

# HbA1c-CHECK-1

## Quantitative determination of glycated haemoglobin in whole blood samples - FOR EASY READER+® USE ONLY - Ref. 96091 (20 tests) / Ref. 96091-10T (10 tests)

### I. INTENDED PURPOSE

The HbA1c-CHECK-1 rapid test is intended for the quantitative determination of glycated haemoglobin in human whole blood samples to be used as an aid for medical healthcare professionals to assess glucose metabolism disorders such as diabetes. The sole determination of concentration in HbA1c is not sufficient to diagnose diabetes or complications due to abnormal levels in glycated haemoglobin. In addition, the HbA1c-CHECK-1 test result should not be used to adapt or modify the treatment of patients suffering from diabetes.

### II. 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 worldwide (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.

### III. HbA1c-CHECK-1 KIT COMPONENTS

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

1- HbA1c-CHECK-1 aluminium pouch 10 20  
containing:

- 1 test device
- 1 disposable capillary pipette (20 µL)

2- Plastic dropper bottle containing lysing reagent: 10 20

3- Leaflet: 1 1

#### 4- Controls (Optional):

**Positive control (ref. V9600) and Negative control (ref. V9601):** a freeze-dried preparation of a non-infectious compound in diluted human serum, tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide is optionally available as a positive and negative control (1x 0.50 mL). The concentration range is indicated on the vial label.

### IV. MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Automatic precision pipette for sampling volume of 20µL and 150µL.

### V. STORAGE AND STABILITY

1- The HbA1c-CHECK-1 kit should be stored as follows:

- +4°C to +30°C for short term storage (up to 3 weeks),
- +2°C to +8°C for long term storage.

2- **Do not freeze the test kit.**

3- The HbA1c-CHECK-1 kit is stable until the expiry date stated on the package label.

### VI. PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only, not for self-testing.

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 the test if one of the components is damaged.

9- **IMPORTANT:** For better results, the test should be performed at an ambient temperature of +20°C as the minimum up to +30°C as the maximum. When the ambient temperature is +25°C or below, the countdown mode (internal incubation) should be preferred while the immediate mode (external incubation) should be used in case of ambient temperature over +25°C.

### VII. 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 lysing reagent 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 20 µL of whole blood sample. **Avoid any air bubbles.**



**Note: For an improved result precision, please use a lab precision pipette and clean the pipette tip using an absorbent paper to eliminate the excess of whole blood around the external tip wall.**

4- Add the complete 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 5 to 10 times and wait 5 minutes for the complete red blood cells lysis before starting the measurements.** Mix from time to time during the 5 minutes incubation to allow the correct lysis of cells.

## VIII. ASSAY PROCEDURE

**IMPORTANT:** Switch the reader on and allow it to warm up for at least 30 minutes before performing any measurements.

**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- Unscrew the cap of the bottle containing the sample. Using a lab precision pipette (not supplied), dispense 150µL of solution into the sample well (▷). Avoid air bubbles.

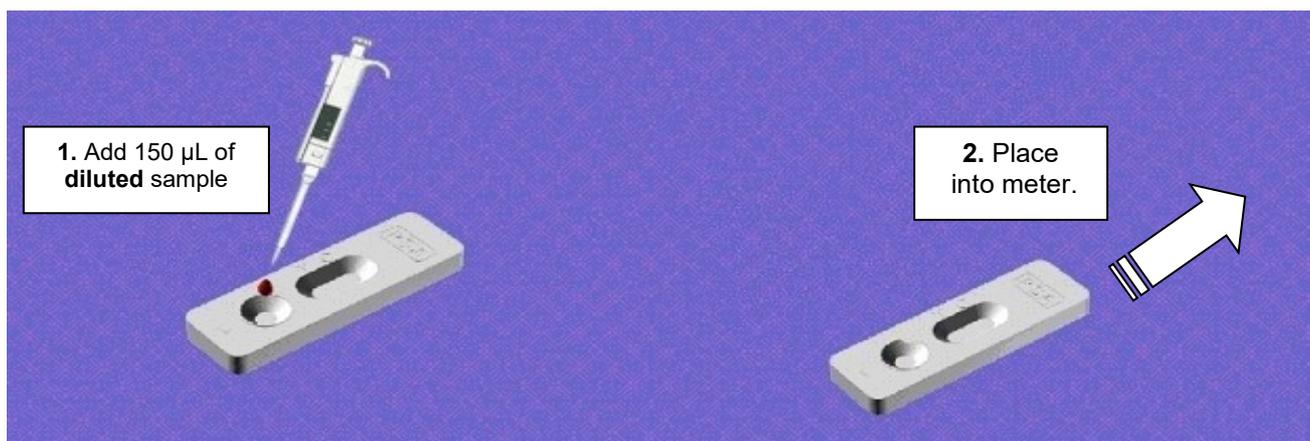
### Important note:

Please enter the device into the reader ("countdown" mode) or start measuring the 10 minutes reaction time using an external timer ("immediate" mode) **only when the migration front of the reagents (reddish colour) has reached about half of the area of the reading window of the cassette.** **In countries where the temperatures are usually high, please use only the immediate mode (external incubation and a timer)!**

**Do not perform the HbA1c-CHECK-1 test if the ambient temperature exceed 30°C.**

5- Read the result (in % or mmol/mol) after **exactly 10 minutes (+/- 30 secondes)**, using the immediate mode when ambient temperature is +25°C or over (or countdown reading mode when the ambient temperature is below +25°C).

For general instructions describing how to use the EASYREADER+® meter, refer to the corresponding leaflet.



Picture n°1

## IX. 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]\*).

\*CI: 95% confidence interval.

### 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) Inter-assay reproducibility

Three pre assayed HbA1c samples (5.3%; 6.5% and 7.2% respectively) have been assayed on three batches of HbA1c-CHECK-1 tests in triplicate and showed acceptable CV's (8.88%; 9.08% and 5.27% respectively).

#### f) 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.

#### g) Cross reactions

There is no cross reactivity against non-glycated haemoglobin A1.

#### h) 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.

#### i) 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

#### X. LIMITATIONS

1- The HbA1c-CHECK-1 quantitative test is designed for use with fresh whole blood samples and in association with VEDALAB's reader (EASYREADER+®).

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- The test must be performed with fresh whole blood samples (< 4 hours). Finger prick samples should be assayed just after collection.**

7- This test can only be used only with EASYREADER+® instrument (ref. 36200). It cannot be used with EASYREADER® instrument (ref. 36100).

8- HbA1c measurements should be performed at an ambient temperature of +20°C as the minimum and +30°C as the maximum. When the ambient temperature is +25°C or below, the countdown mode (internal incubation) should be preferred while the immediate mode (external incubation) should be used in case of ambient temperature over +25°C.

9-Do not use the reader for measurements before at least 30 minutes warm-up after having switched on.

10- This format of test should not be used for visual reading.

11- 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.

#### XI. BIBLIOGRAPHY

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- 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.
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- 8- **Thomas L.** *Clinical Laboratory Diagnostics*. 1<sup>st</sup> Ed. Franckfurt: TH-books Verlagsgesellschaft. 1998. 142-148.

	Read the instructions before use		For <i>in vitro</i> diagnostic use
	Do not reuse		Manufacturer



Manufactured by VEDALAB – France

#### CHANGES DESCRIPTION

##### Changes type:

- N/A: Not Applicable (creation)
- Technical change: Addition, revision and/or removal of information related to the product.
- Administrative: Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
Technical	Precisions in Part VII related to temperature when using the test

**Note:** Minor typographical, grammar, spelling and formatting changes are not reported in the change details.