HEMOGLOBIN TEST KIT

INTENDED USE : Quantitative in vitro determination of Hemoglobin in whole blood on photometric systems. In vitro diagnostic test kit, for laboratory and professional use. This manual contains instructions for operation by qualified personnel only.

CLINICAL SIGNIFICANCE : Hemoglobin conveys dissolved gases in plasma, especially O2 and CO2, and regulates cell gas exchanges. Hemoglobin also takes part in maintenance of the plasmatic buffer power. Increased levels are found in polycythemia, congenital cyanotic heart disease, heat stroke and dehydration. Decreased levels are found in anemia resulting from deficiency of iron or folic acid, red blood hemolysis, defective globin synthesis and structural abnormalities.

PRINCIPLE : Although the Cyanmethaemoglobin method recommended by ICSH is used for measurement of Hemoglobin, the presence of potassium cyanide in the formulation constitutes toxic hazard to the user & from the point of its safe disposal. This reagent is free from potassium cyanide, stable, nontoxic reagent. SLS disrupts the erythrocyte membrane and brings about the change of Hemoglobin by SLS through an oxidation reaction resulting in a stable SLS-Hemoglobin complex. This complex is measured photometrically at 540 or 546 nm. Total conversion to the SLS- Hemoglobin complex is extremely rapid and SLS converts methaemoglobin fully and yields Hemoglobin concentration results that are comparable to the cyanmethaemoglobin method.

REAGENT COMPOSITION :
Reagent : Hemoglobin Reagent

MATERIAL REQUIRED BUT NOT PROVIDED :
- Clean & dry Glassware
- Micropippete & tips.
- Colorimeter or Bio Chemistry Analyser .

SAMPLE : Fresh whole blood collected in EDTA. Discard contaminated specimens.

STABILITY OF REAGENT : The reagents are stable up to the end of the indicated date of expiry on the label, if stored at 20°C to 30°C, protected from light and contamination is avoided.

WASTE MANAGEMENT : For disposal of these biomedical waste refer local biosafety regulations.

WORKING REAGENT : The reagent is ready-to-use.

ASSAY PROCEDURE :

	Blank	Sample
Reagent	1000 µl	1000 µl
Distilled Water	10 µl	----
Sample	----	10 µl

Mix well and allow to stand at 37°C for 5 minutes then read absorbance Reagent blank.

ASSAY PROCEDURE :

PARAMETERS FOR INSTRUMENT SETTING	
Reaction	End Point
Wavelength	546 nm
Temperature	37°C
Zero Setting	Reagent Blank
Factor	14.8
Units	g/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	5 minutes
Reference Range	12 to 16.3
Reagent Linearity	20

CALCULATION : Hemoglobin (g/dl) = (Abs of Sample – Abs of Blank) X 14.8

LINEARITY : Reagent is Linear up to 20 g/dl. Dilute the Sample appropriately and re-assay if Hemoglobin Aconcentration exceeds 20 g/dl. Multiply result with dilution factor.

REFRENCE NORMAL VALUE : 1 - 25 gm/dl
New Borns : 16 - 25 g/dl
Infants : 11 - 14 g/dl
Male : 13.9 - 16.3 g/dl
Female : 12 - 15 g/dl

QUALITY CONTROL: For Accuracy it is necessary to run known controls with every essay

SENSITIVITY / LIMIT DETECTION : The Lower Limit of detection is 0.1 g/dl

LIMITATION & PRECAUTIONS :
- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Before the assay bring all the reagents to room temperature.
- Avoid contamination of the reagent during assay process.
- Every time use new pipette-tips for pipetting out the reagents.
- These Reagent kits meant for laboratory/professional use only, not for Drug use.

BIBLIOGRAPHY :
Sir johm V. Dacie and S.M. Lewis., practical haematology., 8th edition.
Van Kampen E.J And Zijlstra W .G., Clinica.Acta., 6:538 (1961)

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PRECILAB REAGENTS & CHEMICALS PVT. LTD.
A / F-6 & F-8, Udyog Bhawan - 2, Plot K - 3, MIDC,
Ambernath (E), Thane, Maharashtra - 421506, INDIA.

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