

P0401002US

Tosoh Automated Glycohemoglobin Analyzer HLC-723[®]G8

Instructions For Use

TSKgel[®] G8 Variant HSi




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 protective eye gear and 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 purpose.
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



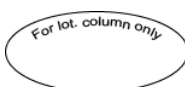
Use by date



Serial number
/ Column number



Net volume
(after reconstitution for
lyophilized material)



For specified
column lot only

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Revised August, 2021

1. Introduction

The TSKgel G8 Variant 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 A_{1c} (HbA_{1c}) (DCCT/NGSP) and mmol/mol hemoglobin A_{1c} (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, HbA_{1c}, which is a complex of glucose and the N-terminus of the β chain, is the most quantitatively prevalent.

HbA_{1c} 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 HbA_{1c} (L-A_{1c})).

Step 2: Stable ketoamine (stable HbA_{1c} (s-A_{1c})) is then formed by a reaction known as amadori rearrangement.

Due to the fact that L-A_{1c} (the intermediate product of this reaction) changes rapidly in response to the changes in whole blood glucose concentrations, s-A_{1c} is now generally used to measure HbA_{1c}. 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-A_{1c} and s-A_{1c} on a column, therefore the pretreatment to remove L-A_{1c} is necessary before assaying s-A_{1c}. The HLC-723G8 features quick separation of L-A_{1c} and s-A_{1c} on the column (1.6 min), thus eliminating the need for treatment when assaying s-A_{1c}.

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-A_{1c} fraction on the HLC-723G8.

2. Prior to Use

Be sure to inspect the TSKgel G8 Variant HSi column package and package components 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 that the following two documents are included in the package.

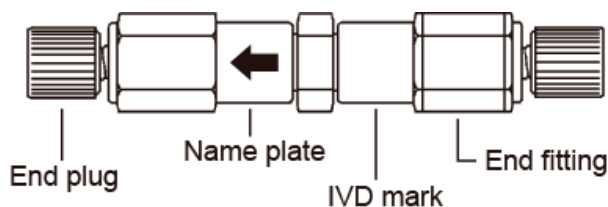
- Instructions For Use 1 copy
- GLYCO COLUMN INSPECTION REPORT 1 copy

3. Content

Part No. : 0021955
Column model : TSKgel G8 Variant HSi
Assay mode : Variant Analysis Mode
Applicable analyzers : Tosoh Automated Glycohemoglobin Analyzer HLC-723G8

4. Part Names

The names of the various parts comprising the TSKgel G8 Variant HSi column are shown below.



< Illustration of Column >

5. Related Components

Hemoglobin A1c Calibrator Set	0018767
Hemoglobin A1c Control	992133
G8 Variant Elution Buffer HSi No. 1 (S)	0021956
G8 Variant Elution Buffer HSi No. 2 (S)	0021957
G8 Variant Elution Buffer HSi No. 3 (S)	0021958
HSi Hemolysis & Wash Solution (L)	018431US

6. Storage

Unopened columns are stable until the expiration date when stored at 4 to 15 °C in a cool dark location away from sunlight.

– Expiration Date indicated on the packaging box.

7. 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 °C) 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.

8. 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.

A step gradient elution is used to separate and assay HbF, s-A_{1c}, Total A₁, and Hb Variants with three-types of G8 Variant Elution Buffer HSi (G8 Variant Elution Buffer HSi No. 1, 2, and 3 (S)) of different salt concentrations.

9. Instruction for Use

The TSKgel G8 Variant HSi column is provided ready to use.

Installing TSKgel G8 Variant HSi column

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

Unscrew column fittings and remove used column.

Remove protective plugs from new column. Do not discard the plugs, as they are needed for storage. Verify that the column master lot matches the Elution buffer lot.

Check flow direction - the arrow on the column should point to the left as it is placed on the instrument.

Slide the inlet tubing until it extends $\frac{1}{4}$ inch past each end fitting. Connect the tubing to the inlet (right) side of the column.

Take special care that buffer coming from the tube does not spill onto the analyzer unit by holding absorbent paper or gauze at the outlet end of the column when priming.

From the second page of the MAIN screen, press PUMP FLOW to start pumping the buffer. When buffer solution flows from the outlet (left) side of the column, press PUMP FLOW again to stop the pump.

