHLORIDE	104.44	90.0 - 110.0	MONU / 1-17-2022

