WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

BIBLIOGRAPHY

1. Bunn HF. Non enzyme glycosyl compounds in protein: related to diabetes. 1981,70:331-8.
2. Jovanovic L, Peterson CM. The clinical efficacy of sugar computerized red blood. AM J Med, 1981, 70:331-8.
3. Molnar GD. The management of the metabolism of diabetes in the clinic. Diabetes, 1978, 27:216-25.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	*In vitro* Diagnostic Medical Device	This side up	Use by
Contains sufficient for <n> tests	Catalogue Number	Batch Number / Lot Number	Device

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

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1123/VER-02

FIAcheck™

HbA1c

Fluorescence Immunoassay for Quantitative determination of HbA1c in Human whole blood

DEVICE

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

INTENDED USE

FIAcheck™ HbA1c Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of HbA1c in human Whole blood.

INTRODUCTION

Glycated hemoglobin (GHb) also commonly known as glycosylated hemoglobin, glycohemoglobin, HbA1, HbA1c or A1c is a term used to describe a series of stable minor hemoglobin components formed slowly and non-enzymatically from hemoglobin and glucose. The glycation of hemoglobin can occur at various sites present on the polypeptide chains of the hemoglobin molecule with different carbohydrate (sugar) molecules. The glycohemoglobin is subdivided into subfractions depending on each of the glycation sites and reaction partners involved in glycation. More recently HbA1c is defined as Hb that is irreversibly glycated at one or both N-terminal valines of the β-chain. The remaining GHbs have glucose, glucose-6-phosphate, fructose1, 6-diphosphate, or pyruvic acid bound to one of the 44 additional sites occurring at e-amino group of lysine residues or at the NH_2 terminal of the α-chain. Formation of HbA1c is irreversible and the blood levels depend on both the life span of the red blood cell (average 120 days) and the blood glucose concentration. The rate of formation of HbA1c is directly proportional to the ambient glucose concentration. The amount of HbA1c therefore represents the integrated values of glucose over the preceding six to eight weeks and provides an additional means of assessing glycemic control. The results of HbA1c are not influenced by recent meals, physical activity or emotional stress. Maintaining glycemic levels as close to diabetic range as possible has been demonstrated to have a powerful beneficial impact on diabetes-specific complications, including retinopathy, nephropathy and neuropathy in the setting of type 1 diabetes; in type 2 diabetes, more intensive treatment strategies have likewise been demonstrated to reduce complications. Intensive glycemic management resulting in lower HbA1c levels has also been shown to have a beneficial effect on cardiovascular disease complications in type 1 diabetes.

The measurement of HbA1c in human blood is therefore considered the most important marker for long-term assessment of glycemic state in patients with diabetes, and goals for therapy are set at specific HbA1c target values. The two seminal studies, The Diabetes Control and Complications trial (DCCT) and the United Kingdom Prospective Diabetes study (UKPDS) proved the usefulness of HbA1c measurement in predicting the risk of developing microvascular complications and, as a consequence, have led to the widespread recommendations of its increased use.

PRINCIPLE OF THE TEST

FIAcheck™ HbA1c is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ HbA1c** test device is coated with immobilized HbA1c monoclonal antibody on the test line, sheep anti chicken IgY in control line and a mixture of Hb mouse monoclonal antibody and Chicken IgY labelled with fluorescent microspheres on the binding pad. HbA1c in sample binds to the Hb mouse monoclonal antibody labelled with fluorescent microspheres in the binding pad.

The fluorescent labelled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized HbA1c monoclonal antibody forming a double antibody sandwich and produces the test line.

Chicken IgY labelled with fluorescent microspheres binds with sheep anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

MATERIALS AND COMPONENTS

Materials provided with the test kits:

- **FIAcheck™ HbA1c** test device in a sealed pouch with desiccant.
- QR Code card for calibration.
- Sample Diluent. Ready to use.
- Empty vials for sample dilution.

Materials required but not provided

- Precision pipettes: 5µl, 50-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- **FIAcheck™** Incubator

- Digital Thermometer
- Stopwatch

STORAGE AND STABILITY

1. **FIAcheck™ HbA1c** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.
2. **FIAcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.
4. Once opened, the sample diluent can be stored between 4°C to 30°C for remaining duration of shelf life.

