ASUREQUAN HbA1c

CE

Test Cartridge for determination of hemoglobin A1c with ASUREQUAN Analyzer

ENG

Intended Use

ASUREQUAN HbA1c, the Test Cartridge used with ASUREQUAN Analyzer, is intended to be used for the quantitative determination of hemoglobin A1c(HbA1c) in human whole blood. The Test Cartridge is for *in vitro* diagnostic use by healthcare professionals only.

Introduction

Glycated hemoglobin(Hemoglobin A1c, HbA1c) is a form of hemoglobin to measure primarily the three-month average plasma glucose concentration. HbA1c testing is recommended for monitoring the blood sugar control in both pre-diabetic persons and chronic elevated blood sugar levels of persons with diabetes mellitus. The American Diabetes Association guidelines are advising that the glycated hemoglobin test should be performed at least twice a year in patients with diabetes who are meeting treatment goals and quarterly in patients with diabetes whose therapy has been changed or who are not meeting glycemic goals.

Method

Enzymatic method

Test Principle

ASUREQUAN HbA1c contains the reagents necessary for the determination of glycated hemoglobin in the sample. The sample material is collected with the sampling device before the Cartridge is placed in the cartridge chamber of ASUREQUAN Analyzer. The blood sample is automatically diluted and mixed with buffer and reagents.

$$\text{HbA1c} \xrightarrow{\text{Protease}} \text{Glycated Dipeptide}$$

$$\text{Glycated dipeptide} + O_2 + H_2O \xrightarrow{\text{FPOX}} \text{Glucosone} + \text{Dipeptide} + H_2O_2$$

$$H_2O_2 + \text{Chromogen} \xrightarrow{\text{POD}} \text{Chromogen} + H_2O$$

Enzymatic HbA1c test is an enzymatic assay in which lysed whole blood samples are subjected to protease digestion. This process releases amino acids including glycated dipeptide from the hemoglobin beta chains. Glycated dipeptide serves as substrates for specific fructosyl peptide oxidase (FPOX) enzyme. The FPOX specifically cleaves N-terminal valines and then produces hydrogen peroxide. This is measured using a horseradish peroxidase(POD) catalyzed reaction and a suitable chromogen.

Reagent Composition

ASUREQUAN HbA1c has the following composition.

Component	Quantity/Cartridge
Protease	≥ 320 unit
Peroxidase(horseradish)	≥ 2 unit
Fructosyl-amino acid oxidase	≥ 0.8 unit
Chromogen	≥ 0.002 mg
Buffer, surfactants, excipients, and preservatives	≥ 39.2 mg

Precautions and Careful Handling

1) For *in vitro* diagnostic use only.
2) Do not use Cartridges which have expired or are damaged.
3) **Use Cartridges within 2 months after opening the cartridge tray.**
4) Do not use Cartridges which are frozen or not stored in accordance with recommendations.
5) Do not reuse any part of the Cartridge.
6) Do not drop Cartridges. If any part of the Cartridge is damaged, do not use the damaged Cartridge.
7) Avoid direct sunlight during the storage and measurement.
8) Do not touch or damage an optical reading area of the Cartridge.
9) Use gloves when collecting blood samples or control solution.
10) Never use lancet that has been used by someone else.

⚠ ***Do not eat silica gel and keep away from children.***

☣ ***The used Cartridge, sampling device and control solution may be potentially infectious and should be disposed of immediately after use. Proper disposal methods should be followed according to your local regulations.***

Materials Provided

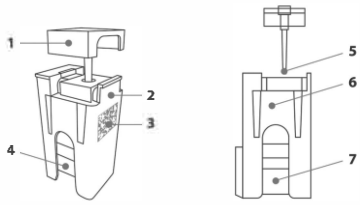
- ASUREQUAN HbA1cs X 25
- Package Insert X 1

Materials required but not provided

- ASUREQUAN Analyzer
- ASUREQUAN Analyzer User Manual (provided with ASUREQUAN Analyzer)
- ASUREQUAN Analyzer Quick Guide (provided with ASUREQUAN Analyzer)
- Control Materials

Description of the Cartridge

A single Cartridge contains all necessary reagents for single test.
The sampling device (1) has a capillary tube tip (5) to be filled with sample material and the reaction container (4) has an optical reading area (7) for absorbance measurement.



