P0501403US

Tosoh Automated Glycohemoglobin Analyzer HLC-723®G8

Instructions For Use

G8 Variant Elution Buffer HSi No. 1 (S)

No. 2 (S)

No. 3 (S)

TOSOH CORPORATION

Safety Precautions

To help protect you and/or your property from potential damage and ensure personal safety, please read this IFU thoroughly before using the product.

[Notational Convention]

Notation	Explanation
⚠ **CAUTION**	Indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

CAUTION

■ **Use only in well-ventilated areas**

In case of insufficient ventilation, flammable and toxic solvents can cause fire, explosion, or poisoning.

■ **First Aid**

Skin exposure

Wash exposed area with plenty of soap and water.

Eye exposure

Open eyes as wide as possible and wash with clean water for at least 15 minutes. Immediately call for medical attention.

Ingestion

Please wash mouth with excess water and immediately call for medical attention.

■ **Do not spill solvents**

Spillage and leakage can cause fire, electric shock, poisoning, injury and corrosion. Wear appropriate protective gear when cleaning up a spill.

■ **Wear eye protection and protective gloves**

Organic solvents and acids should not come in direct contact with the skin.

■ **Handle the package with care**

Inappropriate handling may cause rupturing and/or splattering of the product.

■ **Only use this product as intended**

This product is for separation and purification. Do not use for any other purposes.

US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

■ **Make sure compounds are safe**

Check that obtained compounds and solutions after separation and purification are safe.

■ **Proper disposal**

Dispose in accordance with local laws and regulations.

NOTE

Keep this IFU with the product for future reference.

Symbols on the product labels

Manufacturer

Supplied by

In vitro diagnostic medical device

Consult instructions for use

Catalogue number / Part number

Batch code / Lot number

Temperature limitation

Use by date

Net volume

(after reconstitution for

lyophilized material)

For specified column lot only

Contents

1. Introduction

The G8 Variant Elution Buffer HSi is designed exclusively for use with the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (referred to as HLC-723G8 in this IFU), which is based on the principle of high-performance liquid chromatography assay. It is not designed for and should never be used with any other type of system.

The HLC-723G8 is intended for in vitro diagnostic use for the quantitative measurement of % hemoglobin A1c (HbA1c) (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in whole blood specimens. This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.

Glycohemoglobin (GHb) is a general term for complexes in which the whole blood glucose is non-enzymatically bound to the α and β chains of human hemoglobin. Within these, HbA1c, which is a complex of glucose and the N-terminus of the β chain, is the most quantitatively prevalent.
HbA1c is non-enzymatically synthesized in two steps.

Step 1: The glucose aldehyde group reacts with the free amino group on the valine comprising the N-terminus of the β chain to form the Schiff base (labile HbA1c (L-A1c)).

Step 2: Stable ketoamine (stable HbA1c (s-A1c)) is then formed by a reaction known as amadori rearrangement.

Due to the fact that L-A1c (the intermediate product of this reaction) changes rapidly in response to the changes in whole blood glucose concentrations, s- A1c is now generally used to measure HbA1c. It provides the best indication of average glucose levels over the most recent 1 to 3 month period because it does not fluctuate in response to physiological factors.

Until recently, it was difficult to achieve quick separation of L-A1c and s-A1c on a column, therefore the pretreatment to remove L-A1c is necessary before assaying s-A1c. The HLC-723G8 features quick separation of L-A1c and s-A1c on the column (1.6 min), thus eliminating the need for treatment when assaying s-A1c.

The hemoglobin found in a normal adult is hemoglobin A, which comprises about 97 % of

the total hemoglobin. On the other hand, various hemoglobin abnormalities have also been reported in different regions, especially in areas with a large immigrant population.

Abnormal hemoglobins are eluted out together with other Hb components and lead to misinterpretation. Therefore, it is necessary to remove the abnormal hemoglobin affect. The TSKgel® G8 Variant HSi and the G8 Variant Elution Buffer HSi separate most abnormal hemoglobin fractions from the s-A1c fraction on the HLC-723G8.

2. Prior to Use

Be sure to inspect the packaging and the exterior of the aluminum pack for any signs of damage prior to use. If any damage is evident, contact your local Tosoh sales representative at the address indicated at the end of this IFU.

