DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 29, 2017

ARKRAY, INC.
C/O NAVEEN THURAMALLA
ARKRAY AMERICA, INC.
5182 WEST 76TH STREET
EDINA MN 55439

Re: K162822
Trade/Device Name: ADAMS A1c HA-8180V
Regulation Number: 21 CFR 862.1373
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: PDJ, LCP, JIT
Dated: May 30, 2017
Received: May 31, 2017

Dear Naveen Thuramalla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162822

Device Name
ADAMS A1c HA-8180V

Indications for Use *(Describe)*
The ADAMS A1c HA-8180V system is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood and hemolysate samples using Ion Exchange high performance liquid chromatography (HPLC).

Hemoglobin A1c measurements obtained from the ADAMS A1C HA-8180V are used as an aid in the diagnosis of diabetes mellitus, an aid in the identification of individuals who may be at risk of developing diabetes, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. The ADAMS A1c HA-8180V is intended for Professional Use Only.

The CALIBRATOR 80 is for the calibration of the ADAMS A1c HA-8180V system used for the quantitative determination of hemoglobin A1c in human whole blood and hemolysate samples.

For In Vitro Diagnostic Use Only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Summary of Safety & Effectiveness

k162822

Date Prepared: June 21, 2017

This summary of 510(k) Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. Applicant Name:

ARKRAY, INC.
Yousuien-Nai, 59 Gansuin-Cho,
Kamigyo-Ku Kyoto, JAPAN 602-0008
Telephone: +81 75-662-8979; Fax: +81 75-431-1202
Establishment Registration # 3002807423

2. Contact Person:

Naveen Thuramalla
Vice President, Regulatory Affairs
Telephone: 202-738-8303; Fax: 952-646-3230
Email: thuramallan@arkrayusa.com

3. Device Name/Trade Name:

Device

Trade Name: ADAMS A1c HA-8180V
Classification Name: Hemoglobin Alc Test System
Common Name: HbA1c
Product Codes: PDJ, LCP
Classification Panel: Clinical Chemistry
Device Classification: Class II
C.F.R. Sections: Primary: 21 CFR § 862.1373;
Secondary: 21 CFR § 864.7470

Calibrator

Trade Name: Calibrator 80
Classification Name: Calibrator
Common Name: Calibrator
Product Codes: JIT
Classification Panel: Clinical Chemistry
Device Classification: Class II
C.F.R. Sections: 21 CFR § 862.1150

4. Predicate Device K131580 – Automated Glycohemoglobin Analyzer HLC-723G8 (Tosoh Bioscience, Inc.)
K071132 – Hemoglobin A1c Calibrator Set (Tosoh Bioscience, Inc.)

5. Device Description

The ADAMS A1c HA-8180V system is a fully automated analyzer that uses ion exchange high performance liquid chromatography (HPLC) technology to separate glycated (labile A1c(L-A1c) and stable A1c (S-A1c)) and non-glycated (HbA0) forms of hemoglobin.

Hemoglobin A1c measurements obtained from the ADAMS A1C HA-8180V are used as an aid in the diagnosis of diabetes mellitus, an aid in the identification of individuals who may be at risk of developing diabetes, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. The subject device consists of the ADAMS A1c HA-8180V test analytical instrument and CALIBRATOR 80, which is used to calibrate the HA-8180V. The ADAMS A1c HA-8180V system is for use in professional clinical laboratory settings.

This method is certified by the National Glycohemoglobin Standardization Program (NGSP).

DEVICE:

Hemoglobin test samples are prepared by automated dilution of anticoagulated whole blood in Hemolysis Washing Solution 80H. Alternately, hemolysis samples may be prepared "off-line" by manual dilution of anticoagulated whole blood with Diluent 80. The sample is then injected into the column, which contains a filter to remove sample impurities. The differing polarity and ionic charges of the released hemoglobin fractions bind with variable strength to the negatively charged stationary phase of the column. The mobile phase, consisting of three eluents of increasing ionic strength, is injected into the column. Hemoglobin fractions eluted from the column are identified and quantified using light absorption, and are measured at 420 nm and 500 nm. The dual wavelength colorimetric analysis of the separated peaks is processed by a microcomputer to obtain peak identification and hemoglobin fraction quantitation. All pre-analytical and analytical steps are performed automatically by the ADAMS A1c HA-8180V system. Tests may be ordered in batch or for STAT measurement.

HbA1c and HbF results are reported in the presence of HbC, HbD, HbE, or HbS. A result of the detected HbC or HbS, and a peak resulting from HbD or HbE is also listed in the peak information. When a peak resulting from HbD or HbE is detected, a 'V' is listed in the peak information. HbA1c and HbF results are not reported when the instrument detects other peaks that affect HbA1c measurement value. The identification of any of these variants is not intended for use in diagnosis of hemoglobinopathies.

CALIBRATOR:

Value assignment for HA-8180V HbA1c Calibrators are traceable to International Federation of Clinical Chemistry (IFCC) reference method and can be transferred to Diabetes Control and Complications Trial (DCCT)/NGSP values by calculation.

The Calibrator 80 consists of two levels of single-use, lyophilized calibrators. Diluent used to reconstitute the calibrators is also included. Three eluent solutions, a washing solution, and a control dilution set (used for sample dilutions and control material preparation) are also provided by ARKRAY for use on the HA-8180V system.

6. Indications for Use: (Prescription Device)

Device Name: ADAMS A1c HA-8180V

The ADAMS A1c HA-8180V system is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood and hemolysate samples using Ion Exchange high performance liquid chromatography (HPLC).

Hemoglobin A1c measurements obtained from the ADAMS A1C HA-8180V are used as an aid in the diagnosis of diabetes mellitus, an aid in the identification of individuals who may be at risk of developing diabetes, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. The ADAMS A1c HA-8180V is intended for Professional Use Only.

The CALIBRATOR 80 is for the calibration of the ADAMS A1c HA-8180V system used for the quantitative determination of hemoglobin A1c in human whole blood and hemolysate samples.

For In Vitro Diagnostic Use Only.

7. Substantial Equivalence Information:

Predicate Device Information

Predicate Device Name	***Predicate Device 510(k) Number***
Tosoh Bioscience, Inc. Automated Glycohemoglobin Analyzer HLC-723G8	K131580
Tosoh Bioscience, Inc. Hemoglobin A1c Calibrator Set	K071132

The ADAMS A1c HA-8180V System (candidate device) utilizes principles of ion-exchange high-performance liquid chromatography (HPLC) similar to the same technology of the Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (predicate device).

Following tables (**Table 1** and **Table 2**) provide the similarities and differences between the HA-8180V system and the predicates (for both the device and calibrator).

