Tosoh India Pvt. Ltd.,

Tosoh HLC-723GX

Automated Glycohemoglobin Analyzer

INSTALLATION QUALIFICATION

For

Lupin Healthcare Limited,

Bardhaman, West Bengal, India.

MARKETED BY:

Tosoh India Pvt. Ltd.

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

TOSOH

Validation protocol # Installation Qualification

System/ Instrument: HLC-723GX

Protocol Written by: Tosoh India Pvt Ltd.,

Lupin Healthcare Limited, Bardhaman, West Bengal

Engineering Approval by: Lalit Patra

Laboratory Approval by: - Dr. Koushik Samanta (30.11.21)

QA Approval by: Sushadeep Pal

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 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 Healthcare Limited, Bardhaman Site will review the IQ results. Quality Assurance Department at Lupin Healthcare Limited, Bardhaman Site will approve the IQ Protocol and Report.

System/ Equipment: HLC -723GX **Instrument ID:** Sr. No 12080812

a.) Description of the System/ Instrument being Installed:

The HLC-723GX is intended to assay A_{1c} (%) 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 A_{1c} every 2.2 minutes with sampling and dilution. In addition to A_{1c} (HbA_{1c}), both HbA_1 and hemoglobin F (HbF) can be measured.

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. LED panel

Three kinds of Light Emitting Diodes (LEDs) indicate the analyzer status: Power, Run, and ERROR.

3. 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.

4. 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 12,000 sets of assay results (approximately 500 days) can be stored on one card (32 MB) formatted by the analyzer. The last 800 sets of assay results are also automatically saved in the analyzer's internal memory.

5. 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.

6. Column oven

The column oven contains the column, a critical component in assaying. The column must be kept at a constant temperature at all times 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 and can be easily replaced without any special tools.

7. 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.

8. Injection valve

This valve is used to inject a sample into the assay line after it is diluted. The sample loop volume is 6 µL.

9. Rotary valve

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

10. 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.

11. 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 minute cycles by switching the solenoid valves. It also forms a gradient (concentration control), and the hemoglobin fractions are separated by the column.

12. 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.

13. 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 Vial 50
- Flared Type Union 1
- Printer Paper (Thermal paper roll) 1
- Holder for Reagent pack 1
- 5 L Bottle Cap 1
- Accessory box 1

Additional accessories

*Accessory list attached

Procedure

Prepare a checklist for all components and parts, including spare parts according to the purchase order and manufacturers specifications.

Record the information for each actual part, component, auxiliary instrument, supporting facilities and compare to the manufacturer's specifications.

Perform: -Installation of Hardware,

(See chapter 2.0 Installation of the Operators manual)

-Installation checks,
(See chapter 2.0 Installation of the Operators manual)

Record any deviations to the system / Instrument.

Prepare a Deviation Report including the justification of acceptance and impact on the function.

Prepare an Installation Qualification Report:

This should include:

Date study initiated;
Date completed;
Observations made;
Problems encountered;
Completeness of information collected;
Results of any tests;
Sample data if appropriate;
Other information relevant to the study;
And conclusion on the validity of the installation.

Submit the report to Customers Quality Assurance department for approval

Checklist
System: HLC-723GX Instrument ID: Sr. No 12080812

	Required/ Ordered	Actual	Deviations
Model	HLC-723GX	HLC-723GX	
System Description	Glycohemoglobin Analyzer	Glycohemoglobin Analyzer	Nil
Dimensions of Analyzer Unit			
Width	370mm	370mm	Nil
Depth	525mm	525mm	
Height	482mm	482mm	
Weight	25Kg	25Kg	
Electrical Power Requirements			
Line Voltage	100 – 240 VAC	100 – 240 VAC	
Frequency	50/60HZ	50/60HZ	Nil
Power consumption	180VA	180VA	

	Required/ Ordered	Actual	Deviations
Model	HLC-723GX	HLC-723GX	
Environmental Conditions Temperature Humidity Dust	15deg C – 30deg C 40% – 80%, (No condensation) Typical office level	15deg C – 30deg C 40% – 80%, (No condensation) Typical office level	Nil
Water requirements	Nil	Nil	Nil
Liquid Waste Liquid waste Container	5 litres	5 litres	Nil
Throughput Rate Assay measurements	2.2 Samples/min	2.2 Samples/min	Nil

