Diagnostic Kit for HbA1c

A test for measuring HbA1c value in whole blood with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

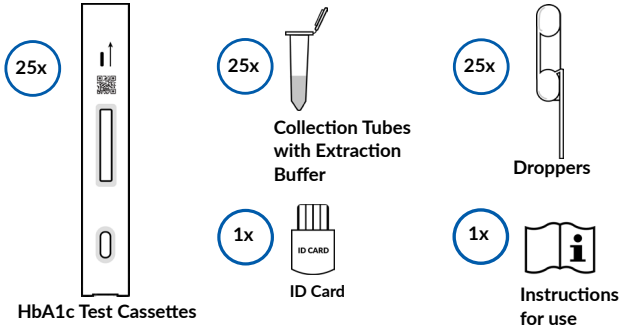
PACKING SPECIFICATION
25 Tests/ Kit (07HBA5025)

INTENDED USE
The HbA1c Test Cassette (Whole Blood) is based on Fluorescence immunoassay for the quantitative detection of HbA1c in human whole blood.The measure of HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus. This test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. The test is intended for healthcare professionals use.

SUMMARY
The human erythrocyte is freely permeable to glucose. Within each erythrocyte a slow, continuous, non-enzymatic process between hemoglobin A and various sugars takes place. The product formed is known as glycated hemoglobin, or glycohemoglobin[1].
The chronic elevated blood sugar level of persons with diabetes mellitus will over time cause damage to the small vessels of the body. This damage develops slowly over years and is known to cause late complications. Good metabolic control, i.e. lowering the HbA1c concentration, has proven to delay the onset and slow the progression of diabeteslate complications[2,3,4].
It is concluded that measurements of HbA1c can be used to diagnose diabetes mellitus. When in agreement with national regulations, HbA1c Test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabete.

PRINCIPLE
The HbA1c Test Cassette (Whole Blood) detects HbA1c based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. HbA1c in the sample, attaches to the HbA1c antibody which is conjugated with fluorescent microspheres. Then captured by hemoglobin (Hb) antibody coated on the nitrocellulose membrane.The concentration of HbA1c in the sample correlates linearly with the fluorescence signal intensity. According to the two fluorescence intensity, Immunofluorescence Analyzer could calculate the value of HbA1c percentage in the sample.

REAGENTS
The test includes HbA1c antibody coated fluorophores, Rabbit IgG coated fluorphoers, Hb antibody and Goat anti Rabbit IgG coated on the membrane.

MATERIALS PROVIDED


MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Timer

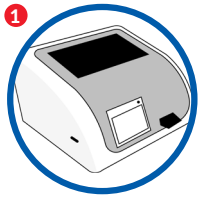
PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The HbA1c Test Cassette should only be used with the Analyzer by approved medical professionals.

STORAGE AND STABILITY
1. The kit should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

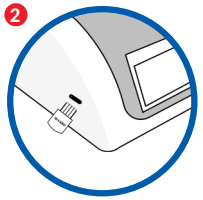
SAMPLE COLLECTION AND PREPARATION
Blood Sample Taking
1. Collect the specimen according to standard procedures.
2. To collect Fingerstick Whole Blood specimens:
   - Wash the patient's hand with soap and warm water or clean with an alcohol pad. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
   - Add the fingerstick whole blood specimen to the buffer tube by using a dropper or a pipette.
3. Do not leave specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2 - 8 °C if the test is to be run within half-day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
4. Bring specimens to room temperature prior to testing.
5. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

Sample Dilution / Sample Stability
1. The specimen (10 µL of whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample rest for approximately **5 minutes**.
4. It is recomended to test the diluted sample immediately.

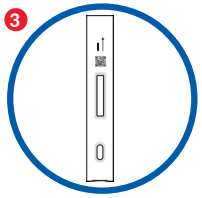
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



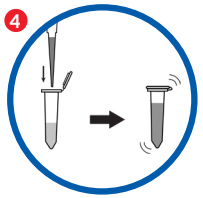
Turn on the Analyzer power.



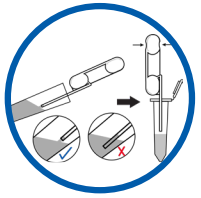
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch. Place the test on a flat and clean surface.