Table 1: Device Similarities and Differences

Parameter	ADAMS A1c HA-8180V (Candidate Device)	Tosoh Bioscience, Inc. Automated Glycohemoglobin Analyzer HLC-723G8 K131580 (Predicate Device)
Similarities		
Indications for Use	The ADAMS A1c HA-8180V system is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood and hemolysate samples using Ion Exchange high performance liquid chromatography (HPLC). Hemoglobin A1c measurements obtained from the ADAMS A1C HA-8180V are used as an aid in the diagnosis of diabetes mellitus, an aid in the identification of individuals who may be at risk of developing diabetes, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. The ADAMS A1c HA-8180V is intended for Professional Use Only.	The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 is intended for *in vitro* diagnostic use for the 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 identifying patients who may be at risk for developing diabetes.
Specimen Type	Whole blood, hemolysate sample	Whole blood, diluted blood
Assay Principle	Ion exchange HPLC	Ion exchange HPLC
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP)	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP)

Parameter	ADAMS A1c HA-8180V (Candidate Device)	Tosoh Bioscience, Inc. Automated Glycohemoglobin Analyzer HLC-723G8 K131580 (Predicate Device)
System Components	Sampling unit, liquid pump, degasser, column, detector, microprocessor, sample loader, operation panel, printer	Sampling unit, liquid pump, degasser, column, detector, microprocessor, sample loader, operation panel, printer
Detection Method	Dual wavelength (420 nm and 500 nm) LED colorimetric detector	Dual wavelength (415 nm and unknown) LED colorimetric detector
STAT Capability	Yes	Yes
HbA1c Reporting Units	%HbA1c, mmol/mol, chromatogram	%HbA1c, mmol/mol, chromatogram
Differences		
Measurement Range (HbA1c)	4-15% (NGSP) 20 to 140 mmol/mol (IFCC)	4-16.9% (NGSP) 20 to 161 mmol/mol (IFCC)
Sample Volume (Consumed)	Whole blood: 14 µL Hemolysate: 400 µL	Whole blood: 4 µL Diluted blood: 80 µL
Anticoagulant	K_2-EDTA and K_3-EDTA Whole Blood	K_3-EDTA Whole Blood
Operating Temperature	10 – 30°C	15 – 30°C

Table 2: Calibrator Similarities and Differences

Parameter	ADAMS A1c HA-8180V (Candidate Device)	Tosoh Bioscience, Inc. Hemoglobin A1c calibrator K071132 (Predicate Device)
Indications for Use	The CALIBRATOR 80 is for the calibration of the ADAMS A1c HA-8180V system used for the quantitative determination of hemoglobin A1c in human whole blood and hemolysate samples.	The Tosoh A1c Calibrator Set is a reference agent designed for calibrating Tosoh Automated Glycohemoglobin Analyzer HLC-723G8.
Calibrator Description	Bi-level calibrators (low and high) with human-source material	Bi-level calibrators (low and high) with human-source material

Parameter	ADAMS A1c HA-8180V (Candidate Device)	Tosoh Bioscience, Inc. Hemoglobin A1c calibrator K071132 (Predicate Device)
Concentrations	HbA1c (NGSP Value): Calibrator 80 Low – approximately 5.0-6.0% Calibrator 80 High – approximately 10.0-11.0% Varies according to lot	HbA1c (NGSP Value): Calibrator 1 – approximately 5.5-6.5% Calibrator 2 – approximately 10.5-11.5% Varies according to lot
Standardization/ Traceability	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP)	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP)
Matrix	Lyophilized calibrator from human-sourced hemoglobin	Buffered human red blood cells, 2 mg/mL Human hemoglobin
Storage & Stability	Shelf life: 18 months at 2 – 8°C Open bottle: 8 hours at 2 – 8°C after reconstitution	Shelf life: 2 years at 2 – 8°C Open bottle: One week at 2 – 8°C after reconstitution* * Based on manufacturer's Instructions for Use (0T012070/Rev March 2013)

The candidate ADAMS A1c HA-8180V system is similar to the legally marketed predicate Tosoh G8 system in general design and assay principles, technology, performance characteristics and indications for use. The minor differences between the candidate and predicate device do not raise new issues of safety or effectiveness. The same applies to the candidate calibrator to be used with HA-8180V system and the Tosoh's HLC-723G8 system. The performance of the ADAMS A1c HA-8180V system is substantiated in various sections throughout the submission. Therefore, we consider that the ADAMS A1c HA-8180V system is Substantially Equivalent to the predicate.

8. Precision/Reproducibility:

The precision of the ADAMS A1c HA-8180V system was evaluated based on CLSI EP05-A3, *Evaluation of Precision Performance of Quantitative Measurement Methods*. The study design included three lots and three instruments. All data was collected at ARKRAY, (a Point of Care (POC) claim is not being made), consistent with the FDA recommendations in pre-IDE I110310. EDTA whole blood samples from four donors at the approximate targeted HbA1c concentrations

of ~5.0% (Patient 1), ~6.5% (Patient 2), ~8.0% (Patient 3) and ~12.0% (Patient 4) were utilized in the study.

Three quality control materials were also tested. Precision was evaluated using three reagent lots and three HA-8180V HbA1c Testing Systems at one site (ARKRAY USA, Edina, MN). All samples were run in duplicate in two runs per instrument per day for 20 days. National Glycohemoglobin Standardization Program (NGSP) results and International Federation of Clinical Chemistry (IFCC) results are shown in the **Table 3 – Table 10**.

Table 3: Instrument 1 Whole Blood Samples (NGSP):

Mean %HbA1c	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient1, 5.2%	0.01	0.3%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.01	0.3%
Patient 2, 6.4%	0.02	0.3%	0.01	0.2%	0.00	0.0%	0.05	0.8%	0.05	0.8%
Patient 3, 7.9%	0.03	0.4%	0.03	0.4%	0.01	0.2%	0.06	0.7%	0.07	0.9%
Patient 4, 11.8%	0.03	0.3%	0.02	0.1%	0.04	0.3%	0.07	0.6%	0.08	0.7%
Control 1, 5.2%	0.03	0.7%	0.03	0.7%	0.02	0.3%	0.02	0.4%	0.05	1.1%
Control 2, 9.0%	0.03	0.3%	0.03	0.3%	0.01	0.2%	0.01	0.1%	0.04	0.5%
Control 3, 13.4%	0.02	0.2%	0.04	0.3%	0.03	0.2%	0.02	0.1%	0.06	0.4%

Table 4: Instrument 2 Whole Blood Samples (NGSP):