	Required/ Ordered	Actual	Deviations
Model	HLC-723GX	HLC-723GX	
Sampling System Sample Pipette principle Sample volume per Test Tube / sample cup detection Sample loading capacity Continuous loading	 Cap Piercing 3ul whole blood, 80ul diluted sample Possible Maximum 10 Possible	 Cap Piercing 3ul whole blood, 80ul diluted sample Possible Maximum 10 Possible	Nil
Reagent System Reagents No extra wash solution	 Buffer 1, Buffer 2, Buffer 3 and Hemolysis/wash solution Yes	 Buffer 1, Buffer 2, Buffer 3 and Hemolysis/wash solution Yes	Nil

	Required/ Ordered	Actual	Deviations
Model	HLC-723GX	HLC-723GX	
Column Temperature Peltier control	Yes, 25deg C	Yes, 25deg C	Nil
Measuring System Measuring method Sampling Time	2 Wavelength Absorption Detection 2.2 Minutes	2 Wavelength Absorption Detection 2.2 Minutes	Nil
Standard conformity	EMC standard IEC60601-1-2:2001	EMC standard IEC60601-1-2:2001	Nil
Output	Thermal Printer/RS 232 Serial communication port	Thermal Printer /RS 232 Serial communication port	Nil
Calibration Method	2- Point Method for HbA1c	2- Point Method for HbA1c	Nil

Installation Procedure	Protocol Location	Performed Yes/No	Sign/Date
Installation of Hardware	See chapter 2 Installation of the Operators manual)	Yes	Lalit Patra 30.11.21
Installation checks	See chapter 2 Installation of the Operators manual)	Yes	Lalit Patra 30.11.21

Performed by: Tosoh India Pvt. Ltd.	Sign /Date: Lalit Patra 30.11.21
Deviation:	
Reviewed by: Engineering Dept – Tosoh India Pvt. Ltd.	Sign /Date: Lalit Patra 30.11.21

Tosoh India Pvt. Ltd.,

Tosoh HLC-723GX

Automated Glycohemoglobin Analyzer

OPERATIONAL QUALIFICATION

For

Lupin Healthcare Limited,

Bardhaman, West Bengal, India.

Tosoh India Pvt. Ltd.

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

TOSOH

Validation protocol # Operational Qualification

System/ Instrument: HLC-723GX

Protocol Written by: Tosoh India Pvt Ltd.,

Lupin Healthcare Limited, Bardhaman, West Bengal

Laboratory Approval by: Dr. Koushik Samanta (30.11.21)

QA Approval by: Subhadeep Pal.

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, after the installation qualification 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

1. Daily operating procedures – Operators manual chapter 3.0
2. Maintenance procedures – Operators manual Chapter 5.0
3. Special operation – Operators 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 competed; observations mode; 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.

Preparation: Document check

SOP Title and number	File Location	QA/QC approval date
Daily Operation	----	30.11.21
Maintenance	----	30.11.21
Special functions	----	30.11.21

Training records:

	Staff Name	**Signature**
1	Mr. Dipankar Majhi	Dipankar Majhi
2	Mr. Souvik Pal	Souvik Pal
3	Mr. Subhadeep Pal	Subhadeep Pal
4	Mr. Soumyajit Banerjee	Soumyajit Banerjee
5	Mr. Prithwi Nandi	Prithwis Nandi
6	Ms. Suravi Mukherjee	Suravi Mukherjee.

For training certificates contact Local Support Team members

Equipment make and model

Tosoh HLC-723GX

Manual available

Y{✓} N{ }

Performed by: Tosoh India Pvt. Ltd.,

Lalit Patra
Sign/date

Deviations:_____

Verified By: Subhadeep Pal.

Lalit Patra
Sign/date

Results

Calibration and Control data:

Calibration data
Lot: ZS0003 **Expiry: 31-01-2023**
Level 1: 5.9% **Level 2: 10.5%**

Test	Date performed	Results	Acceptable Y/N
HbA1c	30.11.2021	4.6	Y
HbA1c	30.11.2021	4.7	Y
HbA1c	30.11.2021	4.7	Y
HbA1c	30.11.2021	8.7	Y
HbA1c	30.11.2021	8.7	Y

