

respons[®] A1c

HEMOGLOBIN A1C TEST KIT

Read this entire insert thoroughly before using the respons[®] A1c Hemoglobin A1c Test Kit with the respons[®] A1c analyzer. Keep this insert for future reference. If you have any inquiry or question, please contact your local distributor.

Product description

Intended Use

The respons[®] A1c Hemoglobin A1c Test Kit is intended for the quantitative determination of glycated hemoglobin (hemoglobin A1c, HbA1c) in human blood. It also provides the estimated average glucose (eAG) value, in addition to the glycated hemoglobin result, allowing for easier diabetes care.

Test Principle

The respons[®] A1c Hemoglobin A1c Test Kit is a fully automated boronate affinity assay for the determination of hemoglobin A1c in human whole blood. The respons[®] A1c Hemoglobin A1c Test Kit is composing of a cassette and a reagent pack. The reagent pack contains reaction solution and washing solution for the determination of the HbA1c concentration. The reaction solution contains reagent that lyse erythrocytes and boronate reagents that bind cis diol of glycated hemoglobin. After opening the analyzer cover, insert the cassette of the respons[®] A1c Hemoglobin A1c

Test Kit into the analyzers' holder. Collect blood sample with the blood sampling area at the end of the reagent pack, and insert the reagent pack into the cassette. When the reagent pack is inserted into the cassette, the sealed part on both sides of the reagent pack is released. The user closes the cover of the analyzer. The analyzer automatically starts the measurement operation. The result is displayed on the screen when the measurement is completed. The percent HbA1c in the sample is calculated as follow

$$\text{HbA1c \%} = \frac{\text{Glycated Hemoglobin}}{\text{Total Hemoglobin}} \times 100$$

Kit Contents (per 10 tests unit)

- 10 Cassettes packaged separately in foil pouches with a reagent pack
- 1 Insert Paper

Reagent Composition

1. Reagent: CM sepharose fast flow (Resin), Aminophenylboronic acid, HEPES buffer.
2. Washing Solution: HEPES buffer.

How to use

Sample material

The following sample materials can be used with respons[®] A1c Hemoglobin A1c Test Kit.

- Capillary blood (from finger prick)
- Venous whole blood with anticoagulants (K2-EDTA)

Sample storage

- Venous whole blood with anticoagulants (K2-EDTA) can be stored refrigerated (2-8°C) for 7 days.

Preparing for analysis

- The respons[®] A1c Hemoglobin A1c Test Kit must reach an operating temperature before use.
- Open the foil pouch just before use.

Caution

- Do not use scissors to cut open foil pouch.
- Do not touch the Cassette optical reading area.

Sample Collecting and handling

1. Capillary blood
 - Make sure that the finger is clean, warm and dry.
 - Use a suitable lancet to prick the finger.
 - Allow to form a good drop of blood before sampling.
 - Bring the tip of reagent pack sampling area just beneath the surface of the patient blood sample. The blood is automatically drawn up.
 - Avoid air bubbles and excess sample on outside of the reagent pack sampling area.
 - The Test Kit should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with local or national regulations.

Caution

- Do not wipe off the sampling area.

2. Venous blood

- Allow blood samples to reach room temperature.
- Anti-coagulated blood should be mixed well prior to testing.
- Take out a drop of blood sample on a clean and suitable surface.
- Bring the tip of reagent pack sampling area just beneath the surface of the venous blood sample. The blood is automatically filled.
- Wait until the sampling area is completely filled.

Preparation before use

1. Power on

Connect the DC 12V power adapter to a grounded outlet, connect the power plug to the power port on the back side of analyzer, and check the operation. After the analyzer turns on, the main screen is displayed.

During the initialization screen display, it performs operations such as setting the data and setting values, setting the instrument and heating the heater temperature. After the initialization, Standby mode is displayed.

2. Preparation of Test Kit

Open the foil pouch just before use, and separate a cassette and a reagent pack.

Note

- Allow the test kit and analyzer to reach room temperature 30 minutes before use.