Mean % HbA1c	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.02	0.4%	0.01	0.2%	0.00	0.0%	0.01	0.2%	0.03	0.5%
Patient 2, 6.4%	0.01	0.1%	0.00	0.0%	0.00	0.0%	0.06	0.9%	0.06	0.9%
Patient 3, 7.9%	0.03	0.4%	0.02	0.3%	0.01	0.1%	0.08	1.0%	0.09	1.1%
Patient 4, 11.8%	0.05	0.4%	0.01	0.1%	0.03	0.2%	0.10	0.9%	0.12	1.0%
Control 1, 5.2%	0.02	0.4%	0.03	0.5%	0.01	0.3%	0.04	0.9%	0.06	1.1%
Control 2, 9.0%	0.02	0.2%	0.03	0.4%	0.01	0.2%	0.04	0.5%	0.06	0.6%
Control 3, 13.4%	0.03	0.2%	0.03	0.3%	0.04	0.3%	0.05	0.4%	0.08	0.6%

Table 5: Instrument 3 Whole Blood Samples (NGSP):

Mean % HbA1c	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.02	0.4%	0.02	0.4%	0.00	0.0%	0.01	0.2%	0.03	0.6%
Patient 2, 6.4%	0.02	0.4%	0.01	0.2%	0.00	0.0%	0.06	0.9%	0.06	1.0%
Patient 3, 7.9%	0.03	0.4%	0.02	0.2%	0.02	0.3%	0.05	0.7%	0.07	0.9%
Patient 4, 11.8%	0.02	0.2%	0.03	0.2%	0.02	0.2%	0.11	1.0%	0.12	1.0%
Control 1, 5.2%	0.02	0.5%	0.02	0.3%	0.01	0.2%	0.02	0.4%	0.04	0.8%
Control 2, 9.1%	0.03	0.4%	0.03	0.3%	0.03	0.3%	0.05	0.5%	0.07	0.8%
Control 3, 13.4%	0.03	0.2%	0.04	0.3%	0.04	0.3%	0.08	0.6%	0.10	0.7%

Table 6: Instruments Combined Whole Blood Samples (NGSP):

Mean %	Repeatability		Between Run		Between Day		Between Lot		Between Instrument		Total	
HbA1c	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.02	0.4%	0.01	0.2%	0.00	0.1%	0.01	0.1%	0.01	0.1%	0.03	0.5%
Patient 2, 6.4%	0.02	0.3%	0.01	0.2%	0.00	0.0%	0.05	0.9%	0.00	0.0%	0.06	0.9%
Patient 3, 7.9%	0.03	0.4%	0.02	0.3%	0.02	0.3%	0.06	0.8%	0.02	0.3%	0.08	1.0%
Patient 4, 11.8%	0.04	0.3%	0.02	0.2%	0.04	0.3%	0.09	0.8%	0.03	0.3%	0.11	1.0%
Control 1, 5.2%	0.03	0.5%	0.03	0.5%	0.02	0.4%	0.03	0.5%	0.02	0.4%	0.05	1.1%
Control 2, 9.0%	0.03	0.3%	0.03	0.3%	0.02	0.3%	0.03	0.4%	0.02	0.2%	0.06	0.7%
Control 3, 13.4%	0.03	0.2%	0.04	0.3%	0.04	0.3%	0.05	0.4%	0.03	0.2%	0.08	0.6%

Table 7: Instrument 1 Whole Blood Samples (IFCC):

Mean	Repeatability		Between Run		Between Day		Between Lot		Total	
mmol/mol	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.2	0.7%	0.2	0.7%	0.0	0.0%	0.3	0.9%	0.4	1.4%
Patient 2, 47	0.3	0.6%	0.2	0.5%	0.1	0.2%	0.4	0.9%	0.5	1.2%
Patient 3, 62	0.3	0.5%	0.1	0.2%	0.1	0.1%	0.6	1.0%	0.7	1.1%
Patient 4, 105	0.3	0.3%	0.2	0.2%	0.2	0.2%	0.7	0.7%	0.8	0.8%
Control 1, 33	0.2	0.7%	0.2	0.7%	0.1	0.2%	0.2	0.5%	0.4	1.1%
Control 2, 75	0.3	0.4%	0.3	0.3%	0.2	0.2%	0.0	0.0%	0.4	0.6%
Control 3, 123	0.2	0.2%	0.4	0.3%	0.2	0.2%	0.2	0.2%	0.6	0.5%

Table 8: Instrument 2 Whole Blood Samples (IFCC):

Mean mmol/mol	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.2	0.7%	0.1	0.3%	0.0	0.0%	0.5	1.4%	0.5	1.6%
Patient 2, 47	0.3	0.7%	0.0	0.0%	0.2	0.5%	0.5	1.1%	0.7	1.4%
Patient 3, 63	0.4	0.6%	0.2	0.4%	0.2	0.3%	0.8	1.2%	0.9	1.4%
Patient 4, 106	0.5	0.5%	0.3	0.3%	0.2	0.2%	1.1	1.0%	1.2	1.2%
Control 1, 33	0.2	0.7%	0.3	0.8%	0.1	0.4%	0.1	0.5%	0.4	1.2%
Control 2, 75	0.3	0.3%	0.4	0.5%	0.0	0.0%	0.5	0.7%	0.7	0.9%
Control 3, 123	0.3	0.3%	0.3	0.3%	0.3	0.3%	0.6	0.5%	0.8	0.7%

Table 9: Instrument 3 Whole Blood Samples (IFCC):

Mean mmol/mol	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.2	0.6%	0.2	0.5%	0.0	0.0%	0.5	1.6%	0.6	1.8%
Patient 2, 47	0.3	0.7%	0.2	0.3%	0.2	0.4%	0.3	0.7%	0.5	1.1%
Patient 3, 63	0.3	0.5%	0.2	0.4%	0.3	0.4%	0.6	1.0%	0.8	1.3%
Patient 4, 106	0.3	0.3%	0.3	0.3%	0.3	0.2%	1.3	1.2%	1.4	1.3%
Control 1, 33	0.2	0.6%	0.2	0.5%	0.2	0.6%	0.1	0.4%	0.4	1.1%
Control 2, 75	0.3	0.4%	0.3	0.4%	0.3	0.4%	0.5	0.6%	0.7	0.9%
Control 3, 123	0.3	0.2%	0.4	0.3%	0.4	0.3%	0.9	0.7%	1.1	0.9%

Table 10: Instruments Combined Whole Blood Samples (IFCC):

Mean mmol/mol	Repeatability		Between Run		Between Day		Between Lot		Between Instrument		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.22	0.7%	0.17	0.5%	0.06	0.2%	0.44	1.3%	0.07	0.2%	0.53	1.6%

Patient 2, 47	0.31	0.7%	0.14	0.3%	0.27	0.6%	0.35	0.7%	0.27	0.6%	0.61	1.3%
Patient 3, 63	0.32	0.5%	0.20	0.3%	0.24	0.4%	0.64	1.0%	0.21	0.3%	0.81	1.3%
Patient 4, 106	0.39	0.4%	0.29	0.3%	0.33	0.3%	1.00	0.9%	0.31	0.3%	1.20	1.1%
Control 1, 33	0.22	0.7%	0.22	0.7%	0.14	0.4%	0.14	0.4%	0.13	0.4%	0.39	1.2%
Control 2, 75	0.28	0.4%	0.31	0.4%	0.27	0.4%	0.32	0.4%	0.23	0.3%	0.63	0.8%
Control 3, 123	0.28	0.2%	0.40	0.3%	0.43	0.4%	0.53	0.4%	0.34	0.3%	0.90	0.7%

NGSP results and IFCC results for Hemolyzed Samples are shown in **Table 11** – **Table 18**.