QC Data

Tosoh Diabetes HbA1c Control Set

Lot: AB0050 **Expiry:30-12-2022**
Level 1: 5.0% ± 0.3 **Level 2: 10.0% ± 0.5**

Test	Control	Results	Acceptable Y/N
HbA1c Level 1 Control	30.11.2021	5.0	Y
HbA1c Level 2 Control	30.11.2021	10.1	Y

Performed by: Tosoh India Pvt. Ltd., Sign/date Lalit Patra 30.11.21

Deviations:_____

Verified By: Subhadeep Pan. Sign/date Lalit Patra 30.11.21

Maintenance procedures of the Instrument or System

Daily

Startup

Shut Down

Filter replacement checking based on number of Injections

Waste Bottle Checking

Column Injection Checking

Weekly

Updating Calibration curves

Replace filters based on Number of Injections

Clean the instrument with Wet/ Dry cloth

Column Injections Checking

6 Months Once

Instrument Calibration

Cleaning of Probe

Internal Cleaning of Teflon tubes.

Column Injections checking

Performed by: Tosoh India Pvt. Ltd.,

Sign/date Lalit Patar 30.11.21

Deviations:_____

Verified By: Subhadeep Pal

Sign/date Lalit Patar 30.11.21

Deviation Report

Deviation(s):

NIL

Justification for Acceptance:

All operational requirements qualified

Impact on Operation:

Instrument ready for its performance qualification & routine operation

Written by: Tosoh India Pvt. Ltd.,

Sign/Date

Lalit Batra
30.11.21

Operation Qualification Report

Date study initiated: 30/11/2021

Date study completed: 01/12/2021

Observations Mode:

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.

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 Lalit Patar 30.11.21

QA Approved by: Subhadeep Pal

Sign/Date Lalit Patar 30.11.21

Tosoh India Pvt. Ltd.,

Tosoh HLC-723GX

Automated Glycohemoglobin Analyzer

PERFORMANCE QUALIFICATION

For

Lupin Healthcare Limited,

Bardhaman, West Bengal, India.

Tosoh India Pvt. Ltd.

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

TOSOH

Instrument Serial No. - 12080812

System/ Instrument: HLC- 723GX Automated HPLC Analyzer

Protocol Written by: Tosoh India Pvt.Ltd.

Lupin Healthcare Limited, Bardhaman, West Bengal

Laboratory Approval by: Dr. Koushik Samanta (30.11.21)

QA Approval by: Subhadeep Pal

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, 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

Instrument interfaced either with 10 samples Turn Table (Sample loader).

Procedure:

Provide SOP's and data sheets for normal operation of the system

Provide basic operation training and documenting the operators have 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 Performance qualification report:

This should include data study initiated; data competed; observations mode; 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:

1. TSK gel HLC – 723 Variant HSi column
2. Variant Elution Buffer HSi No. 1
3. Variant Elution Buffer HSi No. 2
4. Variant Elution Buffer HSi No. 3
5. HSi Hemolysis & Wash Solution
6. Filter Element
7. Calibrator - 2 levels

Accessories:

1. Printer Paper
2. Control Level 1 & Level 2

Performed by: Tosoh India Pvt.Ltd., Sign/date 30.11.21

Deviations: _____

Verified By: Subhadeep Pal Sign/date 30.11.21

Results:

Calibration and Control Data

Calibration data
Lot: ZS0003 Expiry: 31-01-2023
Level 1: 5.90% Level 2: 10.50%

Test	Date performed	Results (%)	Acceptable Y/N
Tosoh Calibrator 1	30/11/2021	4.7	Y
Tosoh Calibrator 2	30/11/2021	8.7	Y

QC Data

Tosoh Diabetes HbA1c Control Set
Lot: AB0050 Expiry:30-12-2022
Level 1: 5.0% ± 0.3 Level 2: 10.0% ± 0.5

Test	Control Range	Results (%)	Acceptable Y/N
Tosoh HbA1c Control Level 1	5.0 (+/-) 0.3	5.0	Y
Tosoh HbA1c Control Level 2	10.0 (+/-) 0.5	10.1	Y

For Cal and QC results data refer to attachment

Performed by: Tosoh India Pvt. Ltd.,
Sign/date Lalit Patar 30.11.21

Deviations: _____

Verified By: Sushadeep Pal
Sign/date Lalit Patar 30.11.21

Purpose & Scope: Performance Validation Of Tosoh HLC-723GX

Specimen: Whole Blood

Experiments:

1. Inter Assay Run (Day 1 & Day 2)

.Accuracy Check & Precision Study (Intra Assay Run)

Control:

Name: TOSOH Diabetes HbA1c Control Set (AB0050)

Level 1-Target Value: 5.0 %(NGSP) Level 1 range: (+/-) 0.3%

Level 2-Target Value: 10.0 %(NGSP) Level 2 range: (+/-) 0.5%

ACCURACY & PRECISION STUDY(Inter Assay Run)			
S.No	**Date**	**Tosoh Diabetes HbA1c Control L1 Target (5.0)**	**Tosoh Diabetes HbA1c Control L2 Target (10.0)**
1	30/11/2021	5.2	10.1
2	30/11/2021	5.2	10.1
3	30/11/2021	5.2	10.0
4	30/11/2021	5.1	10.1
5	30/11/2021	5.0	9.9
6	01/12/2021	5.3	10.4
7	01/12/2021	5.3	10.3
8	01/12/2021	5.3	10.3
9	01/12/2021	5.3	10.4
10	01/12/2021	5.3	10.3

TOSOH Control Data			
Level	**Average**	**SD**	**CV%**
Level 1	5.22	0.10	1.9%
Level 2	10.19	0.17	1.6%

Performed by: Tosoh India Pvt. Ltd., Sign/date Lalit Patra 30.11.21

Deviations: _____

Verified By: Subhadeep Pal. Sign/date Lalit Patra 30.11.21

Performance Qualification Report

Date study initiated: 30/11/2021

Date study completed: 01/12/2021

Observations Mode:

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.

Operation qualification completed/ not completed successfully

The system is ready after its performance qualification for routine operations.

Performed by: Tosoh India Pvt. Ltd., Sign/date 30.11.21

Deviations: _____

Verified By: Sushadeep Pal Sign/date 30.11.21

TOSOH INDIA : SERVICE CALL REPORT

INSTRUMENT NAME & MODEL	SERIAL NO.	TICAN NO.
HLC-723 G8.	12080812	

CUSTOMER DETAILS

Name	Address	
Lupin Diagnostics	CARE Hospital, Bamchandipur, Tajpur. Balasore.	
Contact Person	Contact Number	E.Mail ID

SERVICE CALL DETAILS

Complaint Received On	Complaint Attended On	Complaint Addressed On	Complaint Resolved On
✓	01/12/22	01/12/22	01/12/22

Work Carried Out: ON SITE | SERVICE HUB	Man Hour Deployed	Travel Time Consumed

Service Call Executed As : WARRANTY | EX-WARRANTY | AMC | CMC | RRC / PRC | NSC | OTHERS

Purpose Of Visit (Tick Wherever Applicable)						
	Pre-Installation Check	Demonstration	Installation	Application Issues	Preventive Maintenance ✓	PM-1 MP-2 ✓ PM-3 PM-4
	Breakdown	Hardware Complaint	Software Complaint	Reagent Issues	Calibration	Training
	Others (Please Specify)					

ENGINEER'S OBSERVATIONS

Reported Issue	Preventive maintenance
Observed Damage (If Any) Before Service	NO
Engineer's Diagnosis	P.M. Required.
Job(s) Carried Out :	Preventive maintenance carried out. Machine was good. Results are ok.
Attached Documents	NO

PRE-REPLACEMENT REPAIR ESTIMATE / APPROVAL

Sr.No.	Code No.	Description Of Spare Part / Item	Quantity	Source	Unit Price	Total Price
1						
2						
3						
4						
5						

Above mentioned replacement of part/s and related service charges have been approved to proceed for necessary service / repair.	Please Invoice In The Name Of The Laboratory Mentioned Above	Cost Of Spare Part	
Name, Signature & Stamp		Service Charge	
For Billable Transactions: Customer may kindly note that this SCR duly signed and stamped will be treated as "Purchase Order" from you. If the same does not meet internal procedural requirements, please treat this SCR as a quotation and kindly issue a separate P.O. This estimate will be valid for next 30 days from the date of issuance.		Tax	
		Total	

STATUS AFTER SERVICE (PLEASE TICK)

Normal Functioning Observed ✓	Instrument Under Observation	Operative But Requires Action
Needs Spare Parts / Consumables	Requires Follow Up	Referred To National Service Hub

Pending Job (If Any)	NO	Customer Remarks :

LUPIN DIAGNOSTICS