Tosoh India Pvt. Ltd.,

Tosoh HLC-723GX

Automated Glycohemoglobin Analyzer

INSTALLATION QUALIFICATION

For

LUPIN DIAGNOSTICS, Bhopal.

MARKETED BY:

Tosoh India Pvt. Ltd.

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



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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Validation Protocol

Installation Qualification

System / Instrument

HLC-723GX

Protocol Written By

Tosoh India Pvt. Ltd.

Laboratory

Engineering Approval By

Lupin Diagnostics, Arera Colony, Bhopal.

Laboratory Approval By

Tosoh India Pvt. Ltd.

Laboratory Approva

Lupin Diagnostics, Arera Colony, Bhopal.

QA Approval By

Mr. Manish Kumar Patel

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.

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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 Diagnostics, Arera Colony, Bhopal Site will review the IQ Results.

Quality Assurance Department at Lupin Diagnostics, Arera Colony, Bhopal Site will approve the IQ Protocol and Report.

System / Equipment: HLC-723GX

Instrument ID:Sr. No. 12030510

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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

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 cappierced 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. 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 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 and can be easily replaced without any special tools. Manich

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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

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 $6 \mu L$.

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 minutes 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.

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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

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
- System USB Stick (Smart Media) 1
- Holder for Reagent pack 1
- 5 L Bottle Cap 1
- Accessory box 1

c) Additional Accessories

*Accessory list included with the instrument

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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Checklist:

System / Equipment: HLC-723GX

Instrument ID:Sr. No. 12030510

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

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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Water Requirements	Nil	Nil	Nil
Liquid Waste -			
Liquid Waste Container	5Litres	5Litres	Nil
Throughput Rate -			
Assay Measurement	2.2 Samples/min	2.2 Samples/min	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 Continuous Loading	Maximum 10 Possible	Maximum 10 Possible	Nil
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

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System/Instrument: HLC-723GXLaboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Installation Procedure	Protocol Location	Perfo	ormed	Sign	Date	
Installation / Toocdure	r rotocor Eccation	Yes	Yes No Sign	Date	ato	
Installation of Hardware	See Chapter 2 – Installation of the Operators Manual	Yes		Do	reful	v
Installation Checks	See Chapter 2 – Installation of the Operators Manual	Yes		930	78/17	122

Performed By: Engineering Dept – Tosoh India Pvt. Ltd.

1er all 12 2022 Signature / Dates

Deviation: Nil

Reviewed By: Lupin Diagnostics, Arera Colony, Bhopal.

Signature / Date: Man

Ground Floor, SRP Arcade. E-5/48, Opp. Ajwani Eye Care Center, Arera Colony, Vitthal Market, Bhopal, Madhya Pradesh- 462016.

Tosoh India Pvt. Ltd.,

Tosoh HLC-723GX

Automated Glycohemoglobin Analyzer

OPERATIONAL QUALIFICATION

For

LUPIN DIAGNOSTICS, Bhopal.

MARKETED BY:

Tosoh India Pvt. Ltd.

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



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Validation Protocol: Operational Qualification

System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Validation Protocol : Operational Qualification

System / Instrument : HLC-723GX

Protocol Written By :Tosoh India Pvt. Ltd.

Laboratory : Lupin Diagnostics, Arera Colony, Bhopal.

Engineering Approval By : Tosoh India Pvt. Ltd.

Laboratory Approval By : Lupin Diagnostics, Arera Colony, Bhopal.

Q.A. Approval By : Mr. Manish Kumar Patel

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.

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

Validation Protocol : Operational Qualification

System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

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 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.

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Validation Protocol : Operational Qualification

System/ Instrument: HLC-723GX

Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Preparation: Document check

SOP Title and number File LocationQA/QC approval date

Daily Operation

Maintenance

Special operations

Training Records:

Name	Signature
Mr. Manish Kumar Patel	Manse
Mr. Salman Sheikh	Aghair
Ms. Pooja Sursuje	
Mr. Laxmi Narayan Umre	Thumpe
<u> — и — — — — — — — — — — — — — — — — — </u>	

For training certificates contact local Support team members

Equipment make and model

Tosoh HLC 723GX

Manual available

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Validation Protocol: Operational Qualification

System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Results

Calibration and Control data:

Calibration data

Test	Date performed	Results	Acceptable Y/N
HbA1c	25/12/2022	4.8	Y
HbA1c	25/12/2022	4.8	Υ
HbA1c	25/12/2022	4.8	Y
HbA1c	25/12/2022	9.3	Y
HbA1c	25/12/2022	9.3	Y

QC Data: Tosoh HbA1c Control AB6050

Test	Control	Results	Acceptable Y/N
HbA1c Level 1 control	5.2 +/- 1.04	5.4	Y
HbA1c Level 2 control	10.8+/- 2.18	10.9	Y

Deviation Report

Deviation(s)

: NIL

Justification for Acceptance: All operational requirements qualified.

