

Hb-TOTAL-CHECK-1

Quantitative determination of haemoglobin in whole blood samples

- FOR EASY READER+[®] USE ONLY -

Ref. 140091 (20 tests)/Ref. 140091-10T (10 tests)

I. PRINCIPLE

Haemoglobin, abbreviated Hb or Hgb, is the main component of red blood cells of all vertebrates (1). Hb in the blood serves as the transporter for the oxygen from the respiratory organs to the rest of the body (2, 3). Hb also carries carbon dioxide as carbaminoglobin in which CO₂ is bound to the globin protein (4).

In mammals, the Hb makes up about 96% of the red blood cell by content (by weight) and around 35% of the total content (including water) (5). Hb deficiency can be used to determine the presence of anaemia while elevated levels of Hb are associated with polycythemia (6). Normal Hb ranges vary among men and women (with different values for pregnancy), different age groups, different altitudes, cigarettes smokers...etc.

The measurement of Hb, which is typically assayed spectrophotometrically, is generally considered accurate and more useful than Hct (Hematocrit) or RBC (Red Blood Cells) count for the diagnosis of anaemia.

Hb concentration is usually reported as grams of Hb per decilitre of blood (g/dL).

The Hb-TOTAL-CHECK-1 test is a very innovative rapid lateral flow test designed to quickly provide accurate Hb 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 and is converted into an Hb concentration value.

The control line appearance indicates that the test performed well.

II. Hb-TOTAL-CHECK-1 KIT COMPONENTS

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

1- Hb-TOTAL-CHECK-1 test devices:	10	20
2- Plastic dropper bottle containing 1 mL diluent:	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 Hb-TOTAL-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 Hb-TOTAL-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. SPECIMEN COLLECTION AND PREPARATION

a) Sample collection

- 1- Hb-TOTAL-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

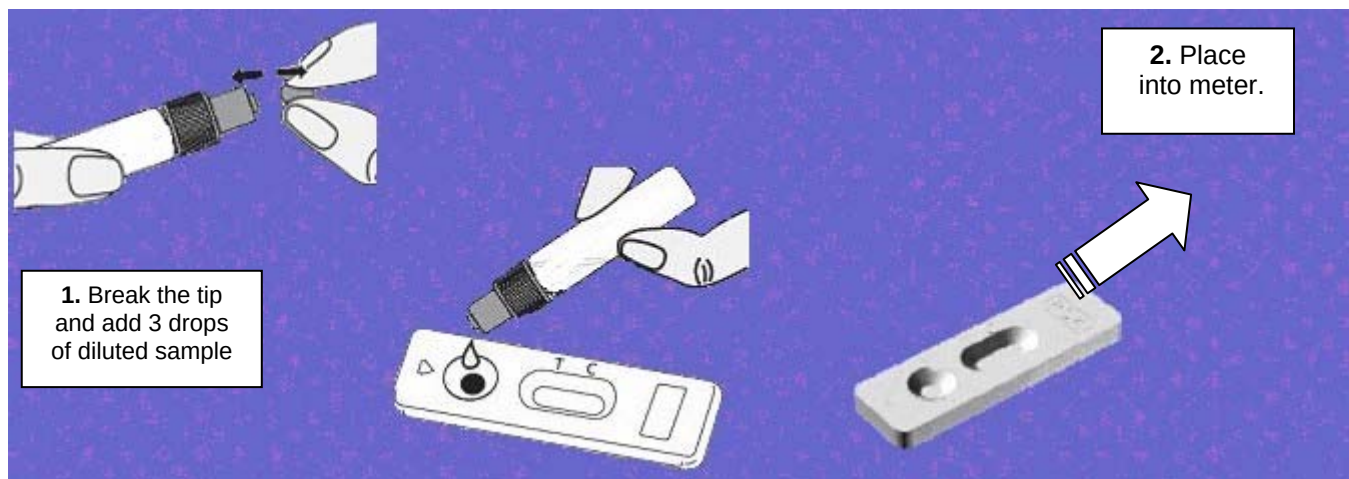
- 1- Label one plastic tube containing the diluent with patient's name.
- 2- Unscrew the tube.
- 3- Using a laboratory precision pipette (not supplied) collect exactly 20µL of whole blood sample. **Avoid any air bubbles.**
- 4- Add the whole blood sample into the diluent vial and rinse the tip by pipetting a few times.
- 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



VII. ASSAY PROCEDURE

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

- 1- Allow samples and Hb-TOTAL-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. Add 3 drops (90µL) of diluted sample into the sample well (▷).
 - 5- Read the result (**in g/dL**) after 3 minutes, either using the immediate or countdown reading mode.
- For general instructions describing how to use the EASYREADER+[®] meter, refer to the corresponding leaflet.



