SPECTRUM

The Creative Approach to Bioscience

Haemoglobin
(Single Reagent)
Drabkin's Solution

REF:610 001 (2 x 20 ml) 800 test
REF:610 002 (5 x 20 ml) 2000 test

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	
REF Catalogue Number	Manufactured by
Consult instructions for use	(Xi) - Irritant
Temperature Limitation	

Intended Use

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

Background

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.

Assay 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	31 mmol/l
Potassium phosphate	52 mmol/l
Potassium cyanide	77 mmol/l
Surfactant	2 %

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.

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

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.

Reagent Preparation Storage and Stability

All reagents are stable until expiration date stated on label when stored at 15 - 25 ^{O}C. Prepare the working solution by diluting the contents of the concentrated reagent (R) to 1000ml using distilled water (add one bottle of reagent (R) to 980 ml of dist.water), mix thoroughly. Working reagent can be prepared according to the volume needed by mixing 1 ml of the concentrated reagent **(R)** plus 49 ml distilled water.Once opened, the reagent is stable for 6 months at the specified temperature if contamination is avoided.
Stability: 6 months in a brown glass bottle at 15-30 ^{O}C

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 ^{O}C
4 days at 20 - 25 ^{O}C

System Parameters

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 0.02 AU

Procedure

Pipette into test tubes

working solution	2.5 ml
Blood sample	10 µl

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

Calculation

Haemoglobin concentration (g/dL) = Aspecimen x 36.77

Haemoglobin concentration (mmol/L)= Aspecimen x 22.83

Quality Control

Normal & abnormal commerical control blood of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (g/dL)	10	14
SD	0.23	0.182
CV%	2.3	1.3

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (g/dL)	11.1	14.1
SD	0.322	0.296
CV%	2.9	2.1

Methods Comparison

A comparison between Spectrum Diagnostics Haemoglobin reagent and a commercial reagent of the same methodology was performed on 40 human blood samples. A correlation (R) of 0.983 was obtained

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)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

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.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
610 001	2 x 20 ml
610 002	5 x 20 ml

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CE

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