HbA1c FIA Rapid Test Device

(Whole Blood)

FI2-HBA-001

A rapid test for measuring HbA1c value in whole blood with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The HbA1c FIA Rapid Test Device is based on Fluorescence immunoassay for the quantitative detection of HbA1c in 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.

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 diabetes late complications[2,3,4].

It is concluded that measurements of HbA1c can be used to diagnose diabetes mellitus. When in agreement with national regulations, the Biopanda HbA1c FIA Rapid 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.

PRINCIPLE

The HbA1c FIA Rapid Test Device detects HbA1c based on Fluorescence Immunoassay. The sample moves through the strip from the sample pad to the absorbent pad. HbA1c and hemoglobin (Hb) in the sample, attaches to the HbA1c antibody and Hb antibody which is conjugated with fluorescent microspheres. Then captured by another A1C antibody and Hb antibody coated on the membrane. The concentration of HbA1c and Hb in the sample correlates linearly with the fluorescence signal intensity. According to the two fluorescence intensity, the Biopanda Fluorescence Immunoassay Device calculates the value of HbA1c percentage in the sample.

REAGENTS

The test includes HbA1c antibody coated fluorophores, Hb antibody coated fluorophores, another HbA1c antibody and Hb antibody coated on the membrane.

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. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. 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.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda HbA1c FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device 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. 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.

KIT COMPONENTS

- 25 x foil wrapped HbA1c test cassettes
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (HbA1c)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. 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.
3. Bring specimens to room temperature prior to testing.
4. 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 a 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 best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Device. Then according to the user requirement, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Device port.
3. Follow the appropriate steps below for the chosen specimen type:

For venipuncture whole blood specimens:

i. **Transfer 10 µl of whole blood** into the buffer tube with pipette; mix the specimen and the buffer thoroughly.
ii. **Pipette 75 µl of diluted specimen** into the sample well of the test cassette. Start the timer at the same time.

For finger-prick whole blood specimens:

i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.
ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.
iii. Use a sterile lancet to puncture the skin. Wipe away the first sign of blood.
iv. Gently apply pressure from the palm to the pricked finger so a rounded drop of blood forms over the puncture site.
v. Using the provided capillary dropper and ensuring the dropper is level,

touch the open end to the rounded drop of blood without squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 10 µl), *see Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µl), then add to the specimen well (S) of the test cassette. Start the timer.

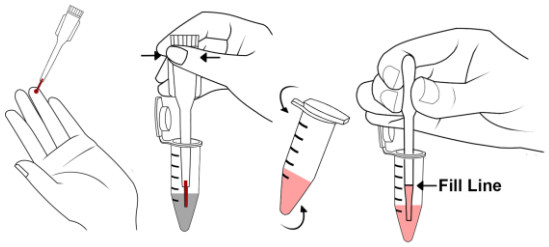

Figure 1

4. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

"Quick test" mode: Insert the test cassette into the Device at **10 minutes** after sample application and click "Test", the Device will automatically give the test result after a few seconds.

"Standard test" mode: Insert the test into the Device immediately after sample application, click "New test" at the same time, the Device will automatically counting down the 10 minutes. After the countdown, the Device will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for HbA1c is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda HbA1c FIA Rapid Test is 4~14.5%.

Reference range: 4.0~6.0%.

QUALITY CONTROL

Each Biopanda HbA1c FIA Rapid Test Device 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 device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. 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 Biopanda HbA1c FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of HbA1c.
2. The Biopanda HbA1c FIA Rapid Test Device 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 the Biopanda HbA1c FIA Rapid Test Device 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 RESULTS

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 of blood glucose control in diabetic patients.

Concentrations	Clinical Reference
4~6%	Normal range/Non diabetics
6~6.5%	Goal for diabetics/Higher risk for getting diabetes
6.5-8%	Good control for diabetics/Diabetes
>8%	Action suggested for diabetics/Diabetes

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 is ≤±15%.
2. **SENSITIVITY**: The Biopanda HbA1c Test Cassette 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: 50mg/dL Bilirubin: 200mg/dL

Glucose: 600mg/dL Triglycerides: 1,600mg/dL

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

REFERENCES

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. Clin Chem 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.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalogue #
4°C 30°C	Store between 4-30°C	LOT	Lot Number		Consult instructions
	Do not use if package is damaged		Manufacturer		

Thank you for purchasing Biopanda's HbA1c FIA Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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