1. **Sampling device**: To collect patient sample or control solution.
2. Handle: To grip the Cartridge.
3. Barcode: To contain lot-specific information about the cartridge.
4. Reaction container: Space to be filled with necessary buffer for one test.
5. **Capillary tube tip**: Area to be filled with patient sample or control solution.
6. ID memo area: Space for writing down sample identification.
7. Optical reading area: Area for absorbance measurement.

Storage and Stability

1) The Cartridge is stable until the expiry date shown on the cartridge when stored in the refrigerator at **2~8°C (36~46°F)**. The expiry date is also encoded in the barcode printed on the Cartridge. An error code will appear on the screen of ASUREQUAN Analyzer if the Cartridge has expired.
2) Do not freeze.

Testing at operating temperature

1) The Cartridge must reach an operating temperature of **18~32°C (64~89°F)** before use. Upon removal from refrigerated storage, leave the Cartridge at the room temperature for at least 30 minutes to reach the operating temperature.
2) It is recommended to test at **20~25°C (68~77°F)** for accurate test results.

Sample Type and Volume

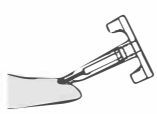
1) The following sample materials can be used with ASUREQUAN HbA1c.
   Capillary whole blood, Venous whole blood with anticoagulants,
   Control solution
2) Required sample volume: **4uL**

You may get wrong results if the sample is excessively hemolyzed, coagulated, or turbid.

Sample Collection

Sampling from finger blood

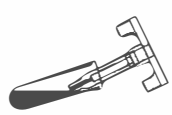
1) Use gloves when collecting blood samples.
2) Gently massage a finger, clean the site with an alcohol swab, and dry thoroughly.
3) Firmly prick the selected site with a lancet and a lancing device. Properly dispose of the used lancet.
4) Squeeze the finger gently to obtain the first drop of blood. **Wipe away this first drop of blood as it may contain tissue fluid.**
5) **Squeeze the finger gently again to get the second drop of blood.**
6) Hold the capillary tube tip horizontally or at a slightly descending angle. Put it to the drop of blood without touching the skin. The capillary tube will be filled automatically.



Remove an excess of the sample on the outside of the capillary tube without touching the hole of capillary tube tip.

Sampling from a tube

1) Allow the sample material in a tube to reach ambient operating temperature before use, which takes approximately 30 minutes.
2) Mix the sample material well by inverting the tube before collecting a sample.
3) Hold the capillary tube tip at a slightly descending angle. Put it to the surface of sample material in the tube. The capillary tube will be filled automatically.



Remove an excess of the sample on the outside of the capillary tube without touching the hole of capillary tube tip.

NOTE

- Bring the capillary tube tip just beneath the surface of blood drop or control solution.
- Make sure that patient sample or control solution is completely filled.

You may get wrong result if excessive or insufficient blood is collected. Avoid air bubble.

(A) Correct (O) (B) Excessive sample (X) (C) Insufficient sample (X) (D) Air bubble (X)

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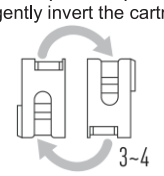
Test Procedure

For more information on operation, see ASUREQUAN Analyzer User Manual.

1) Leave Cartridges at the room temperature for at least **30 minutes** to reach the operating temperature after taking out the Cartridges from the refrigerator. It is recommended to test at **20~25°C (68~77°F)** for accurate test results.
2) Before collecting samples, gently invert the cartridge 3~4 times.



3) Collect a sample. Once the capillary tube tip is filled, immediately insert the sampling device into the cartridge body.
4) Place the Cartridges into the cartridge chamber of the Analyzer and close the lid manually and then touch "Start" button within 20 seconds. The measuring time is approximately 7 minutes.
   Do not open the lid during the analysis.
5) Record the test results according to the laboratory guidelines. The results will be saved in the memory of the Analyzer and can be printed if necessary.
6) Take out the used Cartridges immediately from the Analyzer.
7) Keep the lid closed when the Analyzer is not in use.

Interpretation of Test Result

For diagnostic purposes, each individual test result should be interpreted with other data such as the patient's medical history, other clinical examinations, clinical observations and other laboratory results. If the test result is questionable or if clinical signs and symptoms appear different from the test result, test the ASUREQUAN System with control material for re-test.

Calibration

No calibration is required for users. Each lot of Cartridge is calibrated by the Manufacturer prior to shipment. The barcode printed on the Cartridge provides the Analyzer with lot-specific calibration information.