Table 11: Instrument 1 Hemolysate Samples (NGSP):

Mean	Repeatability		Between Run		Between Day		Between Lot		Total	
% HbA1c	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.02	0.4%	0.03	0.5%	0.01	0.2%	0.00	0.1%	0.04	0.7%
Patient 2, 6.4%	0.01	0.2%	0.02	0.3%	0.02	0.3%	0.05	0.8%	0.06	0.9%
Patient 3, 7.9%	0.03	0.4%	0.02	0.2%	0.02	0.3%	0.04	0.6%	0.06	0.8%
Patient 4, 11.9%	0.03	0.3%	0.03	0.3%	0.02	0.2%	0.07	0.6%	0.08	0.7%
Control 1, 5.2%	0.03	0.5%	0.07	1.3%	0.06	1.2%	0.05	0.9%	0.11	2.1%
Control 2, 9.1%	0.03	0.3%	0.02	0.2%	0.04	0.4%	0.01	0.2%	0.05	0.6%
Control 3, 13.5%	0.03	0.2%	0.05	0.4%	0.04	0.3%	0.03	0.3%	0.08	0.6%

Table 12: Instrument 2 Hemolysate Samples (NGSP):

Mean	Repeatability		Between Run		Between Day		Between Lot		Total	
% HbA1c	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.01	0.2%	0.02	0.4%	0.02	0.3%	0.01	0.2%	0.03	0.6%
Patient 2, 6.4%	0.02	0.3%	0.01	0.1%	0.02	0.3%	0.05	0.8%	0.06	0.9%
Patient 3, 7.9%	0.02	0.2%	0.02	0.3%	0.01	0.1%	0.06	0.8%	0.07	0.9%
Patient 4,	0.03	0.3%	0.02	0.2%	0.03	0.3%	0.10	0.8%	0.11	0.9%

11.9%										
Control 1, 5.2%	0.03	0.5%	0.05	1.0%	0.05	1.0%	0.04	0.8%	0.09	1.7%
Control 2, 9.1%	0.02	0.3%	0.05	0.5%	0.05	0.5%	0.03	0.4%	0.08	0.8%
Control 3, 13.6%	0.03	0.2%	0.05	0.4%	0.05	0.4%	0.06	0.4%	0.10	0.7%

Table 13: Instrument 3 Hemolysate Samples (NGSP):

Mean % HbA1c	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.02	0.3%	0.00	0.0%	0.01	0.3%	0.00	0.1%	0.02	0.4%
Patient 2, 6.5%	0.03	0.5%	0.02	0.4%	0.00	0.0%	0.03	0.5%	0.05	0.8%
Patient 3, 7.9%	0.01	0.1%	0.01	0.1%	0.00	0.0%	0.06	0.7%	0.06	0.8%
Patient 4, 11.9%	0.03	0.2%	0.03	0.2%	0.02	0.2%	0.10	0.9%	0.11	0.9%
Control 1, 5.2%	0.02	0.4%	0.04	0.7%	0.04	0.8%	0.03	0.5%	0.07	1.2%
Control 2, 9.1%	0.03	0.3%	0.04	0.4%	0.03	0.4%	0.04	0.5%	0.07	0.8%
Control 3, 13.6%	0.04	0.3%	0.05	0.4%	0.04	0.3%	0.08	0.6%	0.11	0.8%

Table 14: Instruments Combined Hemolysate Samples (NGSP):

Mean % HbA1c	Repeatability		Between Run		Between Day		Between Lot		Between Instrument		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 5.2%	0.02	0.3%	0.02	0.4%	0.01	0.3%	0.01	0.1%	0.00	0.0%	0.03	0.6%
Patient 2, 6.5%	0.02	0.4%	0.02	0.3%	0.02	0.3%	0.04	0.7%	0.02	0.2%	0.06	0.9%
Patient 3, 7.9%	0.02	0.2%	0.02	0.2%	0.02	0.2%	0.05	0.7%	0.01	0.1%	0.06	0.8%
Patient 4, 11.9%	0.03	0.3%	0.03	0.2%	0.03	0.3%	0.09	0.7%	0.03	0.3%	0.11	0.9%
Control 1, 5.2%	0.02	0.5%	0.05	1.1%	0.05	1.0%	0.04	0.7%	0.01	0.3%	0.09	1.7%

Control 2, 9.1%	0.03	0.3%	0.04	0.4%	0.04	0.5%	0.03	0.3%	0.02	0.2%	0.07	0.8%
Control 3, 13.6%	0.03	0.2%	0.05	0.4%	0.05	0.4%	0.05	0.4%	0.03	0.3%	0.10	0.8%

Table 15: Instrument 1 Hemolysate Samples (IFCC):

Mean	Repeatability		Between Run		Between Day		Between Lot		Total	
mmol/mol	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.3	0.8%	0.3	0.8%	0.2	0.7%	0.4	1.1%	0.6	1.7%
Patient 2, 47	0.3	0.6%	0.2	0.3%	0.2	0.4%	0.2	0.5%	0.4	0.9%
Patient 3, 63	0.3	0.5%	0.3	0.5%	0.2	0.3%	0.5	0.8%	0.7	1.2%
Patient 4, 106	0.3	0.3%	0.3	0.2%	0.2	0.2%	0.7	0.6%	0.8	0.8%
Control 1, 33	0.2	0.6%	0.7	2.0%	0.7	2.0%	0.3	1.0%	1.0	3.0%
Control 2, 76	0.3	0.4%	0.3	0.4%	0.4	0.5%	0.2	0.2%	0.6	0.8%
Control 3, 125	0.3	0.3%	0.6	0.5%	0.5	0.4%	0.4	0.3%	0.9	0.7%