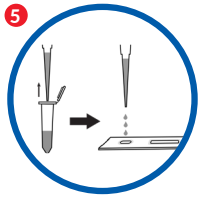
Use a pipette: Transfer **10 µL of whole blood** into the buffer tube with pipette; mix the specimen and the buffer throughly.



Use a dropper: Without squeezing the dropper, put the glass capillary tube end incontact with the liquid sample surface tilted. Liquid sample will migrate into thecapillary tube automatically.

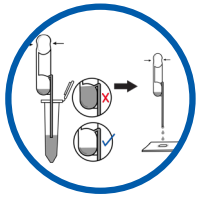
Note: Make sure do not take the plastic part of thedropper in contact with the sample.

Then release the sample into the buffer tube by squeezing the bulb at the top end of the dropper vertically. Wash the tube 2 - 3 times by squeezing the top bulb. Mix the sample and the buffer well.



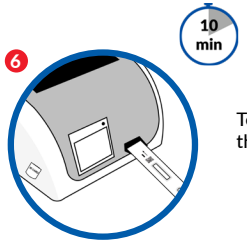
Add diluted specimen to the sample well of the test cassette within 5 - 10 minutes after sample dilution.

Use a Pipette: Pipette **75 µL of diluted specimen** into the sample well of the test cassette. Start the timer at the same time.



Use a dropper: Immerse the tube end (plastic tube) into the diluted sample; squeeze the top bulb to absorb the solution into the lower bulb (no more than the lower bulb).

Squeeze the top bulb vertically to release the diluted solution into the sample well of the test cassette and start the timer.



Test results should be interpreted at **10 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.
The result of tests for HbA1c is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.
Linearity range of HbA1c Test is 4 ~ 14.5%.
Reference range: 4.0 ~ 6.0%.

QUALITY CONTROL

Each HbA1c Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer and indicates that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The HbA1c Test Cassette (Whole Blood) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of HbA1c.
2. The HbA1c Test Cassette (Whole Blood) will only indicate the HbA1c level in the specimen and should not be used as the sole criterion for evaluating Diabetes. Laboratories can have their separate reference values for HbA1c to be under control.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of HbA1c Tests are based on measuring the levels of HbA1c in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

The following cut-off points have been established by the Diabetes Control and Complications Trail Research Group and have been adapted by many countries for the evaluation of the degree blood glucose control in diabetic patients.

Concentrations	Clinical Reference
4 ~ 6%	Non diabetics
6 ~ 6.5%	Goal
6.5 ~ 8%	Good control
>8%	Action suggested

It is recommended that each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the HbA1c results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation ≤±15%

2. Sensitivity
The HbA1c Test Cassette (Whole Blood) can detect levels of HbA1c as low as 4% in whole blood.

3. Detection range
4 ~ 14.5%

4. Linearity range
4 ~ 14.5% , R≥0.990

5. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 specimens containing 5%, 10% of HbA1c. C.V. is ≤ 15%.
Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 5%, 10% of HbA1c. C.V. is ≤15%.

6. Interfering Substances
The following potentially interfering substances were added to 5% and 10% HbA1c specimens, respectively.

Ascorbic Acid: 50 mg/mL	Bilirubin: 200 mg/dL
Glucose: 600 mg/dL	Triglycerides: 1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

7. Method comparison
The HbA1c Test Cassette was compared with the results obtained with Roche for 100 samples. The correlation coefficient (r) is 0.981.

BIBLIOGRAPHY

1. Bunn F et al. The Biosynthesis of Human Hemoglobin A1c. Slow glycosylation of hemoglobin in vivo. J Clin Invest 1976; 57:1652-1659.
2. The Diabetes Control and Complications Trial Research Group, The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329:977-986.
3. Sacks DB et al., Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. ClinChem 2002; 48:436-472.
4. Stratton IM et al., Association of glycemia with macrovascular and microvascular complications of type 2 diabetes: prospective observational study (UKPDS 35). BMJ 2000; 321:405-412.

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
4 °C 30 °C	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
LOT	Lot Number	CE	European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date	Σ	Tests per Kit
UDI	Unique Device Identifier		

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