

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, 3rd 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.

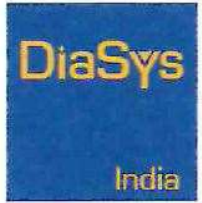
For DiaSys Diagnostics India Pvt. Ltd.,



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, 3rd 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.,



Asmat Sami

RSM (NORTH)

Date: 30/08/2022