Confirm the following document is included in the package.

- Instructions For Use 1 copy

3. Content

The following types of elution buffers are designed for exclusive use with the HLC-723G8.

Part No.	Reagent Name	Package contents
002195	G8 Variant Elution Buffer HSi No. 1 (S)	1 × 800 mL
002195	G8 Variant Elution Buffer HSi No. 2 (S)	1 × 800 mL
002195	G8 Variant Elution Buffer HSi No. 3 (S)	1 × 800 mL

G8 Variant Elution Buffer HSi are organic acid buffers. Each contains less than 0.05 % sodium azide as a preservative.

4. Related Components

Hemoglobin A1c Calibrator Set	0018767
Hemoglobin A1c Control	992133
TSKgel G8 Variant HSi	0021955
HSi Hemolysis & Wash Solution (L)	018431US

5. Storage

All unopened materials are stable until the expiration date on the label when stored at 4 to 30 °C.
The expiration date is indicated on the packaging box and the aluminum pack labels.
They are stable for use for up to 3 months after opening when stored at 4 to 25 °C.

6. Specimens

Whole blood samples in primary tubes containing K2-EDTA or K3-EDTA.

Collect whole blood specimens in vacuum collection tubes containing K2-EDTA or K3-EDTA and mix thoroughly. Specimens may be stored up to fourteen days at 2-8 °C before analysis. Specimens may be stored up to twenty four hours at room temperature (10-25 ºC) before analysis. The minimum volume required for analysis directly from collection tubes is 1 mL of whole blood. Whole blood samples as small as 50 µL may be used when appropriate sample vial and software options are selected.

7. Assay Principle

The HLC-723G8 is based on the high-performance liquid chromatography (HPLC) principle. Cation exchange columns employ the differences in ionic interactions between hemoglobin components to separate them in a span of 1.6 min.

8. Instruction for Use

The G8 Variant Elution Buffer HSi is provided ready to use.

Installing G8 Variant Elution Buffer HSi

Press the **STOP** key to put system in STAND-BY status.

Remove buffer containers to be replaced.

Break the seal on the storage caps of the new buffer containers, leaving the caps in place.

Carefully place the capped buffer bags on the rack on the instrument. Verify that the buffer bag is supported on the rack by the octagonal shaped lip at the base of the threads.
For each reagent, remove the cap, carefully squeeze the buffer bag by hand to minimize air pockets, and then place the appropriate color-coded tubing into the corresponding bag. Ensure that the end of the tubing is touching the bottom of the container.

Securely tighten reagent caps.

From the MAIN screen, select **MAINTE**, then **REAGENT CHANGE**. Once the buffers have been correctly installed, select the appropriate buffer, then press **CHANGE**.

9. Assay Procedures

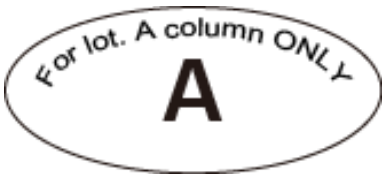
Refer to the HLC-723G8 Operator's Manual for detailed description.

10. Precautions for Use

1. Be sure to carefully read the instructions contained in this IFU and related instructions provided in the HLC-723G8, TSKgel G8 Variant HSi and HSi Hemolysis & Wash Solution manuals.

2. G8 Variant Elution Buffer HSi is designed exclusively for use in combination with the analyzer system, columns and hemolysis wash solutions indicated below, never in any other combinations.
   - Tosoh Automated Glycohemoglobin Analyzer HLC-723G8
   - TSKgel G8 Variant HSi
   - HSi Hemolysis & Wash Solution (L)

3. Always use the G8 Variant Elution Buffer HSi in combination with a TSKgel G8 Variant HSi column of the identical lot number. The column lot number is indicated by a single uppercase alphabetical character (A, B, etc.) on the label of column box. The Elution Buffer label displays an alphabetic character corresponding to column lot number, as shown below.



4. Always return elution buffer to room temperature before use.

5. When first opening the aluminum pack to insert the suction tube, gently squeeze the elution buffer pack by hand to remove all excess air and tighten bottle cap firmly into place to create a vacuum that will prevent air from entering during operation.

6. Never use reagents that have exceeded the expiration date indicated on their labels. Assay results for expired reagents will not be reliable. Also note that reagents must be used within three months of the opening of the cap on the aluminum pack (provided that the container is correctly maintained in vacuum state).

