INSTALLATION QUALIFICATION

Tosoh HLC-723GX - Automated Glycohemoglobin Analyzer

For

Lupin Diagnostic Ltd.

1st Floor, Kiran Plaza; 84 District Centre, Chandrasekharpur,
Odisha – 751016

MARKETED BY:

Tosoh India Pvt. Ltd.

GEBI Industrial Park, Building No. “C”, Bhiwandi, Thane- 421302

TOSOH

Validation Protocol	**:**	**Installation Qualification**
System / Instrument	**:**	**HLC-723GX**
Sr. No.	**:**	**12723302**
Protocol Written By	**:**	**Tosoh India Pvt. Ltd.**
Laboratory	**:**	**Lupin Diagnostic Ltd., Bhubaneshwar**
Engineering Approval By	**:**	
Laboratory Approval By	**:**	
QA Approval By	**:**	

Objective

To ensure that the system / Instrument installed confirms to the purchase specifications and the manufacturers literature, and to document the information that the equipment meets the specifications.

Scope

To be performed at time of installation, modification or relocation.

Responsibility

Person overseeing the installation from Tosoh India Pvt. Ltd. will perform the qualification and record the information. He will verify the records and write the IQ Report.

Engineering Department at: **Lupin Diagnostic Ltd., Bhubaneshwar** will review the IQ Results.

Quality Assurance Department at **Lupin Diagnostic Ltd., Bhubaneshwar** will approve the IQ Protocol and Report.

System / Equipment: HLC-723GX **Instrument ID: Sr. No.12723302**

a) Description of the System / Instrument being installed:

The HLC-723GX is intended to assay A1C (%) out of the total hemoglobin in blood for in vitro diagnostic use based on High Performance Liquid Chromatography principle with the cationic non-porous ion exchanger using the ionic difference. To use the analyzer, simply place the cap-pierced primary tube on the rack of the sample loader, and the analyzer will assay for A1C every 2.2 minutes with sampling and dilution.

Analyzer Characteristics:

1. Operation Panel

The operation panel is a monochrome LCD with touch keys. The operation is controlled with the touch keys on the screen. Various settings can be made on the screen. Individual basic function keys such as POWER, START, STOP, HOME and ERROR RESET are provided on the right side of the display. Routine operations are executed with these keys.

2. Printer

The printer paper roll is thermal-sensitive. It prints out assay results, error messages and parameter status. The assay results can be printed out in two different formats. A roll can handle about 350 sample results depending upon the format.

3. Storage Device

The analyzer is equipped with an internal USB socket. It is used to store assay results, update and backup program versions. A maximum of 250 thousand sets of assay results can be stored on one USB Stick (1GB) formatted by the analyzer. The last 800 sets of assay results are also automatically saved in the analyzer's internal memory.

4. Line Filter

The line filter prevents impurities (such as dust from a broken valve seal) from entering the assay line. The filter element can easily be replaced by hand without any tools.

5. Column Oven

The column oven contains the column, a critical component in assaying. The column must be kept at a constant temperature always to prevent temperature fluctuations that can have an effect on the test results. The column oven maintains a constant temperature so that no wait time is required, unless the main power switch (left side) is turned off. The column can be manually connected. This allows the column to be easily replaced without using any special tools.

6. Drain Valve

If air enters the pump, open this valve and perform a drain flush in order to remove all air out of the instrument. Do not open this valve during assay.

7. Injection Valve

This valve is used to inject a sample into the assay line after it is diluted. The sample loop volume is 6.5μL.

8. Rotary Valve

The rotary valve is used to switch flow paths during sampling and elution buffer priming.

9. Sampling Mechanism

By means of detectors the instrument can make a difference between sample cups and whole blood samples. In case of whole blood, the sample is automatically diluted and injected into the assay line. When the sample is injected into the column, the sample holder is rotated and will continue till last sample arranged on turn table.