Impact on Operation

: Instrument ready for its performance qualification & routine operation.

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Validation Protocol: Operational Qualification

System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Operation Qualification Report

Date Study Initiated :

25-12-2022

Date Study Completed

26-12-2022

Observations Made

Performance qualification complies as per manufacturer

Recommendations

· Problems encountered

Nii

Completeness of

All information found to be complete

Information Collected

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.

Performed By: Tosoh India Pvt. Ltd.	Signature / Date: La Lolly
Deviations: Nil	26 12 1
Verified By: Lupin Diagnostics, Arera Colony, Bh	nopal UPIN DIAGNOSTICS ITE
	E-5/48 Opp Aircade,

E-5/48, Opp. Ajwani Eye Care Center, Arera Colony, Vitthal Market, Bhopal, Madhya Predesh- 462016. Tosoh India Pvt. Ltd.,

Tosoh HLC-723GX

Automated Glycohemoglobin Analyzer

PERFORMANCE QUALIFICATION

For

LUPIN DIAGNOSTICS, Bhopal.

MARKETED BY:

Tosoh India Pvt. Ltd.

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



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System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

System / Instrument : HLC-723GX

Protocol Written By : Tosoh India Pvt. Ltd.

Laboratory : Lupin Diagnostics, Arera Colony, Bhopal.

Laboratory Approval By : Lupin Diagnostics, Arera Colony, Bhopal.

QA Approval By : Mr. Manish Kumar Patel.

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.

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System/ Instrument: HLC-723GX

Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

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 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 PerformanceQualification Report:

- This should include data study initiated; data competed; 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

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Page 3 of 8

System/ Instrument: HLC-723GX Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Reagents Used to Estimate the requested Test:

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

Accessories:

Printer Paper

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System/ Instrument: HLC-723GX

Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Results:

Calibration and Control Data

Calibration Data: 25.12.2022

Test	Date performed	Results (%)	Acceptable Y/N
Tosoh Calibrator 1	25.12.2022	4.8	Y
Tosoh Calibrator 2	25.12.2022	9.3	Y

QC Data:

Test	Control Range	Results (%)	Acceptable Y/N
HbA1c Control Level 1	5.2(+/-)1.04	5.4	Y
HbA1c Control Level 2	10.8(+/-)2.18	10.9	Y

^{*}For Calibration and QC results data refer to attachment

Performed By: Tosoh India Pvt. Ltd.	Signature / Date: Sudhwy
Deviations:Nil	25/10
Verified By: Lupin Diagnostics, Arera Colony, Bhopal.	Signature / Date: CODE / Arcade, LUPIN Date: SRP Arcade, Center, Ground Front, SRP Arcade, Market, Mar
	Ground Floot, SEP Arcade, Care Center. Ground Floot, SEP Arcade, Arca

System/ Instrument: HLC-723GX

Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Purpose & Scope

Performance Validation of Tosoh HLC-723GX

Specimen

Whole Blood

Experiments

1. Accuracy check & Precision check

2.Carry over

3.Sample Dilution

4. Method Comparison

1. Accuracy check & Precision check -

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A. External Control:

Name: RANDOX HbA1c Controls.

Level 1: Target Value: 5.2 %(NGSP)

Level 1 range: (+/-) 1.04%

Level 2: Target Value: 10.8 %(NGSP)

Level 2 range: (+/-) 2.18%

ACCURACY & PRECISION STUDY			
S.No	RANDOX L1 Target (5.2)	RANDOX L2 Target (10.8)	
1	5.4	10.9	
2	5.4	10.9	
3	5.5	10.8	
4	5.4	10.8	
5	5.4	10.9	
6	5.4	10.9	

TOSOH Control Data Summary				
Level	Mean	SD	CV%	
Level 1	5.42	0.10	0.93	
Level 2	10.87	0.151	0.87	

2. Carry Over Study:

S. No.	Carry Over Study
Sample 1	5.4
Sample 1	5.4
Sample 2	6.5
Sample 2	6.5
Sample 1	5.4
Sample 1	5.4

Inference: No Carryover was observed.

