## AAMX BIOMEDICALS



Shop No. 01 Shiv Mandir Tara Nagar District Sonepat-131001, State - Haryana, India Email: <a href="mailto:aamxbiomedicals@rediffmail.com">aamxbiomedicals@rediffmail.com</a>, Mob: +91 9813151502

#### INSTALLATION QUALIFICATION

The Installation for Trace 120 Marketed By AAMX Biomedicals Sr.No.

AE2K0KH09127carried at Sanjivani Diagnostics, 2085, Near Delite Cinema, Behind
Asaf Ali Road, Petrol Pump, Delhi- 110002

Checked all the Mechanisms through the Software like Reagent Arm/Sample Arm/Mixer, Reagent Disk/ Sample Disk/ Reaction Disk Movement for different position.

Checked the system performance for different Parameters .

Calibration & Control for all the Assays was satisfactory.

Carried out the Precision Check for above parameters which was also good.

For AAMX Biomedicals,

Nitin Choudhary Zonal Manager

Delhi

Date: 05/04/2022

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#### INSTALLATION CERTIFICATE

This is to certify that the Trace 120 Marketed By AAMX Biomedicals Bio Chemistry Analyzer Sr.No.: AES2KOKH09127 has been successfully Installed and Commissioned at Sanjivani Diagnostics, 2085, Near Delite Cinema, Behind Asaf Ali Road, Petrol Pump, Delhi-110002 as per the Installation Procedure & Checklist.

For AAMX Biomedicals

For Sanjivani Diagnostics

Name: Nitin Choudhary

Designation: Zonal Manager

Signatue:

Date: 05/04/2022

SHIVKUMAR Name:

Director. Designation:

8hw kumar 05/04/2022 Signatue:

Date:

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#### PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the System Trace 120 Marketed By AAMX Biomedicals Sr. No. AE2K0KH09127

Run the TruCal U Calibrator, TruLab N control (DiaSys).

Quality Checks for which the performance is OK & the Results are Satisfactory, within the Specified range.

Precision Checks: Carried out the Precision checks for different Parameters for which Precision was found to be satisfactory.

For AAMX Biomedicals,

Nitin Choudhary

Zonal Manager Delhi

Date: 05/04/2022

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#### **Calibration Certificate**

Following voltages have been checked & adjusted on Trace 120 Marketed By AAMX Biomedicals (Sr. No. –AE2KOKH09127) at Sanjivani Diagnostics, 2085, Near Delite Cinema, Behind Asaf Ali Road, Petrol Pump, Delhi-110002.

#### System Voltages DC:

S.No.	Module	Observed Value	Acceptable Range
1	Main Power Voltage	225 VAC	220 +/- 10.0 VAC
2	24 Voltage Supply	24.4 VDC	24.0 +/- 1.0 VDC
3	12 Voltage Supply	12.3 VDC	12.0 +/- 0.5 VDC
4	Liquid Level Sensor Board Supply	4.52 VDC	4.50 +/- 0.1 VDC

#### System Temperature:

S.No.	Module	Observed Value	Acceptable Range
1	Reaction Disk Temp.	37 °C	37 +/- 0.4 °C
2	Reagent Compartment Temp.	10 °C	8 to 12 °C

#### Photometer Adjustment:

S.No.	Module	Observed Value	Acceptable Range
	I the house to the contract of	40,000 to 49,000	20,000 to 60,000
1	Background Count for all Wavelength	40,000 (0 45,000	207000

### Syringes Module:

S.No.	Module	Observed Value	Acceptable Range
5.100.	1313311	500 uL	500 +/- 1uL
1	Reagent Syringe	100 uL	100 +/- 0.1uL
2	Sample Syringe	100 00	The second secon

#### Washing Dispense:

	Las data	Observed Value	Acceptable Range
S.No.	Module	3.01 mL	3.00 +/- 500uL
1	Interior Washing	3.01 mL	3.00 +/- 500uL
7	Exterior Washing	3.01 mL	2100 17 200

- > All other mechanisms have been checked through software and found OK.
- Performed calibration for End Point, Kinetic & Fixed Time-Kinetic. Run control & sample, Results were satisfactory.
- > Next Calibration will be performed on 04/04/2023

For AAMX Biomedicals

Nitin Choudhary Zonal Manager

Delhi

Date: 05/04/2022