7. For cases in which there is leftover Reagent in the aluminum pack that must be removed from the analyzer and stored, again gently squeeze the elution buffer pack by hand to remove all excess air, and tighten bottle cap firmly into place to create a vacuum that will prevent air from entering during storage and store at 4 to 25 °C.

8. Always replace with a new container when elution buffer is about to run out. Avoid refilling leftover elution buffer into containers as this can produce unreliable assay results.

9. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

10. The HLC-723G8 is for prescription use only.

11. Hemoglobin A_{1c} should not be used to diagnose Diabetes Mellitus in patients with iron deficiency and hemolytic anemia, various hemoglobinopathies, thalassemias, hereditary spherocytosis, malignancies and severe chronic hepatic and renal disease.

12. Hemoglobin A_{1c} should not be used in pregnant patients, patients with heterozygous sickle cell trait, hemolytic diseases and recent significant or chronic blood loss.

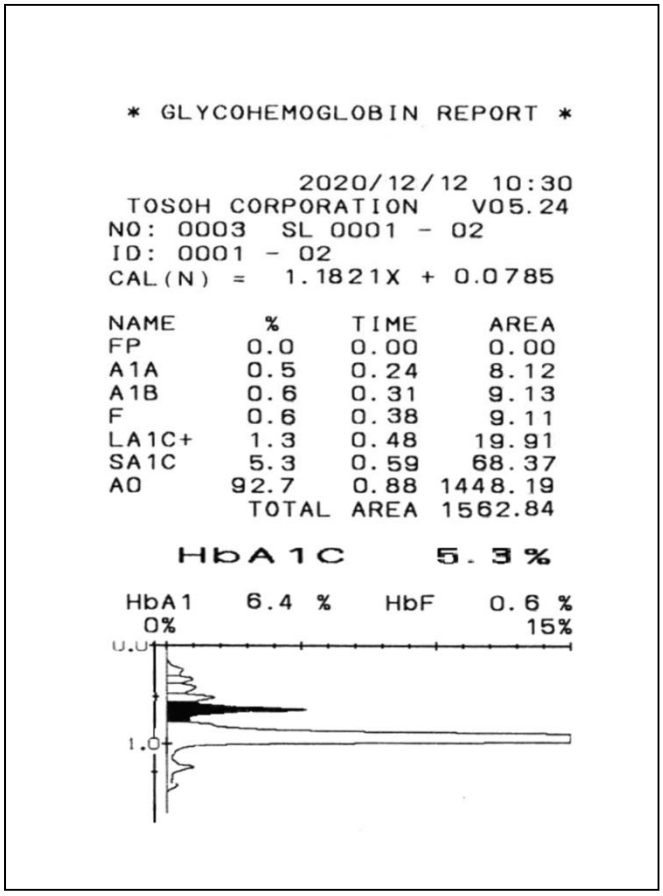
13. Hemoglobin A_{1c} should not be used in the diagnosis of gestational diabetes.

14. In cases of rapidly evolving type 1 diabetes the increase of HbA_{1c} values might be delayed compared to the acute increase in glucose concentrations. In these conditions diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms

11. Reference Data

(from the HLC-723G8 Assay Examples)

Example of normal sample chromatogram



12. Measurement Values

Measurement values (%) indicate the percentage of each peak in relation to the Total Area (excluding the front peak (FP)). Note the minimum unit of measurement displayed is 0.1 %.

13. Evaluation of Results

Quality Control

In order to monitor and evaluate the accuracy and precision of the analytical performance, Tosoh controls should be assayed daily and after column replacement. Tosoh suggests running at least two levels of quality control material. The mean of one should be in the non-diabetic range (4-7 % HbA_{1c}) with the second in the range of 9-12 % HbA_{1c}.

If the value of one or more control specimens is out of the acceptable range, recalibrate the system and rerun the controls before testing patient samples.

QC materials should be used in accordance with local, state, federal and accredited organizations.

Controls should be diluted with HSi Hemolysis & Wash Solution to obtain a Total Area (TA) in the range of 700-3000. The optimal TA is between 700-3000. However, a TA in the range of 500-4000 is acceptable and reportable for whole blood specimens.