Table 16: Instrument 2 Hemolysate Samples (IFCC):

Mean	Repeatability		Between Run		Between Day		Between Lot		Total	
mmol/mol	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.2	0.7%	0.2	0.5%	0.2	0.5%	0.4	1.1%	0.5	1.5%
Patient 2, 47	0.3	0.5%	0.2	0.5%	0.2	0.4%	0.3	0.7%	0.5	1.1%
Patient 3, 63	0.2	0.4%	0.3	0.4%	0.2	0.3%	0.6	1.0%	0.7	1.2%
Patient 4, 107	0.4	0.3%	0.4	0.4%	0.2	0.2%	1.0	0.9%	1.2	1.1%
Control 1, 33	0.2	0.6%	0.6	1.7%	0.7	2.0%	0.2	0.6%	0.9	2.7%
Control 2, 76	0.3	0.4%	0.6	0.8%	0.5	0.7%	0.4	0.6%	0.9	1.2%
Control 3, 125	0.3	0.3%	0.5	0.4%	0.6	0.5%	0.7	0.5%	1.1	0.9%

Table 17: Instrument 3 Hemolysate Samples (IFCC):

Mean mmol/mol	Repeatability		Between Run		Between Day		Between Lot		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.2	0.7%	0.2	0.7%	0.1	0.4%	0.4	1.2%	0.5	1.6%
Patient 2, 47	0.2	0.4%	0.2	0.3%	0.1	0.3%	0.4	0.8%	0.5	1.0%
Patient 3, 63	0.2	0.3%	0.2	0.3%	0.0	0.0%	0.6	1.0%	0.7	1.0%
Patient 4, 107	0.4	0.4%	0.3	0.3%	0.2	0.2%	1.2	1.1%	1.3	1.2%
Control 1, 33	0.2	0.7%	0.5	1.5%	0.4	1.2%	0.2	0.7%	0.7	2.2%
Control 2, 76	0.3	0.4%	0.4	0.5%	0.4	0.5%	0.5	0.6%	0.8	1.0%
Control 3, 125	0.4	0.3%	0.5	0.4%	0.5	0.4%	0.9	0.7%	1.2	0.9%

Table 18: Instruments Combined Hemolysate Samples (IFCC):

Mean mmol/mol	Repeatability		Between Run		Between Day		Between Lot		Between Instrument		Total	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Patient 1, 33	0.25	0.7%	0.22	0.7%	0.18	0.5%	0.38	1.2%	0.06	0.2%	0.54	1.6%
Patient 2, 47	0.24	0.5%	0.19	0.4%	0.21	0.4%	0.29	0.6%	0.13	0.3%	0.49	1.0%
Patient 3, 63	0.27	0.4%	0.26	0.4%	0.18	0.3%	0.57	0.9%	0.15	0.2%	0.72	1.1%
Patient 4, 107	0.36	0.3%	0.32	0.3%	0.30	0.3%	0.96	0.9%	0.30	0.3%	1.15	1.1%
Control 1, 33	0.21	0.6%	0.57	1.7%	0.57	1.7%	0.28	0.9%	0.00	0.0%	0.88	2.7%
Control 2, 76	0.28	0.4%	0.44	0.6%	0.44	0.6%	0.36	0.5%	0.23	0.3%	0.81	1.1%

Control 3, 125	0.35	0.3%	0.53	0.4%	0.58	0.5%	0.62	0.5%	0.34	0.3%	1.12	0.9%

9. Linearity/Reportable Range

A linearity study was performed per CLSI EP06-A: *Evaluation of the Linearity of Quantitative Measuring Procedures; A Statistical Approach*. Linearity across the reportable range was performed using controlled samples ranging from low (3% HbA1c) to high (19% HbA1c) EDTA whole blood patient samples. These samples were mixed together in varying ratios. The measured values were compared to the theoretical values based upon the dilution factor. Acceptance criteria was no more than ±0.15% bias (NGSP% units, not actual percentage) from the theoretical value.

The study demonstrated linearity of ADAMS A1c HA-8180V system over 3.0 to 19.0% (NGSP) and 9 to 184 mmol/mol (IFCC) with a maximum measured difference of -0.10% and -1.09mmol/mol respectively, between the theoretical and measured value. Maximum difference between the predicted 1st order and 3rd order was ±0.08% (NGSP) and ±0.92 mmol/mol (IFCC). This supports the claimed measurement range of 4.0 to 15.0% (20 to 140 mmol/mol) HbA1c.

Table 19: Linearity Regression Parameters

Units	Slope	Intercept	R^2
NGSP	0.9958	0.0064	0.9999
IFCC	0.9958	-0.0275	0.9999

Detection Limit

The claimed measurement range is 4.0 to 15.0 % HbA1c based on the results from the linearity study.

10. Traceability, Stability, Expected Value (Calibrators)

A. Traceability:

The ADAMS A1c HA-8180V test standardization is traceable to the International Federation of Clinical Chemistry (IFCC) reference calibrators. The HA-8180V HbA1c assay is also NGSP certified. The NGSP certification is re-certified by ARKRAY on an annual basis.

The derived results of (%) from the NGSP correlation are calculated from the individual quantitative results for Hemoglobin A1c (HbA1c). The IFCC units of mmol/mol are calculated using the Master Equation:

NGSP (%) = 0.0915 x IFCC (mmol/mol) + 2.15.

The final reportable range is traceable to both the IFCC and the Diabetes Control and Complications Trial (DCCT). HbA1c results are provided to the customers using two different units: NGSP equivalent units (%) and IFCC equivalent units (mmol/mol).

B. Calibrator Materials:

Value assignment for ADAMS A1c HA-8180V Calibrators are traceable to IFCC reference method and can be transferred to DCCT/NGSP values by calculation.

Using an ADAMS A1c HA-8180V instrument calibrated using standard material JCCRM-411 (provided by ReCCS, a primary (APRL) as well as a secondary (ASRL) reference laboratory within the NGSP Network), CALIBRATOR 80 was measured (n=9) over 3 days (total of n=27) to assign values. The mean generated over the 3 days is set as the reference value. Values are given in IFCC value system and converted to NGSP using the master equation.

C. Stability/Shelf Life Claims:

C.1. Shelf life claims: Shelf life studies were performed with three lots of Calibrator 80 as per CLSI EP 25, *Evaluation of Stability of In Vitro Diagnostic Reagents*. Based on the NGSP certification standards, acceptance criteria was defined as: relative bias in HbA1c (%) from 0 month result should be within ± 6% bias at 18 months, when the un-opened calibrators were stored between 2-8^{o}C.

The study results confirmed that the acceptance criteria was met. This supports the recommendation that un-opened calibrators can be stored at 2-8°C until expiration date or for 18 months.

