HbA1c-CHECK-1

Quantitative determination of glycated haemoglobin in whole blood samples

- FOR EASY READER® AND EASY READER+® USE ONLY -

Ref. 96091

I.PRINCIPLE

Glycated haemoglobin (HbA1c) is formed in a non enzymatic reaction by haemoglobin's exposure to plasma glucose (1). The attachment of the glucose occurs continually over the entire lifespan of the red cell (average 100-120 days) and is directly proportional to the concentration of glucose in blood (2, 3).
The HbA1c level therefore reflects the average concentration of glucose in the blood over the past 2-3 months.
It is the gold standard measure for establishing risk for complication in patients with type 1 or type 2 diabetes (4, 5) which is a growing global health disorder affecting about 400 millions people wordwide (6). The HbA1c concentration reported, either as a percentage of the total haemoglobin (NGSP) or in mmol/mol unit system (IFCC), provides a much better information of long term glycemic control than blood and urinary glucose direct measurements.

The HbA1c-CHECK-1 test is an innovative rapid lateral flow test designed to quickly provide accurate HbA1c values in whole blood samples. When the diluted whole blood sample is applied into the sample well of the cassette, a signal is measured by the instrument during migration as well as on the test zone and is converted into an HbA1c percentage value. The estimated average glucose (eAG) value will be displayed at the same time.
The control line appearance indicates that the test performed well.

II. HbA1c-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

1- HbA1c-CHECK-1 aluminium pouch containing:	10	20
- 1 HbA1c device		
- 1 disposable capillary plastic pipette (20 µL)		
2- Plastic dropper bottle containing 2 mL lysing reagent:	10	20
3- Instruction leaflet:	1	1

III. MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Automatic precision pipette for sampling volume of 20µL

IV. STORAGE AND STABILITY

1- All HbA1c-CHECK-1 kit components should be stored at any temperature between +4°C and +30°C in the sealed pouch.
2- **Do not freeze the test kit**.
3- The HbA1c-CHECK-1 kit is stable until the expiry date stated on the package label.

V. PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.
2- Read carefully the instructions before using this test.
3- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.
4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
6- Avoid any contact between hands and eyes or nose during specimen collection and testing.
7- Do not use beyond the expiry date which appears on the package label.
8- Do not use a test from a damaged protective wrapper.

VI. SAMPLE COLLECTION AND PREPARATION

a) Sample collection
1-HbA1c-CHECK-1 test is to be performed on **whole blood only**. Plasma and serum samples **cannot** be used.
2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).
3- Each specimen should be treated as if potentially infectious.
4- The test must be performed with fresh whole blood samples (< 4 hours). Finger prick samples should be assayed just after collection.

b) Sample dilution
1- Label one plastic dropper bottle containing the diluent with patient's name.
2- Unscrew the tube.
3- Using the supplied capillary pipette put it in contact with the whole blood on the finger without pressing the bulb. Let the whole blood migrate into the pipette through capillarity up to the **black mark** indicated on the pipette. **Avoid any air bubbles.**
In the case a laboratory precision pipette is used (not supplied), collect exactly 20µL of whole blood sample. **Avoid any air bubbles.**
4- Add the total volume of the whole blood sample into the lysing reagent vial.
5- Replace the screw cap on the dropper bottle.
6- Mix well by inverting upside-down the tube several times and wait 10 seconds to allow the cells lysis.

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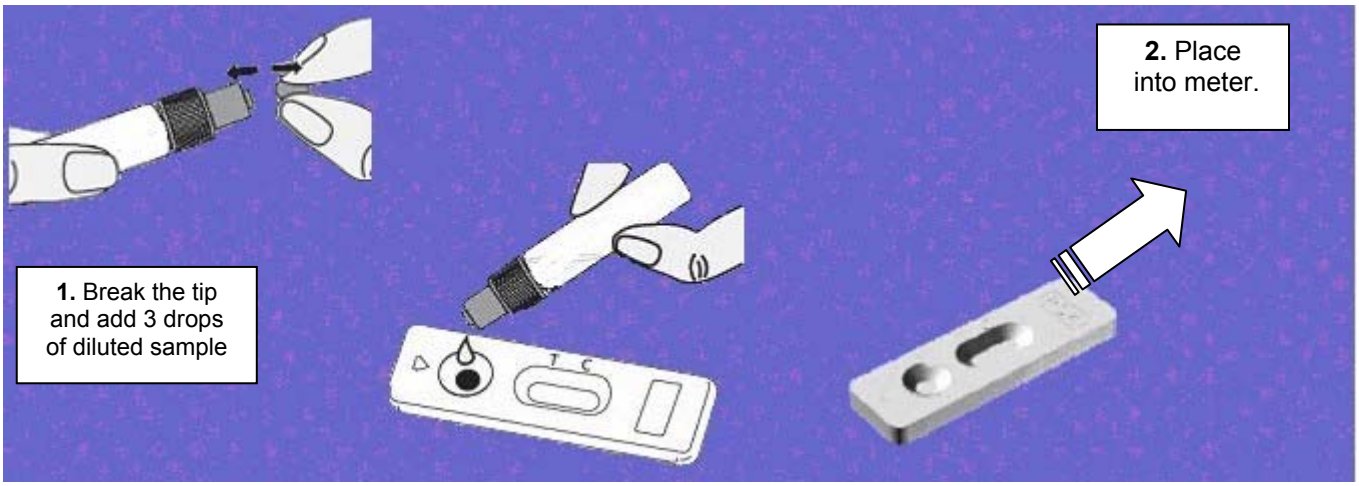
VII. ASSAY PROCEDURE

Follow the instructions below or refer to the picture n°1.