Laboratory policy for this particular assay designates the following:

Control Material: _____

14. Expected Reference Values

Reference Ranges (non-diabetic): HbA_{1c} 4.0-6.0 % (mean 5.0 %, SD 0.5 %)

Ref: American Diabetes Association. "*Standards of Medical Care in Diabetes — 2020; Diabetes Care 2020;43(Suppl. 1).*

146 apparently healthy adults were tested and fell within the range of 4.4-6.1 %.
These were representative of the US population.

Each laboratory should determine a reference interval that corresponds to the characteristics of the population being tested.

The values referred to within this document have been determined with a National Glycohemoglobin Standardization Program (NGSP) certified method. It is known that the relationship between HbA_{1c} results from the NGSP network (%) and the IFCC network (mmol/mol) is expressed by using the following equation (https://ngsp.org/ifcc.asp): NGSP (%) = 0.09148 × IFCC (mmol/mol) + 2.152

The diagnosis of diabetes and identification of persons at increased risk of developing diabetes follows the ADA Guideline of 6.5 % for the cut-off and values between 5.7 % and 6.4 % as being at increased risk.

15. Performance Characteristics

Dilution-Total Area / Linearity

Packed red blood cells from a normal specimen collected in EDTA were diluted with Hemolysis & Wash Solution and assayed. The study demonstrates that the assay is linear in samples with Total Area values from 500 to 4000.

Total Area	Hb A1c%
505	10.6
658	10.6
1144	10.6
1620	10.6
2164	10.7
2846	10.6
3328	10.7
3545	10.7
4047	10.7

Recovery / Linearity

Two studies were conducted on the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 to demonstrate recovery and linearity. In the first study, two whole blood specimens were collected in EDTA. The observed values of the neat specimens were established by HPLC measurement. The theoretical value was a calculated % based upon mixing two samples at different ratios and dividing by the dilution factor. The diluted specimens were run in triplicate, and the average value is listed as the observed % in the table below. The acceptance criteria were 100 ± 5%. The recovery study demonstrates that the results between 2.2% and 16.9% were accurate and are listed on the table below.

High sample (ratio)	Low sample (ratio)	Observed %HbA1c	Theoretical %HbA1c	Recovery %
0	10	2.2	2.2	100.0
1	9	3.6	3.6	100.0
2	8	5.1	5.1	100.0
3	7	6.6	6.6	100.0
4	6	8.0	8.1	98.8
5	5	9.4	9.6	97.9
6	4	11.2	11.0	101.8
7	3	12.4	12.5	99.2
8	2	14.0	14.0	100.0
9	1	15.5	15.5	100.0
10	0	16.9	16.9	100.0

In the second study, linearity was established using a commercially available linearity material. The manufacturer's instructions were followed, and linearity was shown between 3.2% and 18.4%. These observed values are within ± 5% of the assigned values.

Level	Assigned Value	Mean	% Recovery
1	3.1	3.2	103.2
2	5.8	5.9	101.7
3	10.2	10.37	101.9
4	18.6	18.43	99.1

Correlation

To identify and effectively treat people with diabetes it is critical to have accurate and timely diagnostic testing and methods that are aligned to the NGSP standard.

The methods comparison study was conducted in accordance with CLSI EP09c: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition.

This was a two-site study, designed to determine the analytical performance of the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 with Version 5.24 software (G8 v5.24) when compared with the Trinity Premier Hb9210TM (Premier) NGSP SRL method. The analytical instruments were physically located in two independent laboratories, one an NGSP SRL (DDL) and the second at the Tosoh QA lab (TBQAL).

The accuracy was measured by comparing HbA1c values obtained with the G8 v5.24 against HbA1c values assigned to the same matching samples using an NGSP SRL method (Premier).

Regression analysis was conducted to determine if any changes across the measuring interval (4.0-16.9%) were significant between the two methods. Results described below conclude that there is no significant difference between the methods.