Quality Control

Control solution test is required to check if the ASUREQUAN System is working properly.
As long as the control solution test results fall within the known acceptable range provided by the control material manufacturer, the ASUREQUAN System is considered working properly. If your local regulations require specific quality control practices, follow the regulations. See ASUREQUAN Analyzer User Manual for procedures on how to run control solution testing.

Recommended Control Materials

Control materials recommended by the Manufacturer should be used for quality control of your ASUREQUAN Analyzer. Contact your local supplier for the recommended control materials.

Measurement Range

4.0~15.0 % (20~140 mmol/mol)

NOTE

There may be abnormal reactions with non-target substances or other reaction with interfering substances.
If measured results seem unreliable, repeat the measurement or try other type of analysis.

Limitations of the Test

- ASUREQUAN System is only for in vitro diagnostic use by healthcare professionals.
- Do not analyze diluted samples.
- Do not analyze hemolyzed or coagulated samples.
- Do not use cold or frozen Cartridges.
- Do not analyze the sample that has a hemoglobin value below 7.0 g/dL or above 20.0 g/dL.
- Interference

No significant interference (<8%) was found up to the following concentrations.

Substance	Concentration
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Heparin	500 IU/dL
Salicylate	60 mg/dL

Expected Values

The American Diabetes Association's (ADA's) 2023 Clinical Practice guidelines for diagnosing diabetes are as follows:

% HbA1c	Interpretation of results
< 5.7%	Non-Diabetes range
5.7 - 6.4%	Prediabetes range
≥ 6.5%	Diabetes range

Note: The American Diabetes Association's Diabetes Care 2023;46(Suppl.1):S19-S40

IFCC Standardization

The relationship between HbA1c results from the NGSP network and those from IFCC network has been evaluated and a master equation has been developed. IFCC results are consistently 1.5-2% HbA1c lower throughout the range of values compared to NGSP results.

IFCC value = [1.093 x NGSP value] – 2.350

As of 1st October 2008, all IFCC Network Laboratories are reporting their IFCC HbA1c results in mmol/mol. When HbA1c results are expressed in NGSP HbA1c (%), the equation for IFCC HbA1c (mmol/mol) is as follows.

IFCC HbA1c (mmol/mol) = [10.93 x NGSP HbA1c (%)] – 23.50

Performance Characteristics

Clinical Correlation

The system accuracy evaluation was performed with 126 capillary whole blood samples and 126 fresh venous whole blood samples respectively. Each sample was measured by ASUREQUAN Analyzers and Tosoh G11 instrument for comparison.

Sample Type	Capillary blood	Venous blood
N	126	126
Regression Line	y = 0.9879x + 0.0858	y = 0.9916x + 0.0569
Slope	0.9879	0.9916
Y-intercept	0.0858	0.0569
Correlation Coefficient (R^2)	0.9900	0.9887

Precision

Level	Precision		
	Mean(%)	SD(%)	%CV
Low	5.1	0.14	2.7
High	9.8	0.21	2.1

Linearity

R^2 > 0.98 3 Lot test at the HbA1c concentration range 4.0~15.0%

Symbol

Symbol	Description
CE	Conformity to the European directive 98/79/EC on in vitro diagnostic medical devices
LOT	Lot number
REF	Catalogue number
Rev.	Revision letter or number
	Use-by date (Year-month)
	Storage temperature
	Manufacturer
	Date of manufacture
EC REP	Authorized representative within the European Community
	Keep the product away from sunlight and heat
	Warnings and cautions
	Instructions for use
	Do not reuse
	Biological risks
	Handle with care
	Product or container should be oriented in the direction of the arrows

Reference

1. J. Jeppsson, "Approved IFCC Reference Method for the Measurement of HbA1c in Human Blood," Clinical Chemistry and Laboratory Medicine 40(1) (2002): 78-89.
2. Clinical and Laboratory Standards Institute (CLSI), Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline–3rd Edition, (Wayne, PA, 2008). CLSI document C28-A3.
3. D. S. Young and R. B. Friedman, Effects of Disease on Clinical Laboratory Tests, 4th Edition (Washington, D.C.:AACC Press, 2001).
4. Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS), Protocols for Determination of Limits of Detection and Limits of Quantitation, Approved Guideline (Wayne, PA, 2004). NCCLS document EP17-A.
5. The Diabetes Control and Complications Trial Research Group, N.Engl. J.Med. 329: 977-86 (1993)
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7. Hoelzel W et al. IFCC reference system for measurement of hemoglobin A1c in human blood and the national standardization schemes in the United States, Japan and Sweden: a method-comparison study. ClinChem 2004;50:166-74

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