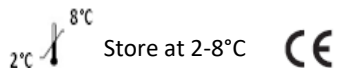


Haemoglobin Drabkin's Colorimetric

IVD For *In-Vitro* diagnostic and professional use only.



INTENDED FOR USE

Haemoglobin Drabkin's reagent used for Quantitative determination of Hemoglobin in human blood.

PRINCIPLE OF THE METHOD

Haemoglobin is oxidized by potassium ferricyanide into methaemoglobin, which is converted into cyanomethaemoglobin, by potassium cyanide.

The intensity of the color formed is proportional to the Haemoglobin concentration in the sample.

CLINICAL SIGNIFICANCE

The Haemoglobin is the red pigmented protein located in the erythrocytes and consists of four subunits that contains iron. The Haemoglobin is the one in charge of oxygen transport by the blood from the lungs to tissues and then transport carbon dioxide out of the tissues back to the lungs. In normal human adults, at least 96% of the haemoglobin is HbA. HbA2 is usually about 2.5-3% of total haemoglobin. Fetal haemoglobin (HbF) predominates during fetal life and diminishes rapidly during the first year of postnatal life. In normal adults less than 1% is HbF. Blood haemoglobin concentration may be diminished as a consequence of haemorrhage or haemolysis or as a result of impaired blood formation in the bone marrow.

When the level of Haemoglobin appears underneath the normal levels it is described as an anemia. Anemia can be of different origins: primary anemia, cancer, pregnancy, renal diseases, and hemorrhages.

If the Haemoglobin levels appear high it can be due to cardiopathies, dehydration and stays in places of much altitude.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRECAUTIONS

- For *In Vitro* diagnostic use.
- **Harmful:** Harmful by inhalation, in contact with skin and if swallowed. Keep container tightly closed. After contact with skin, wash immediately with plenty of water. In case of accident or if you feel unwell, seek medical advice immediately.
- **Cyanide (poison):** The amount of cyanide in the Reagent Concentrate (40x) is appreciably less than the minimum lethal dose for an adult. Gaseous hydrogen cyanide will be released on contact with acids.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and test table with water and soap once the testing is done.
- After contact the reagent with skin, wash immediately with plenty water.
- Do not drink or digest the reagent.
- The reagent is considered toxic, so do not drink or eat beside it.
- Close the vial tightly after each use.
- If spillage of reagent occurs, clean with disinfectant.

REAGENTS:

- Drabkin's Reagent (40x)
- 15 g/dL Haemoglobin Standard (optional).

NOTE: This package insert is also used for individually packed reagent.

PREPARATION

- Drabkin's Working reagent (WR):
The working solution is prepared by diluting 1 part of Drabkin's reagent (40x) with 39 parts of distilled water (i.e. 5 ml of Drabkin's reagent (40x) is to be diluted with 195 ml distilled water).
Stability 3 months at 2-8°C, Protect from light and heat.
- Haemoglobin Standard Preparation **(if the standard is not ready to use):**

Haemoglobin Standard is prepared by mixing 4ml Drabkin's working reagent with 20µl of Haemoglobin Standard (Not ready to use).

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.

Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 540 nm > 0.01.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 540 nm
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

SAMPLES

Venous or capillary blood

Use anticoagulants like EDTA, heparin or oxalate.

Stability of the sample is 1 week at 2-8°C.

PROCEDURE

1. Assay conditions.

Assay type End point
Wavelength 540 nm
Cuvette 1 cm. light path
Temperature 15-25°C
Direction..... Increase

2. Adjust the instrument to zero with distilled water
3. Transfer (1ml) from the ready to use standard and read the absorbance.
4. Pipette according to Table (01):

| Table (01) | Blank | Sample |
|-------------|-------|--------|
| WR(ml) | 4.0 | 4.0 |
| Sample (µl) | ----- | 20 |

5. Mix and incubate for 5 min. at room temperature (15-25°C).
6. Read the absorbance (A) of the samples against the Blank Drabkin's solution.

7. Mix and incubate for 5 min. at room temperature (15-25°C).
8. Read the absorbance (A) of the samples and Standard, against the Blank Drabkin's solution.

CALCULATIONS

$$\frac{(A)_{\text{Sample}}}{(A)_{\text{Standard}}} \times 15 \text{ (Standard conc.)} = \text{g/dl Hemoglobin}$$

QUALITY CONTROL

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES'

Men 14 - 18 g/dL= 8.7 — 11.2 mmol/L
 Women 12-16g/dL= 7.5— 9.9mmol/L

These values are for orientation purpose, each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range:

Detection limit 0.3 g/dL with linearity range from 1.0g/dL up to 25 g/dL.

If the results obtained were greater than linearity limit, dilute the sample 1/2 with saline (NaCl 0.9 g/L) and multiply the result by 2.

Precision:

| | Intra-assay (n=20) | | Inter-assay (n=20) | |
|-------|-----------------------|-------|-----------------------|-------|
| | Mean (g/dl) | 6.21 | 14.9 | 6.119 |
| SD | 0.0549 | 0.211 | 0.261 | 0.511 |
| CV(%) | 0.884 | 1.41 | 4.272 | 3.377 |

Sensitivity:

1 g/dL = 0,029 A

Accuracy:

Results obtained using Atlas Drabkin's reagent did not show systematic differences when compared with other commercial reagents.

The results obtained using 100 samples were as follows:

Correlation coefficient (r) = 0.9908

















Regression equation (y) = 0.9983X-0.0983

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| | | | |
|---|---|---|------------------------------------|
|  | Catalogue Number |  | Temperature limit |
|  | In Vitro diagnostic medical device |  | Caution |
|  | Contains sufficient for <n> tests and Relative size |  | Consult instructions for use (IFU) |
|  | Batch code |  | Manufacturer |
|  | Fragile, handle with care |  | Use-by date |
|  | Manufacturer fax number |  | Do not use if package is damaged |
|  | Manufacturer telephone number |  | Date of Manufacture |
|  | Keep away from sunlight |  | Keep dry |