Table 8 - Summary of Method Comparison Results

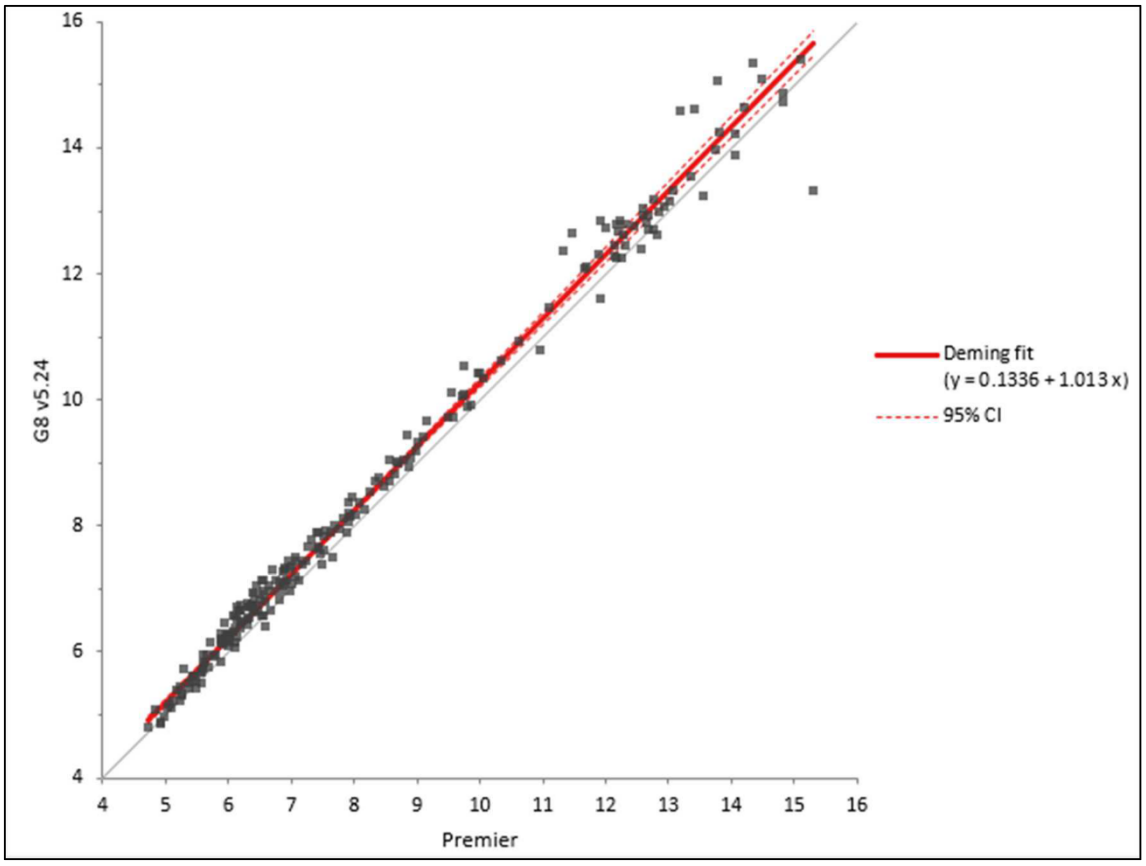
	y-Intercept	95% CI	Slope	95% CI
Deming	0.1336	-0.0331 to 0.3005	1.013	0.9894 to 1.036
Passing-Bablok	0.0720	-0.0472 to -0.1819	1.021	1.007 to 1.037

The method comparison using the Passing- Bablok and Deming regression analysis concluded that the two methods are well within the allowable bias of ± 6 %.

% HbA1c	% Bias (Deming)	% Bias (Passing-Bablok)
5.0	4.0*	3.5
6.5	3.3*	3.2
8.0	3.0*	3.0
12.0	2.4	2.7

*The maximum of Deming and Passing Bablok related bias estimates were used in the calculation of the 'Total Error [%]' estimation.

Method Comparison Deming Regression Analysis of G8 v5.24 vs NGSP SRL (Trinity Premier)



Precision

Total Error [%]					
	Passing Bablok		Deming		
HbA1c Level	`%TE´	%Bias	`%TE´	%Bias	%CV Total
Sample 1 (5%)	5.48	3.5	5.99	4.0	0.974054
Sample 2 (6.5%)	5.31	3.2	5.41	3.3	1.042108
Sample 3 (8%)	5.59	3.0	5.59	3.0	1.281173
Sample 4 (12%)	4.45	2.7	4.15	2.4	0.870450
	Calculated as: `|%Bias| + 1.96 x %CV Total x (1+ %Bias/100)´				

The study is designed in accordance with CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition. It was conducted at two separate sites using three different G8 v5.24 analyzers (two analyzers at TBQAL, and one at DDL). Results were generated with three separate reagent lots (including columns), over 20 non-consecutive days per reagent lot, for a minimum of 60 days. Venous whole blood samples collected from 4 donors at four different concentrations of HbA1c; 5.0%, 6.5%, 8.0% and 12.0%, were tested at each run.

