

FORA[®] A1c pro

Hemoglobin A1c Test Cartridge Cartridge Instruction

INTENDED USE

The FORA Hemoglobin A1c Test Cartridge provides a simple, convenient and quantitative method for measuring the percent of glycated hemoglobin (HbA1c %) levels in capillary (fingertip) or venous whole blood samples. The measurement of hemoglobin A1c concentration is recommended for monitoring the average blood glucose levels in the past three months, for the long-term care of people with diabetes. The test is for professional use in the physician office laboratories and diabetes clinics to monitor metabolic control in people with diabetes. It's not recommended for neonatal use.

PRINCIPLE OF THE PROCEDURE

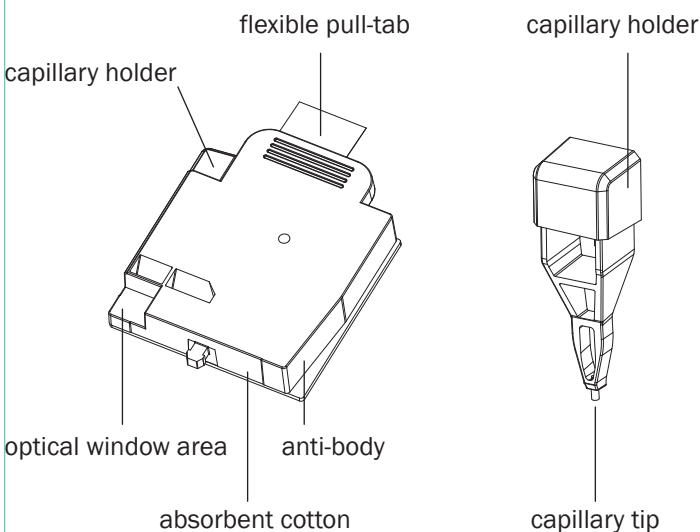
This reagent utilizes antigen-antibody reaction to directly determine the glycated hemoglobin in the blood, the reagent contains the primary antibody in glycated hemoglobin will react with glycated hemoglobin in the blood, this synthetic agglutinator will be in conjunction with the secondary antibody to form aggregation. The synthetic agglutinator will vary with different glycated hemoglobin levels to calculate the blood levels of glycated hemoglobin by measuring the absorbance of the reaction solution.

The ratio of glycated hemoglobin with respect to total Hemoglobin in the blood sample is calculated as %A1C ($A1C \div \text{total Hb} \times 100$).

REAGENTS

FORA A1c pro reagent kit containing:

- Test cartridge
- Capillary holder
- Desiccant bag
- Owner's booklet
- Calibration card



Reagent Components

- Latex: 0.13%
- Antibody: Mouse anti-human HbA1c antibody 0.05 mg/mL
Goat anti-mouse IgG polyclonal antibody 0.08 mg/dL
- Non-reactive ingredient: buffer, stabilizers

Warnings and Precautions

- For in vitro diagnostic use.
- The FORA Hemoglobin A1c test cartridge is intended for use with the FORA A1c pro Hemoglobin A1c Analyzer only.
- The FORA Hemoglobin A1c test cartridge is not recommended for use under such condition: alcoholism, opiate addiction, lead-poisoning and ingest large doses of aspirin.
- Do not use test cartridges after the expiry date or if the test cartridges have not been stored in accordance with recommendations.
- Do not use the test cartridge if the foil pouch, the test cartridge or capillary tip itself has been damaged.
- Avoid dropping the cartridge or hitting it with a hard object, and never try to bend it.
- Avoid dropping the capillary holder, if it happens and may be damaged, discard it and replace with a new one.
- Each foil pouch contains a desiccant bag. This material shall not be used in the test. Discard the desiccant bag in a suitable container. Do not swallow.
- Do not use the test cartridge if the desiccant bag is damaged and desiccant particles are found on the test cartridge. Do not wipe off.
- Always wear gloves when performing tests.
- Do not touch the test cartridge optical window area.
- For single use only. Do not re-use any part of the test cartridge.

Reagent Storage Requirements

- The reagent cartridges can be stored :
in refrigerator (2 °C to 8 °C ; 35.6 °F to 46.4 °F) for 12 months or in room (8 °C to 25 °C ; 46.4 °F to 77 °F) for 3 months.
- When opened, record the opened date on each box. If stored refrigerated, reagent cartridges can be used until the expiration date.
- Operate reagent cartridges at 15 °C to 32 °C (59 °F to 89.6 °F) in room temperature.
- Unopened cartridges may be kept in refrigerator for up to 12 months, but not beyond the printed expiration date on each box.