C.2 Open-Vial Stability: The open-vial stability studies were performed with two lots of Calibrator 80 as per CLSI EP 25, *Evaluation of Stability of In Vitro Diagnostic Reagents*. Based on the NGSP certification standards, acceptance criteria was defined as: relative bias in HbA1c (%) should be within ± 6% for measurement at 0 and 8 hours.

The study resultsconfirmed that the acceptance criteria was met. This supports the recommended open vial stability claim of 8 hours when stored at 2-8^{o}C. On-board stability for the Calibrator 80 pack is not evaluated as the calibrators are intended for single use only.

11. Analytical Specificity:

A. Interferences Study

An Interference study was performed per CLSI EP07-A2 *Interference Testing in Clinical Chemistry*. The study assessed common or known endogenous substances, drugs and hemoglobin derivatives that could interfere with ADAMS A1c HA-8180V system. Whole blood samples with HbA1c values of ~6.5% and ~8.0% were analyzed by spiking the interfering substance into each

of the two whole blood samples as shown in **Table 28** and **Table 29**. Ten replicates of each drug prepared with the test and control samples were analyzed using ADAMS A1c HA-8180V system.

Significant interference was defined as a more than ±7.0% change in %HbA1c value from the control. No significant interference was observed at therapeutic levels up to the stated highest concentrations as summarized below.

Table 28: Exogenous Substances

Interferent	Highest Concentration Without Interference
Acetaminophen	20 mg/dL
Acetylcysteine	330 mg/dL
Acetylsalicylic Acid (Aspirin)	65 mg/dL
Ampicillin-Na	1,000 mg/dL
Ascorbic Acid	200 mg/dL
Cefoxitin-Na	2,500 mg/dL
Cyclosporine	0.67 mg/dL
Doxycyclin	50 mg/dL
Ibuprofen	50 mg/dL
Levodopa	20 mg/dL
Metformin	5 mg/dL
Methyldopa	30 mg/dL
Metronidazole	200 mg/dL
Rifampicin	6.4 mg/dL
Salicylic Acid	60 mg/dL
Theophylline	10 mg/dL

Table 29: Endogenous Substances

Interferent	Highest Concentration Without Interference
Acetylated Hb	50 mg/dL
Albumin (human)	20,000 mg/dL
Bilirubin (conj.)	100 mg/dL
Bilirubin (unconj.)	100 mg/dL
Carbamylated Hb	25 mg/dL

Labile Hb (Glucose)	2,000 mg/dL
Rheumatoid Factor	750 IU/mL
Triglycerides	2,000 mg/dL

B. Hemoglobin Variant Study:

A hemoglobin variant interference study was performed using a total of 165 samples known to contain Hemoglobin variants A_2, C, D, E, F, or S. At least, 10 samples were tested around each of the two HbA1c concentrations of ~6.5% and ~8.0%. Testing of the samples containing the Hemoglobin variants A_2, C, D, E, F, or S was performed at least in duplicate. Testing was performed on the HA-8180V system and compared to results obtained by a reference method that has been demonstrated to be free from the hemoglobin interference being tested. **Table 20** shows the samples that were measured.

Table 20: Hemoglobin Variant Study Samples

Variant	n	Variant Range (%)	Range in % HbA1c Concentration
HbA_2	30	1.9 - 25.4%	4.8 - 8.9%
HbC	26	26.9 - 39.0%	4.6 - 9.2%
HbD	22	31.6 - 35.9%	5.7 - 10.3%
HbE	22	18.0 - 30.0%	4.9 - 9.7%
HbF	24	1.0 - 30.3%	4.7 - 11.7%
HbS	41	12.9 - 42.1%	4.5 - 11.6%

As shown in **Table 21**, HbA1c results are accurate (with no significant interference) in samples containing HbA_2 (≤16%), HbC (≤39%), HbD (≤36%), HbE (≤30%), HbF (≤30%), HbS (≤40%).

Table 21: Hemoglobin Variant Study Bias Results

Hemoglobin Variant	Relative % Bias [Range of % Bias] Observed to Reference Method	
	HbA1c ~6.5% A1c	HbA1c ~8.0% A1c
HbA_2	-1.6% [-6.7% to 1.5%]	1.2% [-1.3% to 3.4%]
HbC	0.1% [-5.6% to 4.6%]	-0.5% [-4.7% to 5.7%]

HbD	-1.7% [-6.8% to 1.7%]	-2.6% [-5.7% to 1.2%]
HbE	-0.1% [-3.0% to 4.8%]	-1.1% [-2.8% to 3.5%]
HbF	-0.3% [-6.5% to 4.0%]	0.5% [-2.7% to 6.9%]
HbS	0.1% [-8.8% to 5.7%]	-0.4% [-4.7% to 5.5%]

12. Comparison Studies:

A. Method Comparison with Predicate Device

A Method comparison study was performed per CLSI EP09-A2-IR, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition.* 143 variant-free whole blood K_2-EDTA samples ranging from 4.1% to 17.7% HbA1c were evaluated using the candidate ADAMS A1c HA-8180V system. The results were compared to testing performed at a secondary NGSP reference laboratory using a previously cleared HPLC method (Tosoh G8).

The distribution of samples spanned the measuring interval are listed in **Table 22** and **Table 23**.

Table 22: Distribution of Samples (Whole Blood)

A1c Level (%)	n	% of Total Samples
<5.0%	5	3%
5.0 – 6.0%	19	13%
6.0 – 6.5%	40	28%
6.5 – 7.0%	36	25%
7.0 – 8.0%	21	15%
8.0 – 9.0%	10	7%
≥9.0%	12	8%
Total	143	100%

Table 23: Distribution of Samples (Hemolysate)

A1c Level (%)	n	% of Total Samples
<5.0%	5	3%
5.0 – 6.0%	19	13%
6.0 – 6.5%	40	28%
6.5 – 7.0%	36	25%
7.0 – 8.0%	21	15%
8.0 – 9.0%	10	7%
≥9.0%	12	8%

Total	143	100%

Bias between Candidate and NGSP methods:

Deming (weighted) analysis was performed for the HA-8180V system versus the NGSP SRL reference method. Summary of the results are shown in **Table 24** and **Table 25**, and **Figure 1** and **Figure 2**.

