BioMed- Hemoglobin

Colorimetric, Endpoint

REF: HB124800 (2000 ml)

INTENDED FOR USE

For quantitative determination of hemoglobin in blood

PRINCIPLE:

Hemoglobin reagent is based on cyanmethemoglobin method that has been adopted as a standard method. In this method, erythrocytes are lysed by a stromalitic agent in the presence of a surfactant and release their hemoglobin into solution. Hemoglobin is oxidized to methemoglobin by Ferricyanide and the methemoglobin is converted to cyanmethemoglobin by addition of KCN. The absorbance of cyanmethemoglobin is measured at 540 nm and color intensity is proportional to hemoglobin concentration.

SPECIMEN COLLECTION :

Whole blood collected with EDTA, heparin, citrate or oxalate. Specimens should be mixed thoroughly but gently to ensure complete solution of anticoagulants. The presence of clots will invalidate results. Hemoglobin in sample is stable for 1 week at room temperature.

REAGENT COMPOSITIONS

R1	Potassium Ferricyanide Potassium Phosphate	0.62 mmol/l 0.6 mmol/l
R2	Potassium Cyanide	0.76 mmol/l

PACKAGE: Collection & storage.

Store in refrigerator (+2-8°C).
Stable until the expiration date reported upon the package.
After the unsealing and the taking of the reagent ,it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination

PRECAUTIONS & WARNING

- This reagent contains CYANIDE. Never pipette by mouth.
- Don't mix with acids.

REAGENT PREPARATION & STABILITY :

Stored the hemoglobin reagent and standard at room temperature (15-30°C).

Working Reagent is :
Reagent 1 1 volume
Reagent 2 1 volume
Distilled water 48 volume
Stability: Two months at 15- 25°C in a dark bottle

REAGENT DETERIORATION

Don't use hemoglobin reagent if:
1. It has become a different color than yellow.
2. the reagent becomes turbid or a precipitation forms.

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

Wavelength	540 nm (Hg 546)
Optical path	1 cm
Incubation temperature	20 - 25°C
Zero adjustment	working solution

Pipette into test tube	
Working solution	2.5 ml
Blood specimen	0.01 ml
Rinse the pipette used for the blood specimen a few times with the reaction mixture. Mix and read the absorbance of specimen ($A_{specimen}$) against working solution after 5 minutes. The color intensity is stable 1 hour protected from strong light.	

CALCULATION:

Hemoglobin concentration (mmol/l) = $A_{specime}$ x 22.82
Hemoglobin concentration (g/dl) = $A_{specimen}$x 36.77

EXPECTED VALUES:

Males:	14- 18 g/dl (8.7 -11.2 mmol/l)
Females:	12- 16 g/dl (7.5 - 9.9 mmol/l)
Children:	12- 16 g/dl (7.5 - 9.9 mmol/l)
Neonates:	16- 24 g/dl (10- 15.5 mmol/l)

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

It is recommended to execute the quality control at every kit utilization to verify that values are With in the reference range indicated by the methodology.

PERFORMANCE :

1. ***linearity:*** 20 g/dl.
2. ***sensitivity:*** Based on an instrument resolution of 0.001 absorbance, the present procedure has a sensitivity of 0.03 g/dl
3. ***comparison:*** Studies conducted against a similar procedure yielded a coefficient of correlation of 0.98 with a regression equation of y= 1.03 x -0.48 on samples with values from 7.2 to 17.9 g/dl (n=20)
4. ***Precision:***

Within Run: Two samples of human blood were assayed twenty (20) time and the following within run precision was obtained.

	Mean (g/dl)	S.D.	C.V.%
Normal	13.8	0.6	4.6
Abnormal	10.2	0.3	3.4

Run-to-Run: Two samples of human blood were assayed for five (5) consecutive days and the following run to run precision was obtained.

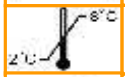
	Mean (g/dl)	S.D.	C.V.%
Normal	14.3	12.3	0.5
Abnormal	12.3	0.5	4.3

METHOD LIMITATIONS:

1- this procedure measures hemoglobin and it's derivatives except sulfhemoglobin.
2- Specimens with values above 20.0 g/l must be re-run using one half the sample volume. Multiply final results by two (2).

REFERENCES:

1. Tietz, N.W., Fundamentals of Clinical Chemistry, 2°Ed., W.B. Saunders & Co., Philadelphia (1976)
2. Walters, M.l., Clin Chem 14(682),1968.
3. Young, R.B., et al., Clin Chem 21(314), (1975).
4. Recommendation for hemoglobinometry in Human Blood, Dr. J. Haematol, Suppl 71(13), 1967.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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