10. Pump

The pump uses the plunger method to deliver the elution buffer required for the assay. The pump operates continuously to deliver the elution buffer during the assay and feeds three different concentration elution buffers in 2.2 minutes cycles by switching the solenoid valves. It also forms a gradient (concentration control), and the hemoglobin fractions are separated by the column.

11. Degassing unit

The degassing unit removes air bubbles in the elution buffer. The vacuum pump runs intermittently to keep a constant vacuum pressure in the chamber.

12. Turn Table

The Turn table has 10 sample holders for setting samples. Primary tubes and sample cups can be set in the sample holders. Detection of the presence of samples and identification of primary tubes and sample cups take place automatically and the samples are aspirated into the sampling mechanism. Whole blood samples are automatically diluted, and taken to the assay line.

b) List of the main components

Main Unit (HLC-723GX) 1

- Power Cord for the Main Unit 2 m 1
- Waste Eluent Bottle 5 L 1
- Waste Tank Container 1
- Screw Driver (+) 100 mm 1
- Sample Cup 50
- Flared Type Union 1
- System USB Stick 1
- Holder for Reagent pack 1
- Accessory box 1

c) Additional Accessories

*Accessory list included with the instrument

Checklist:
System / Equipment: HLC-723GX **Instrument ID: Sr. No.12723302**

	Required / Ordered	Actual	Deviations
Model	HLC-723GX	HLC-723GX	Nil
System Description	Glycohemoglobin Analyzer	Glycohemoglobin Analyzer	Nil
Dimensions of Analyzer Unit -			
Width	370mm	370mm	Nil
Depth	525mm	525mm	Nil
Height	482mm	482mm	Nil
Weight	25Kg	25Kg	Nil
Electrical Power Requirements -			
Line Voltage	100 – 240 VAC	100 – 240 VAC	Nil
Frequency	50/60HZ	50/60HZ	Nil
Power Consumption	180VA	180VA	Nil
Environmental Conditions -			
Temperature	15º C – 30º C	15º C – 30º C	Nil
Humidity	40% – 80%, (No condensation)	40% – 80%, (No condensation)	Nil
Dust	Typical office level	Typical office level	Nil

Water Requirements	Nil	Nil	Nil

Liquid Waste -			
Liquid Waste Container	5 Litres	5 Litres	Nil
Throughput Rate -			
Assay Measurement	2.2 min/sample	2.2 min/sample	Nil
Sampling System -			
Sample Pipette Principle	Cap Piercing	Cap Piercing	Nil
Sample Volume per Test	3ul Whole Blood, 120ul Diluted Sample	3ul Whole Blood, 120ul Diluted Sample	Nil
Tube / Sample Cup Detection	Possible	Possible	Nil
Sample Loading Capacity	Maximum 10 Possible	Maximum 10 Possible	
Reagent System -			
Reagents	Buffer 1, Buffer 2, Buffer 3 and Hemolysis/wash solution	Buffer 1, Buffer 2, Buffer 3 and Hemolysis/wash solution	Nil
No Extra Wash Solution	Yes	Yes	Nil

Installation Procedure	**Protocol Location**	**Performed**		**Sign**	**Date**
		Yes	**No**		
Installation of Hardware	See Chapter 2 – Installation of the Operators Manual	Yes			
Installation Checks	See Chapter 2 – Installation of the Operators Manual	Yes			

Performed By: **Signature / Date:**

Deviation: Nil

Reviewed By: Engineering Dept – Tosoh India Pvt. Ltd. **Signature / Date:**

OPERATIONAL QUALIFICATION

Tosoh HLC-723GX - Automated Glycohemoglobin Analyzer

For

Lupin Diagnostic Ltd.

1st Floor, Kiran Plaza; 84 District Centre, Chandrasekharpur,
Odisha – 751016

MARKETED BY:

Tosoh India Pvt. Ltd.

