Finecare™ HbA1c Rapid Quantitative Test

Catalog No. W207

INTENDED USE

The Finecare™ HbA1c Rapid Quantitative Test along with Finecare™ FIA Meter is intended for vitro quantitative determination of HbA1c in human blood.
-Fluorescence immunoassay
-Diabetics monitoring

For in vitro diagnostic use only.For professional use only.

SUMMARY

Glycated hemoglobin(HbA1c) is a glycated form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. It is formed by the attachment of glucose residue in blood to hemoglobin molecule. The level of glucose is proportional to the amount of glycated hemoglobin. As the average amount of plasma glucose increases, the fraction of glycated hemoglobin increases in a predictable way. This serves as a marker for average blood glucose levels over the previous months prior to the measurement.

Normal Reference Value: < 6.5%
Note: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ HbA1c Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ HbA1c Rapid Quantitative Test uses a sandwich immunodetection method to measure percentage of HbA1c in human blood. After mixing with sample and buffer, sample mixture is added to the sample well of the Test Cartridge, the fluorescence-labeled detector HbA1c antibody binds to HbA1c in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and HbA1c are captured to HbA1c antibody that has been immobilized on test strip. The fluorescence-labeled detector Hb antibody binds to Hb in blood specimen; the complexes are captured to Hb antibody that has been immobilized on test strip. Signal intensity of fluorescence is proportional to concentrations of HbA1c and Hb in blood specimen. The ratio between inflorescent signals of HbA1c and Hb is the ratio between HbA1c and Hb.

PRECAUTIONS

1. Whole blood is only applicable for this test kit. Do not repeat using test kit, do not use test kit beyond the expiration date.
2. Appropriate protective measures should be applied during the process of collection, disposal, storage and sample mixing
3. Do not mix components(buffer, ID chip and Test Cartridge) from different kit lots. Their lot numbers must match each other.
4. The Finecare™ HbA1c Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter.
5. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
6. Test Cartridge contaminated by blood or other liquid must not be inserted into FIA meter, or the meter might be contaminated or damage. Please appropriate dispose used Test Cartridge.
7. High working temperature should be avoided; Test Cartridge stored in low temperature should be recovered to room temperature.
8. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal. Please do not pull out ID chip during testing.
9. Use of fresh blood specimen is recommended, please do not use sample with obvious appearance of hemolysis or blood clot, which might interfere test causing wrong result.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
11. If there is any problem or suggestion please contact manufacture.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25

Leaflet with instructions for use

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (10μL, 100μL size)
3. Specimen Collection Containers
4. Sterile Lancets (for Fingerstick Whole Blood only)
5. Alcohol Pads
6. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ HbA1c Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 24 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with whole blood only.

For Whole Blood Collected by Fingerstick:
1. Usually the lateral side of the ring finger is used to puncture. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
2. Using a sterile lancet to puncture the skin just off the centre of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile swab. Allow a new drop of blood to form. If blood flow is inadequate, the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid 'milking' the finger.
3. Blood is collected into the transfer pipette following the standard procedure.

Whole Blood samples collected by fingerstick should be used immediately after collection.

For Whole Blood Collected by Venipuncture:
1. All blood specimens must be restored to room temperature (25℃), and ensured integrated components and proportion (proportion of serum and red blood cell).
2. Fresh blood must be performing test within 24 hours after collection.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be in room temperature.
Step1: Preparation
Check/insert ID Chip into the instrument.
Step2: Sampling
Draw 10 μL of whole blood with a transfer pipette and add it to the buffer tube.
Step3: Mixing
Mix well the specimen with buffer for 1minute by tapping or inverting the tube.
Step4: Loading
Take 75 μL of sample mixture and load it onto the sample well of the Test Cartridge.
Step5:Testing
1. Finecare™ FIA meter:
Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Test". 5 minutes later, the result will show in the display and print out when click "Print".
Quick test: Put the Test Cartridge on the operation platform. 5 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Test". The result will show in the display and print out when click "Print".
2. Finecare™ multi-channel FIA meter:
Insert the Test Cartridge onto the Test Cartridge Holder. 5 minutes later, the result will show in the display and print out when click "Print".

Please refer to the **Operation** in user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ HbA1c Rapid Quantitative Test Cartridge contains internal control that satisfies routing quality control requirements. This internal control is

performed each time a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood only.
2. The results of Finecare™ HbA1c Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If HbA1c test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated HbA1c that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
5. Other factors may interfere with Finecare™ HbA1c Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

Test Cartridges from same batch were tested with HbA1c control of 5%, 10% and 14%, mean and Bias% were calculated, Bias% was within 10%.

AssayRange and Detection Limit

•**Assay Range:** 4.0~14.5%
•**Detection Limit:** 4%

Linearity

A serial concentration of HbA1c controls of 5%, 8%, 10%, 12% and 14% were tested respectively, the Correlation Coefficient (R) is ≥ 0.99.

Precision

Intra-Run
Within-run precision has been determined by using 10 replicates from same batch to test with 8%HbA1c control. C.V. is ≤ 6%.

Inter-Run
Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with 8%HbA1c control. C.V. is ≤ 10%.

BIBLIOGRAPHY OF SUGGESTED READING

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