Connect the tubing to the outlet side of the column.

Press **PUMP FLOW** to start pumping and check for leaks. The pressure should rise to the pressure level that is indicated on the column inspection report +4 MPa. If leaks occur, tighten fittings.

When the pressure reaches a steady state, press **PUMP FLOW** again to stop pumping.

From the MAIN screen, select **MAINTE**, then **REAGENT CHANGE**. Press **COLUMN RESET** to set column count back to zero.

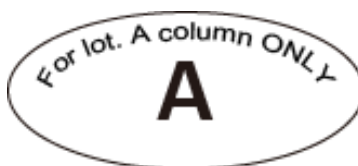
Before calibrating the newly installed column, run at least three whole blood samples to prime the column. Calibrate the system and run controls.

10. Assay Procedures

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

11. Precautions for Use

- 1) Be sure to carefully read the instructions contained in this IFU and related instructions provided in the HLC-723G8, G8 Variant Elution Buffer HSi and HSi Hemolysis & Wash Solution manuals.
- 2) The TSKgel G8 Variant HSi is designed exclusively for use in combination with the analyzer system, elution buffers and hemolysis wash solutions indicated below, never in any other combinations.
 - Tosoh Automated Glycohemoglobin Analyzer HLC-723G8
 - G8 Variant Elution Buffer HSi (No. 1, 2 and 3 (S))
 - HSi Hemolysis & Wash Solution (L)
- 3) When changing column, be sure to assay dummy samples several times and check the chromatogram results.
- 4) Always use the TSKgel G8 Variant HSi in combination with the G8 Variant Elution Buffer HSi 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.

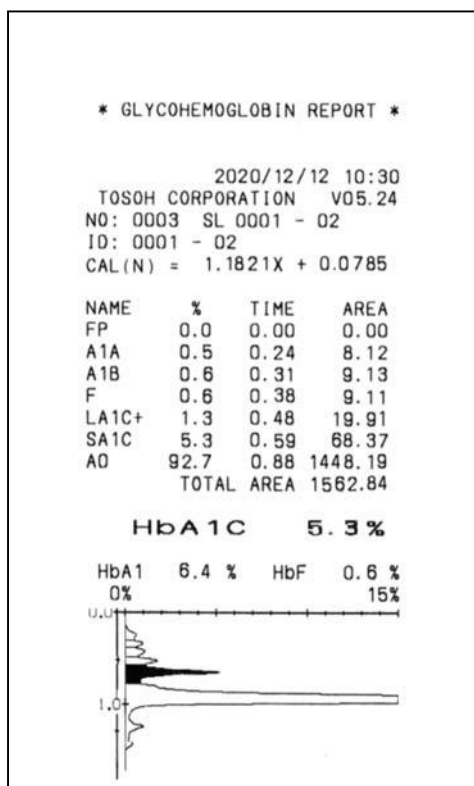


- 5) Care must be taken to ensure that the solutions are delivered only in the direction indicated by the arrow on the name plate on the column being used.
- 6) In cases in which the column is not used for more than one week, remove the column from the analyzer unit, reattach its protective plugs to protect it from drying out and store in a cool dark place at 4 to 15 °C.

- 7) Please do not bump or shake the column.
- 8) If the pressure is more than the pressure (which is indicated on the column inspection report) +4 MPa, first replace the line filter. If the pressure still does not drop, replace the column.
- 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.

12. Reference Data

(from the HLC-723G8 5.24F Assay Examples)



13. 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 %.

14. 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: _____

15. 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 (See http://www.ifcchba1c.net/IFCC_08.asp):

$$\text{NGSP (\%)} = 0.09148 \times \text{IFCC (mmol/mol)} + 2.152$$

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.

16. 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 $100 \pm 5\%$. 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 $\pm 5\%$ 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 standard⁵.

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.