3. Test Procedure

- ① To measure HbA1c, press the cover button of the analyzer.
- ② Insert the cassette into the cassette holder of the analyzer, when "Insert the test cassette" message is displayed. Please insert the cassette at a stroke.
- ③ Shake the reagent pack well 180 degree to mix the reagent pack.
- ④ Apply the blood sample at the sampling collecting area of reagent pack.
- ⑤ Insert the reagent pack into cassette which is placed in the cassette holder of the analyzer.
- ⑥ After the reagent pack is normally inserted, the "Close the cover" indication is displayed. The test starts automatically once the cover is closed.
- ⑦ The rest of test time is displayed if the cover is closed.
- ⑧ After the test is done, the result value is displayed. Confirm the result value, press "OK" button.
- ⑨ Open the cover to remove the test cassette.
- ⑩ Take out the test cassette from the analyzer cassette holder by pulling out.

Test Characteristics

Measuring range

	IFCC	NGSP	eAG	
Unit	mmol/mol	%	mg/dL	mmol/L
Measuring range	20.0 - 140.0	4.0 - 15.0	68 - 384	3.8 - 21.3

Managing HbA1c

	NGSP, A1c %	IFCC, mmol/mol
Pre-diabetes	5.7~6.4	39~46
Diabetes	≥ 6.5%	≥ 48
Diabetic patient care goals	< 7.0%	< 53

Source: American Diabetes Association Clinical Practice Recommendation (2010.01)

IFCC: International Federation of Clinical Chemistry

NGSP: National Glycohemoglobin Standardization Program

HbA1c measuring units

Three different measuring units are in use for reporting HbA1c test results.

- mmol/mol: The HbA1c values are aligned to the IFCC reference method for measurements of HbA1c.
- Percentage (%): The HbA1c values are aligned to the assay used in the DCCT study, also known as NGSP-HbA1c.
- eAG (estimated average glucose): The HbA1c is converted to an equivalent average glucose value.

Performance

Accuracy

This is measured by Tosoh HLC-723 Ghb G7 as reference equipment with respons[®] A1c Hemoglobin A1c Test Kit

	Acceptance ratio
Within ± 3%	50 % (20/40)
Within ± 6%	92.5 % (37/40)
Within ± 10%	100 % (40/40)

Precision

Within Run Precision

HbA1c	5.7 %	9.3 %
Mean(%)	5.5	8.9
STD(%)	0.1	0.2
CV(%)	2.4	1.9

Day to day Precision

HbA1c	5.7 %	9.3 %
Mean(%)	5.4	9.0
STD(%)	0.1	0.2
CV(%)	2.6	1.9

Limitations

- Analyzer should be located on the flat table.
- Do not move the analyzer during operation.
- Operation temperature and humidity.
Temperature Range: 17~32°C
Humidity Range: 15~75% RH
- The reagent must be stored in the designated temperature range (2~30°C). If the reagents are stored in the temperature out of the designated temperature range(2~30°C), the test result can be inaccurate.
- Keep in mind the test kit storage temperature and the analyzer operating temperature.
- Allow the test kit and analyzer to reach room temperature 30 minutes before use.
- When user collects sample (blood, control) using the reagent pack sampling area, bring the tip of reagent pack sampling area just beneath the surface of the blood sample.

- Gently mix the Reagent Pack before testing, and visually check that the beads are not coagulated.
- After the reagent pack is inserted, the "Close the cover" indication is displayed. And then cover should be closed immediately.
- Be careful not to make fingerprints on optical reading area of cassette.

Note

- Do not reuse test kit.
- Do not use serum or plasma.













Interference substances

1. The venous blood collected with an anticoagulant using aseptic technique is available for testing.
2. The Hematocrit lower 25% or higher than 60% can cause inaccurate test results.
3. The test results are not affected by albumin, ascorbic acid, bilirubin, glucose, lipid.
4. The respons[®] A1c system is not affected by HbD, HbE and Elevated HbF of hemoglobin variants. But, HbS and HbC of hemoglobin variants may affect the respons[®] A1c System.

Storage and expiry

Product	Storage condition	Expiration date	Note
respons [®] A1c Hemoglobin A1c Test Kit	2-30 °C	18 months from the date of manufacture	Disposable

Symbol information

	In vitro diagnostic medical device
	Batch code
	Catalogue number
	Temperature limit
	Use-by date
	Caution, consult accompanying documents
	Consult instructions for use
	Manufacturer
	Date of manufacture
	Do not re-use
	Authorized representative in the European community
	This product fulfills the requirements for directive on in vitro diagnostic medical devices.



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