Spectrum For Diagnostic Industries

Hemoglobin
(Ready-To-Use)Drabkin's Solution

IVD

REF.	Pack size
134 05 100	(5 x 100 ml) 200 tests
134 05 125	(5 x 125 ml) 250 tests
134 04 250	(4 x 250 ml) 400 tests

Intended Use

Haemoglobin reagent is intended for the in-vitro quantitative, diagnostic determination of haemoglobin in human blood.

Introduction

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 humanadults, 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

Colorimetric method using Drabkin's solution.

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

Reagents

Reagent

Potassium ferricyanide	0.62 mmol/l
Potassium phosphate	1.04 mmol/l
Potassium cyanide	1.54 mmol/l
Surfactant	< 0.1 %

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 apreciably 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.

Reagents preparation, storage and stability

Reagent is supplied ready to Use.

Reagent is stable until expiration date stated on label when stored at 15 - 25 ^{o}C.Once opened, the reagent vial is stable for 3 months at the specified temperature.

Precautions and Warnings

Do not ingest or inhalate. 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.

Deterioration

Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen collection and preservation

Anticoagulated venous or capillary blood . Blood may be anti - coagulated 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 ^{o}C
4 days at 20 - 25 ^{o}C

Procedure

Wavelength	540 nm (Hg 546 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 250
e.g .: Reagent volume	2.5 ml
Sample volume	10 µl
Temperature	20 – 25 ^{o}C
Incubation time	5 minutes
Zero adjustment	Against reagent blank
Reagent Blank Limits	Low 0.00 AU
	High 0.2 AU

Pipette into test tubes

Reagent	2.5 ml
Blood sample	10 µl

Mix well and rinse the blood pipette several times with the reagent and incubate for 5 minuts at 20-25 ^{o}C. Measure absorbance of specimen (Aspecimen) against reagent blank.

Calculation

Haemoglobin concentration (g/dL) = $A_{specimen}$ x 36.77

Haemoglobin concentration (mmol/L)= $A_{specimen}$ x 22.83

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Expected values

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

Performance Characteristics

Method Comparison

A comparison between Haemoglobin reagent and a commercial reagent of the same methodology was performed on 20 human blood samples. A correlation (r) of 0.983 was obtained.

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (g/dL)	10	14
CV%	2.3	1.3

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (g/dL)	11.1	14.1
CV%	2.9	2.1

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

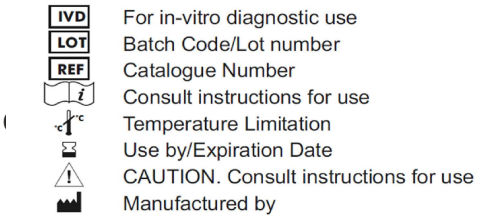
S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

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.

SYMBOLS IN PRODUCT LABELLING



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