HAEMOGLOBIN Drabkin's Solution (Ready to Use)

Diagnostic reagent for the in-vitro quantitative determination of Haemoglobin in human blood.

REF:V/HB01.250	250 test	REF:V/ HB01.500	500 test
REF:V/ HB04.250	1000 test		

CLINICAL SIGNIFICANCE

Haemoglobin (Hb) is the red pigmented protein located in the erythrocytes and consists of four subunits. Its main function is the transport of oxygen and carbon dioxide in blood. In normal human adults, at least 96 % of the haemoglobin is HbA. HbA2 is usually about 2.5 – 3 % of total haemoglobin. Fetal hemoglobin (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 hemorrhage or hemolysis or as a result of impaired blood formation in the bone marrow.

METHOD PRINCIPLE

Haemoglobin is oxidized by potassium ferricyanide which is converted into stable cyanomethaemoglobin by potassium cyanide. The absorbance of the cyanomethaemoglobin is monitored at 540 nm.

REAGENT COMPOSITION

R 1: Reagent 1	
- Potassium ferricyanide	- 0.62 mmol/l
- Potassium phosphate	- 1.04 mmol/l
- Potassium cyanide	- 1.54 mmol/l
- Surfactant	- < 0.1 %

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Harmful (Xn): R20/21/22: Harmful by inhalation, in contact with skin and if swallowed. S7: Keep container tightly closed. S28.1: After contact with skin, wash immediately with plenty of water.

S45: In case of accident or if you feel unwell, seek medical advice immediately. The amount of cyanide present in one bottle of reagent is appreciably less than the minimum lethal dose for an adult. However, hydrogen cyanide is liberated by acidification. Never allow reagent to come in contact with acid.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the **Lab.Vie**. Haemoglobin reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Lab.Vie. Haemoglobin reagents are stable up to the expiry date labeled on the bottles when properly stored at 15–25°C. the opened vial is stable for 6 months at the specified temperature.

Deterioration
The **Lab.Vie**. Haemoglobin reagent is normally clear. Do not use Haemoglobin reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Anticoagulated venous or capillary blood. Blood may be anticoagulated with EDTA, or fluoride. Blood can be taken directly from a finger or heel puncture without use of anticoagulant.
Stability : 7 days at 2 - 8 °C
4 days at 20 - 25 °C

SYSTEM PARAMETERS

Wavelength	540 nm (546 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample Reagent Ratio e.g.: Reagent volume Sample volume	1:250 2.5 ml 10 µl
Temperature	20– 25°C
Incubation time	5 min. at 20–25°C
Zero adjustment	Reagent Blank
Sensitivity	1.0 g/dL
Linearity	20 g/dL

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes and automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Specimen
Working Reagent	2.5 ml
Specimen	10 µl

Mix and incubate for 5 minutes at 20-25°C. Measure absorbance of specimen "A" against reagent blank within one hour.

CALCULATION

Hemoglobin concentration (g/dL) = A specimen x 36.77

Hemoglobin concentration (mmol/L) = A specimen x 22.83

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact Bioscien technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean g/dl	10	14	11.1	14.1
CV. %	2.3	1.3	2.9	2.1

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)

Result obtained from **Lab.Vie**. Haemoglobin reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.983.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 1.0 g/dl.

Linearity
The reaction is linear up to 20 g/dl. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

A list of drugs and other interfering substances with haemoglobin determination has been reported by Young et.al.

EXPECTED VALUES

Serum	***g/dl***	***mmol/L***
1-6 days	15.2 - 23.5	9.4 - 14.6
14-50 days	10.3 – 16.6	6.4 - 10.3
2-10 months	10.0 – 12.9	6.1 - 8.0
1-15 years	11.0 – 14.3	6.8 - 8.8
Adults		
Females	12.0 – 16.0	7.5 - 9.9
Males	14.0 – 18.0	8.7 - 11.2

REFERENCES

1. International committee for standardization in haematology. Brit. J. Haemat., 1967:13 (Suppl.) 71
2. Van Kampen, E. J. and Zijlstra, W.G., Clin. Chem. Acta.,1961:6:538 – 544.
3. Tietz NW, Ed. Clinical guide to laboratory tests. 2ND ED Philadelphia: WB Saunders; 1990:566.
4. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press,1995.
5. Young DS. Effects of drugs on Clinical Lab. 4th ed AACC Press,2001.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

Ismailia – Free zone, Ismailia – Egypt
Post code-41511
E-mail : admin@labvielab.com
Website: www.labvielab.com