GEBI Industrial Park, Building No. “C”, Bhiwandi, Thane- 421302

TOSOH

Validation Protocol : Operational Qualification

System / Instrument	:	**HLC-723GX**
Sr. No.	:	**12723302**
Protocol Written By	:	**Tosoh India Pvt. Ltd.**
Laboratory	:	**Lupin Diagnostic Ltd., Bhubaneshwar**
Engineering Approval By	:	
Laboratory Approval By	:	
Q.A. Approval By	:	

Objective

To determine that the system/ instrument operates according to specifications and to record all relevant information and data to demonstrate it functions as expected.

Scope

To be performed after installation, modification, or relocation has been completed.

Responsibility

Person responsible for operating the system/ instrument from Tosoh India Pvt. Ltd. will perform the qualification and record the information.

He will supervise the study, verify the completion of the records, and write the deviation report and the operational qualification report.

Customer quality assurance department will review and approve the OQ protocol and report.

Materials, SOP's, Documents:

Following are the topics course needed to perform the operation qualification -

- Daily operating procedures – Operator's Manual - Chapter 3.0
- Maintenance procedures – Operator's Manual - Chapter 5.0
- Special operation – Operator's Manual - Chapter Appendix

Procedure:

- Provide SOP's and data sheets for normal operation of the system
- Provide basic operation training and documenting the operators has been trained.
- Ensure adequate practice with general maintenance and some tips to trouble shooting.
- Test and record calibration data with QC report.
- Test and record outputs.
- Record any deviations to the procedures performed
- Prepare a deviation report including the justification of acceptance and impact on the operation.

Prepare an Operational Qualification Report:

- This should include data study initiated, data completed, observations made, problems encountered, completeness of information collected, results of control/ alarm tests, sample data if appropriate, other information relevant to the study, and conclusions on the validity of the instrument/ system operations.

- Submit the reports to QA for review and approval.

System/ Instrument: HLC-723GX **Laboratory:** Lupin Diagnostic Ltd., Bhubaneshwar

Preparation: Document check

SOP Title and number File Location QA/QC approval date

Daily Operation ----

Maintenance ----

Special functions ----

Training Records:

Name	**Signature**

For training certificates contact local Support team members

Equipment make and model **Manual available**

Tosoh HLC-723GX Y {√} N { }

Results:

Calibration and Control Data

Calibration Data:
Tosoh Calibration Lot No.: ZS2001

Test	Date Performed	Results (%)	Acceptable Y/N	Acceptability Criteria
HbA1c Calibrator 1	17.10.2023	4.6	Y	Target: 5.90% ± 30 % from target, ±0.3% within run
HbA1c Calibrator 1	17.10.2023	4.6	Y	
HbA1c Calibrator 1	17.10.2023	4.6	Y	
HbA1c Calibrator 2	17.10.2023	8.3	Y	Target:10.55%±30 % from target, ±0.3% within run
HbA1c Calibrator 2	17.10.2023	8.3	Y	

QC Data:
Randox Control Lot No.: 2341HA & 2343HA

Test	Date Performed	Control Range (%)	Results (%)	Acceptable Y/N
HbA1c Control Level 1	17.10.2023	5.22 - 6.07	5.7	Y
HbA1c Control Level 2	17.10.2023	10.3 - 12.2	11.3	Y

**For Calibration and QC results data refer to attachment*

Performed By: **Tosoh India Pvt. Ltd.**	**Signature / Date:**
Deviations: Nil	
Verified By: ____________________	**Signature / Date:**

System/ Instrument: HLC-723GX **Laboratory:** Lupin Diagnostic Ltd., Bhubaneshwar

Maintenance procedures of the Instrument or System

Daily	Weekly	Once in 6/12 Months
Startup	Updating Calibration curves	Instrument Calibration(12M)
Shut Down	Replace filters based on Number of Injections	Cleaning of Probe(6M)
Filter replacement checking based on number of Injections	Clean the instrument with Wet/ Dry cloth	Internal Cleaning of Teflon tubes(6M)
Waste Bottle Checking	Column Injections Checking	Column Injections checking(6M)
Column Injection Checking		Preventive Maintenance(6M)

Deviation Report

- **Deviation(s)** : NIL
- **Justification for Acceptance** : All operational requirements qualified.
- **Impact on Operation** : Instrument ready for its performance qualification & routine operation.