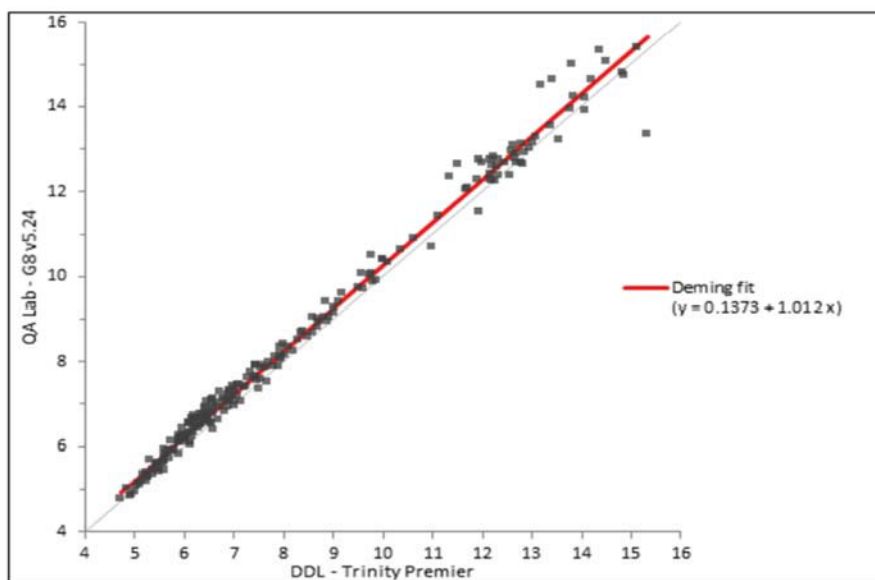
	y-intercept	95% CI	Slope	95% CI
Deming	0.1332	-0.0339 to 0.3002	1.013	0.9894 to 1.036
Passing-Bablok	0.0702	-0.0484 to -0.1864	1.021	1.006 to 1.036

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

% 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 [%]					
HbA1c Level	Passing Bablok		Deming		%CV Total
	`%TE`	%Bias	`%TE`	%Bias	
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: $\sqrt{ \%Bias + 1.96 \times \%CV \text{ Total} \times (1 + \%Bias/100)}$					

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^{6,7,8}. Interference was determined as a variance greater than the measured value \pm 5%.

Potential Interferent	Range tested	%A1c Concentrations	Concentration in 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	100 - 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^{8,9}. The prevalence of hemoglobinopathies varies among populations¹⁰. 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 Capillars 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 $\leq 6\%$ 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
HbC	26	30.8 to 37.8	4.8 to 9.8
HbD	24	22.6 to 40.7	5.3 to 9.347
HbE	26	20.0 to 30.9	4.763 to 9.7
HbS	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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Document Detail

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1

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Revision Notes

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1	Check In	KIMBERLY.HARMESON	14-Mar-2024
Note: Transferred from Source Document while Copying it			
2	Check In	KIMBERLY.HARMESON	20-Mar-2024
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3	Check In	KIMBERLY.HARMESON	25-Apr-2024
Note:			
4	Check In	KIMBERLY.HARMESON	25-Apr-2024
Note:			

Review

Build No.: 4

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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 2:41 pm	GAYLE.BLAIR
Note To Approver: Final approval of the U.S. version of the TSKgel G8 Variant HSi IFU, includes new addresses.				
Note From Approver:No comments				
20	DOCUMENT COLLABORATOR/APPROVER DOCUMENT COLLABORATOR/APPROVER	THOMAS.CARNEIRO Thomas Carneiro	02-May-2024 8:09 pm	THOMAS.CARNEIRO
Note To Approver: Final approval of the U.S. version of the TSKgel G8 Variant HSi IFU, includes new addresses.				
Note From Approver:No comment.				
30	Document RA Collaborator/Approver Document RA Collaborator/Approver	ISABELLE.LANG-ZWOSTA Isabelle Lang-Zwosta	07-May-2024 1:19 pm	ISABELLE.LANG-ZWOST A
Note To Approver: Final approval of the U.S. version of the TSKgel G8 Variant HSi IFU, includes new addresses.				
Note From Approver:No other comments				
40	DOCUMENT QA COLLABORATOR/APPROVER DOCUMENT QA COLLABORATOR/APPROVER	JORGE.PORRAS Jorge Porras	08-May-2024 1:53 pm	JORGE.PORRAS
Note To Approver: Final approval of the U.S. version of the TSKgel G8 Variant HSi IFU, includes new addresses.				
Note From Approver:approved				