

## **PERFORMANCE QUALIFICATION**

**Carried out the following Checks for the Performance of the DiaSys SYS 200 (Sl. No. SYS20190808) at Oscar Path Labs, A-1/1, 3<sup>rd</sup> Floor, Outer Ring Road, Prashant Vihar, New Delhi - 110085**

**Run the Calibration for End Point, Kinetic & Fixed-Time Kinetic Calibration was Successful.**

**Run the Trulab N & Trulab P control for Different Parameters.**

**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.**

***Linearity Check: Carried out the linearity check for different parameters for which linearity was found to be satisfactory.***

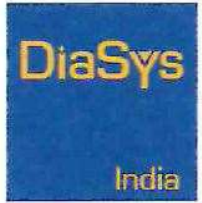
***For DiaSys Diagnostics India Pvt. Ltd.,***



***Asmat Sami***

***RSM (NORTH)***

***Date: 30/08/2022***



## **OPERATIONAL QUALIFICATION**

**For Operational Qualifications carried out the following checks on the SYS 200 (Sl. No. SYS20190808)**

**Checked the overall System Mechanism found the Robotic Arm (Sample/ Reagent Arm), Vertical and Horizontal Movement In/Out) Performance is ok.**

**Software Checks: Carried out the check for Calibration, Control, Assay, Results, Data & the performance is ok.**

**Checked all the Operational Qualifications & found the functioning is Satisfactory.**

**For DiaSys Diagnostics India Pvt. Ltd.,**

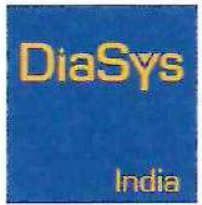
A handwritten signature in blue ink that reads "Asmat Sami".



**Asmat Sami**

**RSM (NORTH)**

**Date: 30/08/2022**



## **INSTALLATION QUALIFICATION**

***The Installation for SYS 200 ((Sl. No. SYS20190808) at Oscar Path Labs, A-1/1, 3<sup>rd</sup> Floor, Outer Ring Road, Prashant Vihar, New Delhi - 110085***

***Checked all the Mechanisms through the Software like Robotic Arm (Sample/Reagent Arm), Reagent Tray & Sample Tray Movement for different position.***

**Robotic Arm: Carried out the Adjustment for Robotic Arm for Wash station for Sample, Reagent, Cuvettes positions.**

**Lamp: The Photometer all channels are within range for all wavelengths.**

**Checked the system performance for different Parameters like End Point, Kinetic & Fixed-Time Kinetic.**

**Calibration & Control for all the Assays was satisfactory.**

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

**For DiaSys Diagnostics India Pvt. Ltd.,**

A handwritten signature in blue ink that reads "Asmat Sami".



**Asmat Sami**

**RSM (NORTH)**

**Date: 30/08/2022**

## **CERTIFICATE OF CALIBRATION**

This is to certify that the below mentioned instrument installed at **Oscar Path Labs, A-1/1, 2<sup>rd</sup> Floor, Outer Ring Road, Prashant Vihar, New Delhi - 110085**

, Has Been Calibrated By Us On **30/08/2022**, The Next calibration is due on before **29/08/2023**, The values are falling within the specified range.

**Instrument - Biochemistry**

**Analyser Model - SYS 200**

**Serial No.- . SYS20190808**

***For DiaSys Diagnostics India Pvt. Ltd.,***



***Asmat Sami***

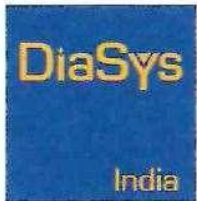
***RSM (NORTH)***

***Date: 30/08/2022***

**DiaSys Diagnostics India Private Limited**

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**Registered Office**

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**DiaSys Diagnostics India Private Limited**

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Point-of care testing and automated Laboratory systems

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