SAMPLE COLLECTION

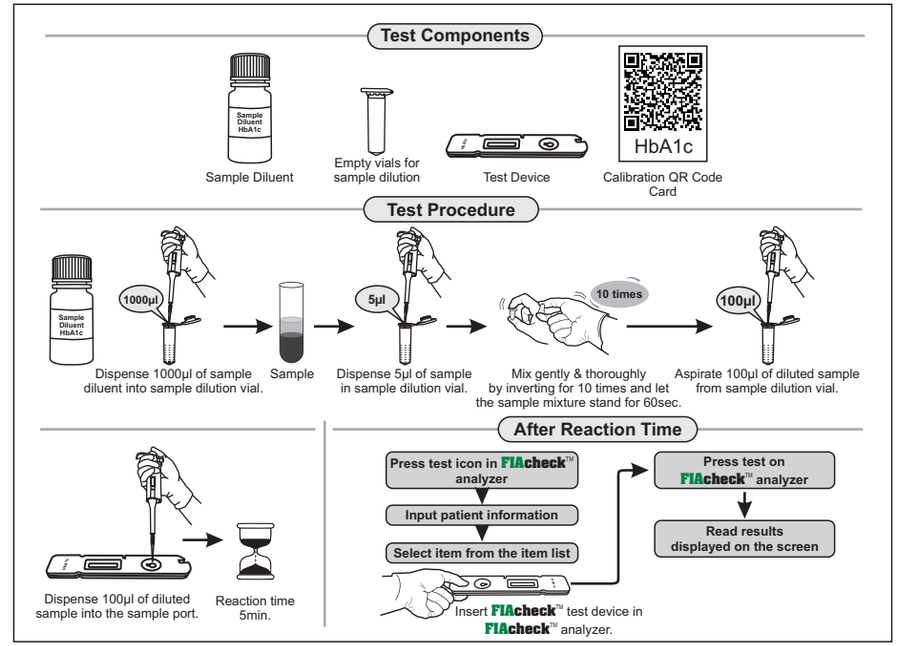
1. Only human whole blood sample should be used. Other bodily fluids and samples may not give accurate result.
2. Whole blood can be anti-coagulated with EDTA under aseptic conditions.
3. The test should be performed within 4 hours after the sample collection at room temperature.
4. Avoid clotted, hemolysed or lipemic whole blood samples.
5. Preferably use fresh samples. However, samples can be stored for 3 days at 2ºC to 8 C, and if more than 3 days, they should be stored at -20ºC.
6. The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect the test values.

PRECAUTIONS

1. Only for In vitro diagnostic use.
2. Bring all reagents and samples to room temperature before use.
3. After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
4. Do not reuse the tested **FIAcheck™** device. Do not use sample dilution vial for more than one sample.
5. Do not use damaged **FIAcheck™** test device or pouch.
6. All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
7. Do not use kit after the expiry date.
8. Do not mix components of one kit with another.
9. Always use new tip for each sample and reagent.
10. Scan QR code card specific to the lot you are using.
11. Ambient temperature of testing environment directly impacts the accuracy of results. For incubation **FIAcheck™** incubator is recommended, refer calibration QR code card for recommended incubation temperature.
12. It is highly recommended to mix the sample diluent and sample mixture thoroughly by gently inverting the vial 10 times. (Refer pictorial presentation.)
13. It is not recommended to use the sample diluent and sample mixture beyond specified time.
14. The **FIAcheck™** test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
15. The **FIAcheck™** test device should be used only in conjunction with **FIAcheck™** analyzer for accurate and reliable results.

TEST PROCEDURE

1. To calibrate the **FIAcheck™ HbA1c** kit, scan the QR code card provided with the kit.
2. Dispense **1000** µl of sample diluent into the empty sample dilution vial.
3. Add **5**µl of the test sample into this sample diluent & mix by rinsing the tip 3 times.
4. Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times. Let it stand for 60 seconds. (See pictorial representation).
5. Remove **FIAcheck™ HbA1c** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
6. Dispense 100 µl of the above mixture at the sample port in the **FIAcheck™ HbA1c** test device.
7. Incubate in **FIAcheck™** incubator for **5 minutes** refer calibration QR code card for recommended incubation temperature.
8. After 5 minutes, insert the test device immediately into the **FIAcheck™** analyzer and read results.



Expected Range
Reference Range: 4%-6.5%
HbA1c concentration is determined using samples obtained from 180 apparently healthy individuals.
It is recommended that each laboratory establish its own reference range for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range: 3%-14%.
2. Lower Detection Limit: ≤3%.
3. Upper Detection Limit: ::≥14%.
4. Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, and the correlation coefficient of r≥0.990 was observed.
5. Within-Run Precision: ≤15%.
6. Between-Run Precision: ≤15%.
7. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
8. In an internal Study, **FIAcheck™ HbA1c** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIAcheck™ HbA1c** has demonstrated 100% clinical correlation with the commercially available licensed kit.

HbA1c Levels	No. of samples	FIAcheck™ HbA1c	Reference method
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIAcheck™ HbA1c** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIAcheck™ HbA1c** has demonstrated 100% correlation with the reference method.
*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

LIMITATIONS OF THE ASSAY

1. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This kit is only for human whole blood.