Table 24: Method Comparison Study Results Summary (Whole Blood)

Regression Type	Slope [95% CI]	y-Intercept [95% CI]	R^2
Weighted Deming	0.9864 [0.9626 - 1.010]	0.09585 [-0.06895 - 0.2607]	0.998

Table 25: Method Comparison Study Results Summary (Hemolysate)

Regression Type	Slope [95% CI]	y-Intercept [95% CI]	R^2
Weighted Deming	0.9906 [0.9670 - 1.014]	0.08047 [-0.08251 - 0.2434]	0.998

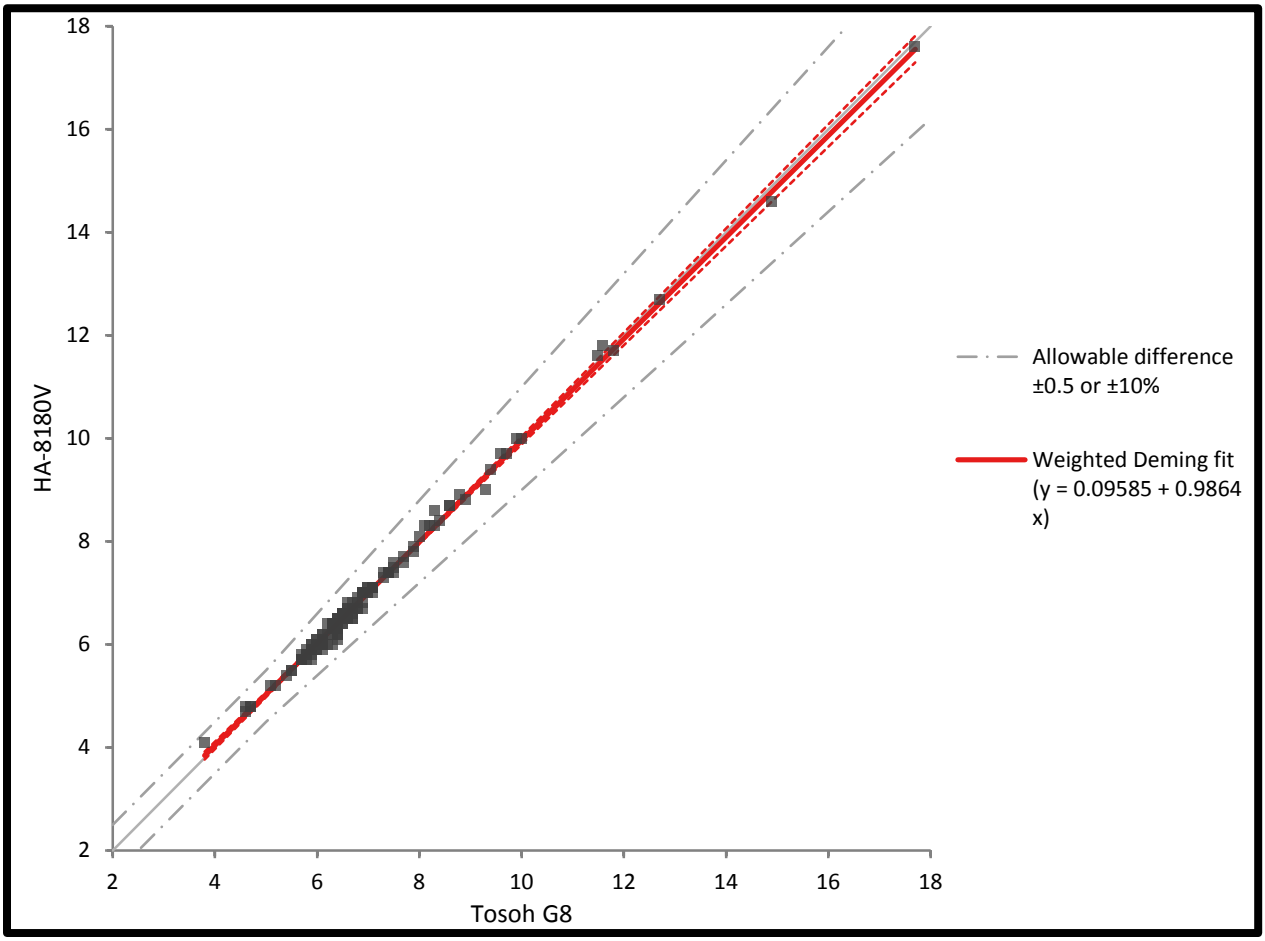

Figure 1: Scatter Plot using Weighted Deming Fit, %HbA1c, Reference Method vs ADAMS A1c HA-8180V (Whole Blood Samples)