Operation Qualification Report

- **Date Study Initiated** : 17.10.2023
- **Date Study Completed** : 17.10.2023
- **Observations Made** : Operational qualification complies as per manufacturer Recommendations
- **Problems encountered** : Nil
- **Completeness of Information Collected** : All information found to be complete
- **Results of the Tests** : Acceptable results.
  For Calibration and QC results refer to the attachment

Conclusions on the validity of the system operations:

- Study data has determined that the system described in this document meets/ ~~does not meet~~ all the criteria outlined in this operational qualification protocol.
- Operation qualification completed/ ~~not completed~~ successfully
- The system is ready for its performance qualification.

Written by: Tosoh India Pvt. Ltd. **Sign/Date**

QA Approved by: _____________ **Sign/Date**

PERFORMANCE QUALIFICATION

Tosoh HLC-723GX - Automated Glycohemoglobin Analyzer

For

Lupin Diagnostic Ltd.

1st Floor, Kiran Plaza; 84 District Centre, Chandrasekharpur,
Odisha – 751016

MARKETED BY:

Tosoh India Pvt. Ltd.

GEBI Industrial Park, Building No. “C”, Bhiwandi, Thane- 421302

TOSOH

Validation Protocol	**:**	**Performance Qualification**
System / Instrument	**:**	**HLC-723GX**
Sr. No.	**:**	**12723302**
Protocol Written By	**:**	**Tosoh India Pvt. Ltd.**
Laboratory	**:**	**Lupin Diagnostic Ltd., Bhubaneshwar**
Laboratory Approval By	**:**	
QA Approval By	**:**	

Objective

To determine that the system/ instrument operates according to specifications and to record all relevant information and data to demonstrate its functions as expected.

Scope

To be performed after installation, modification, or relocation, after the installation qualification and Operational qualification has been completed

Responsibility

Person responsible for operating the system/ instrument from Tosoh India Pvt. Ltd. will perform the Performance qualification report and record the information.

He will supervise the study, verify the completion of the records, and write the deviation report, assay validation and the Performance Qualification report.

Customer quality assurance department will review and approve the PQ protocol and report.

a) Description of the System / Instrument being installed:

HLC-723GX works on the principle of High Performance Liquid Chromatography (HPLC).
The analyzer uses the Cation exchange column to separate hemoglobin components by different ionic charge.

a. Variant Analysis Mode
b. Instrument interfaced with 10 samples Turn Table (Sample Carousel).

Procedure:

- Provide SOP's and data sheets for normal operation of the system.
- Provide basic operation training and documenting the operators has been trained.
- Ensure adequate practice with general maintenance and some tips to trouble shooting.
- Test and record calibration data with QC report.
- Test and record outputs.
- Record any deviations to the procedures performed.
- Prepare a deviation report including the justification of acceptance and impact on the operation.

Prepare a Performance Qualification Report:

- This should include data study initiated; data completed; observations made; problems encountered; completeness of information collected; results of control/ alarm tests; sample data if appropriate; other information relevant to the study; and conclusions on the validity of the instrument/ system operations.
- Submit the reports to QA for review and approval.
- Document the information requested below:
- Instrument Manufacturer: TOSOH Corporation, Japan
- Reagent Manufacturer: TOSOH Corporation, Japan

Reagents Used to Estimate the requested Test:

- TSK gel HLC-723GX column
- GX Elution Buffer No. 1
- GX Elution Buffer No. 2
- GX Elution Buffer No. 3
- HSi Hemolysis & Wash Solution
- Filter Element
- Calibrator - 2 levels

Accessories:

- Printer Paper
- Control Level 1 & Level 2

Results:

Calibration and Control Data

Calibration Data:
Tosoh Calibration Lot No.: ZS2001

Test	Date Performed	Results (%)	Acceptable Y/N	Acceptability Criteria
HbA1c Calibrator 1	17.10.2023	4.6	Y	Target: 5.90% ± 30 % from target, ±0.3% within run
HbA1c Calibrator 1	17.10.2023	4.6	Y	
HbA1c Calibrator 1	17.10.2023	4.6	Y	
HbA1c Calibrator 2	17.10.2023	8.3	Y	Target:10.55%±30 % from target, ±0.3% within run
HbA1c Calibrator 2	17.10.2023	8.3	Y	

QC Data:
Randox Control Lot No.: 2341HA & 2343HA

Test	Date Performed	Control Range (%)	Results (%)	Acceptable Y/N
HbA1c Control Level 1	17.10.2023	5.22 - 6.07	5.7	Y
HbA1c Control Level 2	17.10.2023	10.3 - 12.2	11.3	Y

**For Calibration and QC results data refer to attachment*

Performed By: **Tosoh India Pvt. Ltd.** **Signature / Date:**

Deviations: Nil

Verified By: ____________________ **Signature / Date:**

Purpose & Scope	:	Performance Validation of Tosoh HLC-723GX
Specimen	:	Randox HbA1c Controls
Experiments	:	1. Accuracy and Precision check

These results analyzed with respect to Standard deviations, Coefficient of variation (%) and Total error observed.

1. **Accuracy and Precision Check**

Name: Randox Controls (Lot No.2341HA & 2343HA)

Level 1: Target Value: 5.67%(NGSP) Level 1 Range: 5.22% - 6.07%

Level 2: Target Value: 11.4%(NGSP) Level 2 Range: 10.3% - 12.2%

A. Intra Assay Precision and Accuracy Study:

INTRA ASSAY PRECISION AND ACCURACY		
Replicates	**Level 1 (%)**	**Level 2 (%)**
1	5.7	11.3
2	5.7	11.4
3	5.7	11.4
4	5.7	11.4
5	5.7	11.4

Control Data			
	Average	**SD**	**CV%**
Level 1	5.7	0.00	0.00
Level 2	11.38	0.04	0.39

B. Inter Assay Precision and Accuracy Study:

Inter-Assay Run Data								
Randox Control Level 1								
Date	**Run 1 (%)**	**Run 2 (%)**	**Run 3 (%)**	**Run 4 (%)**	**Run 5 (%)**	**Mean (%)**	**S.D.**	**C.V. (%)**
17.10.2023	5.7	5.7	5.7	5.7	5.7	5.7	0.0	0.0
18.10.2023	5.8	5.8	5.8	5.8	5.8	5.8	0.0	0.0

Inter-Assay Run Data								
Randox Control Level 2								
Date	**Run 1 (%)**	**Run 2 (%)**	**Run 3 (%)**	**Run 4 (%)**	**Run 5 (%)**	**Mean (%)**	**S.D.**	**C.V. (%)**
17.10.2023	11.3	11.4	11.4	11.4	11.4	11.38	0.04	0.4
18.10.2023	11.5	11.5	11.5	11.5	11.5	11.50	0.00	0.0

Control Data			
	Average	**SD**	**CV%**
Level 1	5.75	0.05	0.92
Level 2	11.44	0.07	0.61

Inference: Less than 1% CV% was observed for both Intra-Assay and Inter-Assay Precision

System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostic Ltd., Bhubaneshwar

Performance Qualification Report:

- **Date Study Initiated** : **17.10.2023**
- **Date Study Completed** : **18.10.2023**
- **Observations Made** : Performance qualification complies as per manufacturer Recommendations
- **Problems encountered** : Nil
- **Completeness of Information Collected** : All information found to be complete
- **Results of the Tests** : Acceptable results.
  For Calibration and QC results refer to the attachment

Conclusions on the validity of the system operations:

- Study data has determined that the system described in this document **meets**/ ~~does not meet~~ all the criteria outlined in this operational qualification protocol.
- Performance qualification **completed**/ ~~not completed~~ successfully
- The system is ready after its performance qualification for routine operations.

Written by: Tosoh India Pvt. Ltd., Sign/Date

QA Approved by: _____________ Sign/Date