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Performance Qualification

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Purpose: To have complete certification on Performance Qualification for Architect i1000SR

Performance qualification validates the test procedure performed on the new instrument.
 Performance qualification not only validates instrument performance but also test procedure.

All in-house protocols are validated for performance qualification of instrument and method.

1.Scope: To Calibrate HIV, Anti-HCV, HBsAgQ2 Assay.

- 1) Ordered the HIV, Anti-HCV, HBsAgQ2 Assay from the order list.
- 2) Ran the Assays and the calibration got passed and RLU value are within the limits.
- 3) IQC performed and recovery found satisfactory.

Comments: Assays Passed / Failed.

2. Scope: To check Precision of the instrument with HIV, Anti-HCV, HBsAgQ2 Assay


- 1) Run Precision and the Result are attached along with the PQ.

Comments: Precision study: Passed / Failed

3.Scope: To perform the carry over study for HIV, Anti-HCV, HBsAgQ2 Assay

- 1) Carryover study performed, and the Result are attached along with the PQ

Comments: Carryover study: Passed / Failed

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4. Scope: To perform the Method Comparison study for HIV, Anti-HCV, HBsAgQ2 Assay

- 1) Method comparison study study performed, and the Result are attached along with the PQ

Comments: Method Comparison: [✓] Passed / Failed

Performed by	Signature	Date
Jithin Preetha Lead-TechnicalApplication Specialist	<i>JITHIN PREETHA</i>	<i>04/12/2021</i>
Medical Trust Hospital, Cochin Microbiology Department	<i>[Signature]</i>	<i>4/12/21</i>