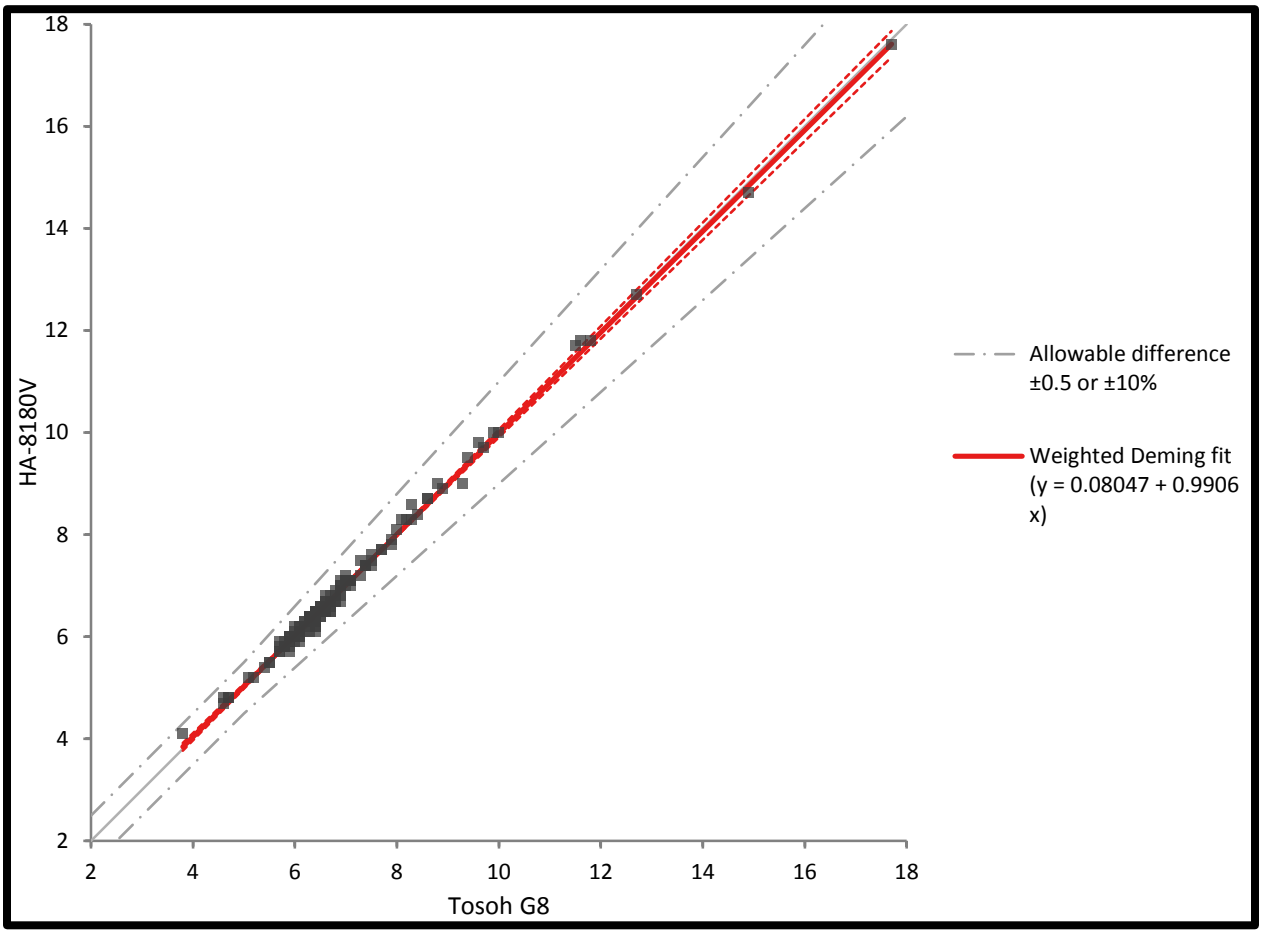

Figure 2: Scatter Plot using Weighted Deming Fit, %HbA1c, Reference Method vs HA-8180V (Hemolysates Samples)

Note: Scatter plots included in the manual will only show up to 15% to be consistent with the ADAMS A1c HA-8180V claimed HbA1c level.

Bias Estimation

Table 26 and **Table 27** show the following biases between the candidate HA-8180V system and the reference NGSP SRL (Tosoh G8) system.

Table 26: Bias Estimation (Whole Blood)

HbA1c Level (%)	Bias	% Bias
5.0	0.028	0.56%
6.5	0.007	0.11%
8.0	-0.013	-0.16%
12.0	-0.067	-0.56%

Table 27: Bias Estimation (Hemolysate)

HbA1c Level (%)	Bias	% Bias
5.0	0.033	0.67%
6.5	0.019	0.30%
8.0	0.005	0.07%
12.0	-0.032	-0.27%

Total Error Near the Cutoff

Using the results of bias estimation (%Bias) in the method comparison study and precision estimated in the reproducibility study, Total Error (TE) at four concentrations (5.0%, 6.5%, 8.0% and 12.0%) were calculated as follows: %TE = $|\%bias| + 1.96 * \%CV * (1 + \frac{\%bias}{100})$. The study results, as summarized in **Table 28** and **Table 29** demonstrated that the Total Error was ≤6%.

Table 28: Results Summary (Whole Blood)

A1c Level (%)	% Bias	% CV	% TE
5.0	0.56%	0.5%	1.5%
6.5	0.11%	0.9%	1.9%
8.0	-0.16%	1.0%	2.1%
12.0	-0.56%	1.0%	2.4%

Table 29: Results Summary (Hemolysate)

A1c Level (%)	% Bias	% CV	% TE
5.0	0.67%	0.6%	1.8%
6.5	0.31%	0.9%	2.1%
8.0	0.07%	0.8%	1.6%
12.0	-0.27%	0.9%	2.0%

B. Matrix Comparison:

A matrix study was performed to determine the suitability of K_2-EDTA and K_3-EDTA, anticoagulants used with fresh whole blood for use with the ADAMS A1c HA8180V system. Specimens with concentration values spanning 4.7 to 15.7% HbA1c were collected from a total of 40 different donors.

K_2 EDTA was the reference anticoagulant and K_3 EDTA was the test anticoagulant. Following regression results were obtained:

K_2-EDTA whole blood vs K_3-EDTA: y = 1.005x - 0.047; R^2 = 1.000

The labeling lists K_2-EDTA and K_3-EDTA as the acceptable anticoagulants.

13. Expected Values/Reference Range

Hemoglobin A1c expected values reference range cited below is from the American Diabetes Association (ADA), "Diagnosis and Classification of Diabetes Mellitus" Diabetes Care; 39 (Supplement 1): S13-S22; 2016.

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Suggested Diagnosis	HbA1c (%)	HbA1c (mmol/mol)
Diabetic	≥ 6.5	≥ 48
Prediabetes	5.7 – 6.4	39 – 47
Normal	< 5.7	< 39

14. Special Control Requirements Checklist for Diabetes Diagnosis Claim

ADAMS A1c HA-8180V System performance substantiates that the device meets the FDA's "Special Controls" requirements to support a diagnostic claim as set forth in the Federal Register, "Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of Hemoglobin A1c Test System: FDA, Final Order", 79 FR 164 (25 Aug 2014), pp. 50549-50551.

Requirement Met?	Requirement
Yes	Device must have initial and annual standardization verification by a certifying glycohemoglobin standardization organization deemed acceptable by the FDA.
	Device must meet the following performance testing requirements:
Yes	Performance testing of device precision must, at a minimum, use blood samples with concentrations near 5.0 percent, 6.5 percent, 8.0 percent, and 12 percent hemoglobin A1c. This testing must evaluate precision over a minimum of 20 days using at least three lots of the device and three instruments, as applicable.
Yes	Performance testing of device accuracy must include a minimum of 120 blood samples that span the measuring interval of the device and compare results of the new device to results of a standardized test method. Results must demonstrate little or no bias versus the standardized method
Yes	Total error of the new device must be evaluated using single measurements by the new device compared to results of the standardized test method, and this evaluation must demonstrate a total error less than or equal to 6 percent
Yes	Performance testing must demonstrate that there is little to no interference from common hemoglobin variants, including Hemoglobin C, Hemoglobin D, Hemoglobin E, Hemoglobin A_2, and Hemoglobin S.
Not Applicable	When assay interference from Hemoglobin F or interference with other hemoglobin variants with low frequency in the population is observed, a warning statement must be placed in a black box and must appear in all

	labeling material for these devices describing the interference and any affected populations.

CONCLUSION:

The information and data in this 510(k) notification demonstrates that the ADAMS A1c HA-8180V System is an accurate, reliable, precise test that correlates well with currently cleared methods and NGSP standardized testing for the quantitation of HbA1c.

The contents of this notification demonstrate that the ADAMS A1c HA-8180V System performance is substantially equivalent to its predicate device. The performance criteria as stipulated by the Special Controls requirements for HbA1c systems that diagnose diabetes have been met.