Picture n°1

VIII. PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 5 to 25 g/dL of Hb and results will be given as indicated in the table 1 hereunder.

Sample Hb concentration (g/dL)	Reader results (g/dL)
below 5	"<5 g/dL"
5-25	quantitative results
over 25	"> 25 g/dL"

Table 1

b) Accuracy

A study has been performed using whole blood samples ranging from 6.8 g/dL to 24.3 g/dL. The obtained results show a linear regression factor close to 1 (0.99).

c) Precision

A comparative study has been performed using a panel of 56 whole blood samples. The samples have been assayed using Hemocue 201+ analyser and the Hb-TOTAL-CHECK-1 test together with EASYREADER+[®] analyser. The obtained results show an excellent overall correlation coefficient of 98.5% (CI 95%) between the two methods.

d) Sensitivity

The Hb-TOTAL-CHECK-1 test sensitivity is 5 g/dL.

e) Intra-assay reproducibility

Three Hb-TOTAL pre-assayed samples (8.5 g/dL, 15.5 g/dL and 20.5 g/dL respectively) have been assayed (25 replicates) each and showed excellent CVs (3.41%, 0.96% and 0.70% respectively).

f) Cross reactions / interferences

As there is no immunological reaction involved in the Hb-TOTAL-CHECK-1 quantitative test, cross reactions and interferences cannot occur.

g) Expected values

The normal ranges for haemoglobin depend on the age and, beginning in adolescence, the gender of the person.

The normal ranges are as mentioned in the table 2 hereunder.

Individuals	Hb concentration (g/dL)
New borns	17 to 22
One (1) week of age	15 to 20
One (1) month of age	11 to 15
Children	11 to 13
Adult men	14 to 18
Adult women	12 to 16
Men after middle age	12.4 to 14.9
Women after middle age	11.7 to 13.8

Table 2

All of these values may vary slightly between laboratories and depending of conditions (dietary, geographical...etc). It is therefore recommended that each laboratory establish its own normal range.

h) Expected values (for veterinary use)

The Hb-TOTAL-CHECK-1 can also be used for veterinary purpose. The reference ranges for different animals are indicated in the table 3 hereunder.

Animals	Hb ranges (g/dL)
Dog	15 to 20
Cat	8 to 17
Horse	9 to 18
Rabbit	11.5 to 15.1
Pig	11.0 to 16.5
Sheep	11.0 to 16.5
Cattle	10 to 13
Mouse	11.1 to 18.0
Rat	11.1 to 18.0

Table 3

It is therefore recommended that each laboratory establish its own normal range.

IX- LIMITATIONS

1- The Hb-TOTAL-CHECK-1 quantitative test is designed for use with fresh whole blood samples and in association with VEDALAB's reader.

2- As for any diagnostic procedure, the physician should evaluate the data obtained using this kit in the light of the other available clinical information.

3- Use only fresh whole blood samples (< 4 hours) when test is performed with blood samples. Finger prick samples should be assayed just after collection.

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

5- If the reading time (3 minutes) is not strictly respected, wrong results will be obtained.

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

7- 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- **Maton, Anthea; Jean Hopkins: Charles William McLaughlin; Susan Johnson; Maryanna Quon Warner; David laHart; Jill D. Wright** (1993). *Human Biology and health*. Englewood Cliffs, New Jersey, US: Prentice Hall. ISBN 0-13-981176-1.

2- **Vajpayee N, Graham SS, Bem S.** Basic Examination of Blood and Bone Marrow. McPherson RA, Pincus MR, eds. *Henry's Clinical Diagnosis and Management by Laboratory Methods*. 22nd ed. Philadelphia, PA: Saunders, an imprint of Elsevier Inc; 2011. Chap 30:509-35.

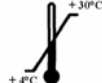
3- **Hemoglobin. A.D.A.M.** Medical Encyclopedia. Atlanta, GA: A.D.A.M., Inc; 1997-2004. Updated February 8, 2012. Available at <http://www.nlm.gov/medlineplus/ency/article/003645.htm>.

Accessed: February 1, 2014.

4- **Patton, Kevin T. (2015-02-10).** *Anatomy and Physiology*. Elsevier Health Science. ISBN 9780323316873.

5- **Elghetany MT, Bank K.** Erythrocytic Disorders. McPherson RA, Pincus MR, eds. *Henry's Clinical Diagnosis and Management by Laboratory Methods*. 22nd ed. Philadelphia, PA: Saunders, an imprint of Elsevier Inc; 2011. Chap 32:557-600.

6- **Sirhan S, Fairbanks VF, Tefferi A.** Red cell mass and plasma volume measurements in polycythemia: evaluation of performance and practical utility. *Cancer*. July 1, 2005. 104(1):213-5. [medline].

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



Manufactured by VEDALAB - France