TESTING PROCEDURE

Import the lot information for each new box of cartridge by calibration card

1. Press "Enter" to select cal card mode.
2. Open the cover and insert the calibration card.

⚠ NOTE

- Do not insert any other metal into the cartridge compartment together with the calibration card.
- Insert the calibration card and lean the card against the left side.

3. Check the cartridge lot number.
4. Press "Confirm" to save the lot information.

⚠ NOTE

To cancel the data importation, press "Cancel". Then the system will return to the main page.

5. The analyzer will return to the main page automatically.

Opening the Foil Package

1. Remove one foil package (containing a reagent cartridge) from refrigerated storage.
2. Upon removal from refrigerated storage, allow the reagent cartridge to warm up at room temperature for 15 minutes (take an individual unopened foil pouch out from the white box).
3. Open the foil package.

⚠ CAUTION!

Do not use scissors to cut open the foil package. Scissors can damage the reagent cartridge, the flexible plastic pull - tab on the cartridge, or the desiccant bag.

4. Remove the reagent cartridge from the foil pouch.

⚠ CAUTION!

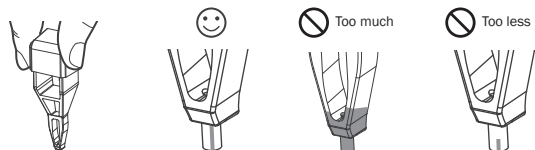
- When handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur.
- After opening the foil package, below 60% relative humidity, the reagent cartridge must be used within 1 hour.

Preparing Patient Samples

1. Clean the finger stick with alcohol swab and let it dry.
2. Prick the finger stick with lancing device.
3. Gently squeeze the finger to assist the flow of blood.
4. Pull up the capillary from the cartridge.
5. Hold the capillary holder at an angle.
6. Touch only the tip of the capillary to the blood drop. Blood will automatically flow into the capillary.

⚠ CAUTION!

Too more or less amount of blood, erroneous test results may occur.



If blood contacts the plastic part of the capillary holder, discard the holder and use another one.

7. Less than 0.2 µL of blood is required to fill the capillary.

⚠ CAUTION!

When the capillary is filled with the sample, analysis must begin within 1 minute. (avoidance of blood dry).

Inserting Capillary Holder into Reagent Cartridge

Carefully insert the capillary holder into the reagent cartridge until the holder gently snaps into place (will hear a click).

⚠ CAUTION!

Avoid harsh insertion of the capillary holder. Do not dislodge the sample from the glass capillary or erroneous results may occur.

NOTE

If the reagent cartridge is damaged or the flexible pull-tab is loose or missing, please discard it and replace with a new one.

1. Inserting the Reagent Cartridge into the System

⚠ CAUTION!

Do not pull the tab, before you insert the reagent cartridge into the cartridge compartment or erroneous results may occur.

2. Hold the reagent cartridge so that the label faces to the left.

NOTE

The cartridge is designed to fit only one way into the system. Do not force the cartridge into system.

3. Insert the reagent cartridge into the cartridge compartment until a gentle snap is heard or felt.

4. Using a smooth, slow, continuous motion, pull the flexible pull - tab completely out of the reagent cartridge, and then **close the cover immediately.**

5. Start measuring. Reaction is completed in 6 minutes.

6. Read percent HbA1c before removing the cartridge.

- The range of the instrument is 4.0% to 16.0% (20 mmol/mol to 151 mmol/mol)
- Results preceded by a < sign indicates a level below the range and a > indicates a level above the range, and should be recorded automatically as such.

7. Remove the cartridge by pushing down the reagent cartridge down until a gentle snap is heard or felt, then pull the reagent cartridge out of the compartment. Discard the cartridge in a proper container, according to your standard laboratory procedures.

DISPOSAL

The used test cartridges, sampling equipment, patient samples and controls are potentially infectious and should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with local regulations.

ACCURACY

Standard: Ion-exchange HPLC testing method. Bias Criteria: compare with standard results within ± 6%

PRECISION

CV ≤ 5%

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Batch code
	Do not reuse		Manufacturer
	Consult instructions for use		Serial number
	Temperature limitation		Use by
	Authorized representative in the European Community		

SPECIFICATION

Model no.: TD-4601

Dimensions & Weight: 73.3 (L) x 58.2 (W) x 12.6 (H) mm, 25g

Sample type: Whole blood - Fingertips capillary or EDTA venous blood

Sample Volume: ≤ 0.2 µL

Reaction Time: ≤ 6 minutes

Operation conditions: 15 °C to 32 °C (59 °F to 89.6 °F)

Storage conditions:

2 °C - 8 °C (35.6 °F - 46.4 °F) for refrigerator temperature;

8 °C - 25 °C (46.4 °F - 77 °F) for room temperature

This device has been tested to meet the electrical and safety requirements of:

IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

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