The results demonstrate that the HLC-723®G8 With Software v5.24 shows an acceptable % bias ranging from 2.7-4.0% and an overall %CV ranging from 0.87 to 1.28%. In combining the data from the Precision and Method studies, the % Total Error was calculated at each % HbA1c level and summarized below:

Summary of Precision Analysis per Concentration Level (% CV)

Mean HgbA1c	Repeatability	Between Run	Between Day	Between Lot	Between Analyzer	Total
5 %	0.35	0.24	0.49	0.53	0.50	0.97
6.5%	0.33	0.13	0.45	0.44	0.75	1.04
8 %	0.26	0.19	0.51	0.58	0.97	1.28
12 %	0.23	0.14	0.56	0.57	0.20	0.87

Matrix study for K2 EDTA and K3 EDTA:

A matrix comparison study with the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (G8) was performed to evaluate the effects of two different EDTA anticoagulants, K2-EDTA and K3-EDTA, on the %HbA1c measurement using version 5.24 software.
Fifty (50) venous whole blood matching samples, collected in K2 EDTA and K3 EDTA tubes with approximately ten specimens per concentration range (>4.7 – 6.0%, >6.0 - 6.5%, >6.5 – 7.0%, >7.0 - >9.0% and 10.0 - 16.9%), were tested by the clinical testing laboratory investigational site.
All analysis was done in accordance with CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition. The statistical methods demonstrate that K2-EDTA and K3-EDTA show no clinical or statistical difference and thus may be used interchangeably for testing HbA1c on the G8 HPLC Analyzer.

Comparison of various regression analysis methods (N=47)

Regression Analysis	Regression Equation
Least-Squares	y=-0.02021+1.004x
Deming	y=0.02062+1.004x
Passing-Bablok	y=0.01676+1.004x

Interference

This interference study was developed according to the CLSI guideline Interference Testing in Clinical Chemistry (EP7-A2).

- Interference studies were conducted on known concentrations of %HbA1c. Specimens were spiked with increasing amounts of the interferent. Interference was determined as a variance greater than the measured value ± 5%.

Potential Interferent	Range tested	%A1c Concentrations	Concentration at which no significant interference was observed
Acetylated Hb	10 - 50 mg/dL	6.5 and 9.5	50 mg/dL
Albumin	500 - 5000 mg/dL	6.6 and 14.7	5000 mg/dL
Aldehyde Hb	5.0 - 25 mg/dL	6.3 and 12.6	25 mg/dL
Ascorbic Acid	3.0 - 25 mg/dL	6.4 and 10.8	25 mg/dL
Carbamylated Hb	5.0 - 25 mg/dL	6.5 and 9.8	25 mg/dL
Bilirubin C	2.0 - 21 mg/dL	6.5 and 14.3	21 mg/dL
Labile Hb	200 – 1000 mg/dL	6.4 and 10.3	1000 mg/dL
Lipemia	1 - 1000 mg/dL	6.4 and 14.1	1000 mg/dL
Rheumatoid Factor	110 - 550 IU/mL	6.3 and 12.6	550 IU/mL
Bilirubin F	2.0 - 18 mg/dL	6.5 and 14.3	18 mg/dL

Hemoglobin Variant Interference Study:

Possible interference when measuring HbA1c in clinical specimens due to variant hemoglobins is well known and documented. Common hemoglobin variants have been shown to interfere with HbA1c results with some assay methods. The prevalence of hemoglobinopathies varies among populations. The most common of the beta chain variants are hemoglobins S, C, D and E.

The study conducted at NGSP SRL site was designed in accordance with CLSI EP07 Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition [5] and CLSI EP09-A3 Measurement Procedure and Bias Estimation 2013. Venous whole blood specimens containing varying levels of the variant were tested in triplicate on both the Tosoh Automated Analyzer HLC-723G8 with software version 5.24 (G8 5.24) and the comparator. The percent of the variant in question was ascertained from the Sebia Capillarys 2 instrument using the Hemoglobin method.