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System/ Instrument: HLC-723GX

Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

2. Sample Dilution Study:

To evaluate the dilution done by the instrument and manual dilution

s.NO	Auto Dilution (Instrument)	Manual Dilution
1	5.4	5.4
2	6.5	6.5
3	5.5	5.5

Inference: No significant change observed between the dilutions.

3.Method Comparison Study:

S No.	Barcode	Existing Method	Other Method
1	*****	6.0	5.9
2	******	6.2	6.2
3	******	6.0	6.1
4	******	5.7	5.7
5	******	5.3	5.2

Inference: Lupin Diagnostics, Arera Colony, Bhopal. results correlated with existing platform.

Performance Qualification Report:

Date Study Initiated

25.12.2022

Date Study Completed

26.12.2022

Observations Made

Performance qualification complies as per manufacturer

Recommendations

Problems encountered

Nil

Completeness of

All information found to be complete

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Page 7 of 8

System/ Instrument: HLC-723GX

Laboratory: Lupin Diagnostics, Arera Colony, Bhopal.

Information Collected

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.

Performed By: Tosoh India Pvt. Ltd.

Signature / Date:

Deviations: ____Nil___

Verified By: Lupin Diagnostics, Arera Colony, Bhopal.

Signature / Date

LUPIN DIAGNO SES LTD. Ground Floor, St. Arcade, E-5/48, Opp. Ajwani E_{5/3} Care Center,

Arera Colony, Vitti al Market, Bhopal, Madhya Praussh- 462016.

HLC-723GX CAL	BRATION REPORT		
Customer Name	Lugin	· Diagnostur	de a manual describir à de la character, cop ser région de management proportion describé
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Customer Address	: <u>E-3/48</u> ,	Horena Col	lony, opp. Ajwan 2 (M.p)-462016
	Exe care	Centure, 13 hope	W (K), P) - 4 62016
Installation Site	: Same	as Above.	The state of the s
		and the contract of the contra	and the second section of the s
Installation Date	: 15/12/2	22 Instrument Model	HLC-7236X
Instrument Serial N	0.: 12030:51	O Firmware Version	1.24
Calibration Date	17/12/200	23 Calibration Due Date	16/12/2024
Sign of Check	OK, V	Replace: X	Adjustment A
	Repair: △R	Cleaning: C	Grease Up L
ANALYZER INFORM	FATION		
Instrument	HLC-7	-23 GX	
Instrument S/N	12030		
Needle type	Standard	□ Side-hole	
AUTO SAVE	YES YES	□ NO	
Bar-code	YES	. D NO	
MEASUREMENT CO			
SYSTEM	MANAGEMENT NO. 1 WALLS	24	
Sample	Whole blood	☐ Centrifuged	** Wexes!
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TOSOH INDIA PVT. LTD.

SAN	MPLING UNIT				
1	Rotor-seal (Injection valve) Arm (Injection valve, check if loosened of not) Rotor-seal (Rotary valve)		Round-head s	Injection valve) crews at the coup	ling (Rotary valve)
	Packing, check leak and worn or not (Syringe-R) Dilution port & needie wash block, clean or not Barcode reader, readable without error		Leak from O-ri	y i axis and SY- ing (F/N:017092)	R
	Turn table rotation sensor & sample sensor Actions of turn table sampling positions (1 & 10) Position Check for sample and calibrator aspiration		Pasition of turn	table calibrator pa able borne sens	5 TO 1 TO
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	Leak from plunger-seal Check if the diaphragm and plunger are not work	n			
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	Vacuum condition				
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TOSOH INDIA PVT. LTD.

RECEIVING INSPECTIONS	
□ CALIB.std. 1: 5.56 96	2 10.68 %
Calib: factors $Y = (1.1600) \times + (0.59)$	
	A15: 0.32 F 0.42
	S-A1c: 0.6 8 A0 1.03.
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	calibrated and working within the specification
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	calibrated and working within the specification
We confirm the above mentioned analyzer is o	alibrated and working within the specification

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