1- Allow samples and HbA1c-CHECK-1 test devices to come to room temperature prior to testing.
2- Remove the reaction device from its protective wrapper by tearing along the split.
3- Label device with the patient's name or control number.
4- Break the tip of the dropper bottle containing the sample. Holding the bottle vertically, add carefully and slowly 3 complete drops (90µL) of diluted sample into the sample well (▷). Avoid air bubbles.
5- Read the result **(in % or mmol/mol)** after exactly 10 minutes, either using the immediate or countdown reading mode.
For general instructions describing how to use the EASYREADER® or EASYREADER+® meter, refer to the corresponding leaflet.



Picture n°1

VIII. PERFORMANCES CHARACTERISTICS

a) Linearity
The measuring range is 4% to 16% (NGSP) or 20 mmol/mol to 151 mmol/mol (IFCC) and results will be given as indicated in the table 1 hereunder. The corresponding estimated average glucose (eAG) will also be indicated in mg/dL.

Sample HbA1c concentration (%)	**Reader results**		
	HbA1c concentration		Estimated average glucose (eAG)
	%	mmol/mol	
Below 4 %	< 4%	< 20.3 mmol/mol	< 68.1 mg/dL
4-16%	Quantitative results		
Over 16%	> 16%	> 151.4 mmol/mol	> 412.5 mg/dL

Table 1

b) Accuracy
A study has been performed using the European Reference Material (ERM) for HbA1c ranging from 4.7 % to 16.2% (28.6 to 153 mmol/mol). The obtained results are all within the 95% confidence interval.

c) Precision
A panel of 51 whole blood samples preassayed using BIORAD D-100 analyser was assayed using the HbA1c-CHECK-1 quantitative test. The obtained results show an overall correlation of 93.2% (CI 95% [88-96]).

d) Intra-assay reproducibility
Three pre assayed HbA1c samples (5.9%; 9.6% and 14% respectively) have been assayed (25 replicates each) and showed acceptable CV's (11.3%; 8.6% and 5.8% respectively).

e) Total haemoglobin
The HbA1c-CHECK-1 test is to be performed for total haemoglobin concentration ranging from 7 up to 23 g/dL. An error message will be displayed when the haemoglobin concentration is out of the specified range.

f) Cross reactions
There is no cross reactivity against non-glycated haemoglobin A1.

g) Interferences
1- Bilirubin:
Low, medium and high HbA1c samples spiked with 0.3 g/L of bilirubin showed repeatedly correct results.

2- Triglycerides:
Low, medium and high HbA1c samples spiked with 15g/L of triglycerides showed repeatedly correct results.

h) Expected values
Reference intervals should be established or verified by the laboratory based on an appropriate non diabetic patient population.
Suggested target values for HbA1c (7) are indicated in the table 2.

	NGSP (%)	IFCC (mmol/mol)
Non-diabetes	< 6	< 42
Prediabetes	6.0 to 6.4	42 to 47
Diabetes	≥ 6.5	≥ 48

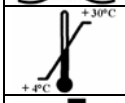
Table 2

IX- LIMITATIONS
1- The HbA1c-CHECK-1 quantitative test is designed for use with fresh whole blood samples and in association with VEDALAB's readers.

2- This assay should not be used as the unique test for the diagnosis of diabetes mellitus. Other tests and all available clinical information must also be considered to establish a correct diagnosis.
3- Falsely increased results have been reported in case of kidney failure, alcoholism (8) and hypertriglyceridemia.
4- Falsely decreased results have been reported in case of acute or chronic blood loss, sickle cell disease or anemia.
5- Diabetes during pregnancy commonly referred as gestational diabetes may be the cause of inconsistent results (increased or decreased HbA1c).
6- Use only fresh whole blood samples (< 4 hours) when test is performed with blood samples. Finger prick samples should be assayed just after collection.
7- This test is to be used only with VEDALAB's rapid test readers (Easy Reader® or Easy Reader+®).
8- If the reading time (10 minutes) is not strictly respected, wrong results will be obtained.
9- This format of test should not be used for visual reading.
10- As it is true for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 10% should be considered for the final value and for the clinical significance of the result.

X- BIBLIOGRAPHY

1- **Ladyzynski P. and al.** Validation of haemoglobin glycation models using glycemia monitoring in vivo and culturing of erythrocytes in vitro. Annals of biomedical engineering. 2008. 36: 1188.
2- **Bunn H.F., Haney D.N, Kamin S., Gabbay K., Gallop P.** The biosynthesis of human hemoglobin A1c. Slow glycosylation of haemoglobin in vivo. Journal of Clinical investigation. 1976. 57: 1652.
3- **Beach K.W.** A theoretical model to predict the behaviour of glycosylated haemoglobin levels; Journal of theoretical biology. 1979. 81: 547.
4- **Larsen M.L. Horder M, Mogensen E.F.** Effect of long-term monitoring of glycosylated haemoglobin levels in insulin-dependent diabetes mellitus. N. Engl. J. Med. 1990. 323 (15): 1021-1025.
5- **Sacks D.B.** Hemoglobin A1c in diabetes: panacea or pointless? Diabetes. 2013. 62: 41.
6- **International Diabetes Foundation.** IDF Diabetes Atlas. 2015 (http://www.idf.org/diabetesatlas).
7- **Nachan and Al.** Translating the A1c assays into estimated glucose values. Diabete Care. 2008. 31: 1473-1478.
8- **Thomas L.** Clinical Laboratory Diagnostics. 1st Ed. Franckfurt: TH-books Verlagsgesellschaft. 1998. 142-148.

	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

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