Interference studies were conducted on known concentrations of %HbA1c and the specified variant in venous whole blood. Non-clinically significant interference was defined as >6% relative difference in the results from the comparator at 6% or 9% HbA1c. Based on the results, the G8 5.24 does not demonstrate any clinical interference on the HbA1c levels at the % levels of variant for each hemoglobin variant as listed below.

Percent Relative Bias from Reference Method at Low and High Concentration of HbA1c Samples

Hemoglobin Variant/ Hemoglobinopathy	Percent Relative Bias from Reference Method at Low and High Concentrations of HbA1c Samples			
	~6.5 % HbA1c		~8.0 % HbA1c	
	Calibrated Relative % Difference	Range	Calibrated Relative % Difference	Range
HbAD	-0.5	0.08 to 0.30	-1.7	-0.04 to 0.36
HbAS	-2.7	-0.04 to 0.13	-3.2	-0.14 to 0.21
HbAC	-1.9	0.03 to 0.17	-1.1	0.06 to 0.34
HbAE	-1.3	0.001 to 0.27	-1.2	-0.10 to 0.49
HbA2	-4.2	-0.17 to 0.06	-5.1	-0.37 to 0.12
HbF	-0.7	0.10 to 0.25	-1.6	-0.01 to 0.34

Variant Samples Used in Hemoglobin Variant Study

Hemoglobin Variant/Hemoglobinopathy	n	Range in % Abnormal Variant/Hemoglobinopathy	Range in % HbA1c Concentration
HbAC	26	30.8 to 37.8	4.8 to 9.8
HbAD	24	22.6 to 40.7	5.3 to 9.347
HbAE	26	20.0 to 30.9	4.763 to 9.7
HbAS	29	28.2 to 38.9	4.9 to 10.5
HbA2*	20	2.7 to 5.5	5.85 to 10.1
HbF*	21	0.4 to 43.35	4.36 to 8.9

*Hemoglobinopathies

Fetal Hemoglobin and interference:

Elevated levels of Fetal Hemoglobin (HbF) seen with Hereditary Persistence of Fetal Hemoglobin (HbFH) may interfere with the A1c result.

Samples spiked with various concentrations of umbilical cord blood were measured by the G8 v5.24 and a cleared diagnostic HbA1c device (Bio-Rad Variant II Turbo 2.0) to compare results at 6% and 8% HbA1c levels. At up to 25% Fetal Hgb the G8 v5.24 device did not interfere at clinically relevant levels of HbA1c.

In the homozygous and double-heterozygous forms of variant hemoglobins (e.g. HbSS, HbCC or HbSC), there is no HbA present; therefore, no HbA1c value can be determined. Other abnormal hemoglobin variants have not been evaluated on the Tosoh HLC-723G8 assay.

An erroneous result including misidentification of hemoglobin variant may be obtained with a deteriorated specimen, therefore it is important to use a fresh specimen.
The Tosoh Automated Analyzer HLC-723G8 TSKgel column is warranted to 2500 injections. Column deterioration is suspected if the chromatogram resolution decreases.

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Revision Notes

Document Build No.	Access Activity	Accessed By	Accessed Date
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2	Check In	KIMBERLY.HARMESON	14-Mar-2024
Note:			
3	Check In	KIMBERLY.HARMESON	20-Mar-2024
Note:			
4	Check In	KIMBERLY.HARMESON	25-Apr-2024
Note:			
5	Check In	KIMBERLY.HARMESON	25-Apr-2024
Note:			

Review

Build No.: 5 **Closed Date:** 5/20/2024 6:07:27PM

Review: Release Review

Review Purpose: Review to capture final CCB and Change Order approval

Review Note: SYSTEM AUTO CLOSE REVIEW

Level	Owner Role	Actor	Sign-off Date	Sign-off By
10	DOCUMENT COLLABORATOR/APPROVER DOCUMENT COLLABORATOR/APPROVER	GAYLE.BLAIR Gayle Blair	30-Apr-2024 2:43 pm	GAYLE.BLAIR

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Note From Approver:No comments

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Note From Approver:No comment.

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