

# HAEMOGLOBIN (2-25°C)

## (CYANMETHEMOGLOBIN)

CATALOGUE NUMBER	KIT SIZE (ml)
MPRHGB1	5x100ml (10x concentration)

### Intended Use:

For *In Vitro* diagnostic use by qualified laboratory personnel only.

Haemoglobin reagent is intended for quantitative determination of haemoglobin in whole blood.

### Clinical Significance:

Haemoglobin is a protein that contains iron and is responsible for the red colour in blood. Haemoglobin is responsible for transport of blood gases from lungs to tissues and vice versa. Lack of haemoglobin will result in a condition called anaemia. Increased levels of Haemoglobin can be seen in polycythemia.

### Test Principle:

Erythrocytes are lysed by a stromatolytic reagent in the presence of a detergent. This releases haemoglobin into the solution which is oxidised into methemoglobin by ferricyanide. Methemoglobin is then converted into a stable cyanmethemoglobin by the addition of potassium cyanide. The colour intensity is measured at 540nm which is directly proportional to the concentration of haemoglobin in the whole blood.

### Reagent Composition

REAGENT	COMPONENT
Haemoglobin Reagent R1	Potassium Ferricyanide
	Activator
	Potassium di hydrogen phosphate
	Sodium Azide & Triton X 100

### Reagent Preparation and Stability:

Haemoglobin Reagent R1 is supplied in concentrated form and must be diluted to generate a Working Reagent for assay. To 100 ml of the concentrated R1 reagent add 900 ml of distilled water. Mix well without formation of foam and allow the reagent to become homogeneous before use.

Haemoglobin Reagent is stable till expiry when stored at room temperature away from sun light.

### Sample / Sample Preparation / Sample Stability:

Collect whole blood into tubes with EDTA using standard aseptic venepuncture technique. Whole blood collected using EDTA is stable up to one week at 2 – 8°C.

### Assay Procedure:

WAVELENGTH	540 nm (520 – 550nm)
TEMPERATURE	Room Temperature
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Sample
Sample	-	20 µl
Working Reagent	5000 µl	5000 µl
Mix incubate at room temperature for 5 minutes. Measure final absorbance of the sample against the reagent blank.		

### Calculation:

Haemoglobin Concentration (g/dl) =  $\Delta \text{Abs Sample} \times 36.77$

### Performance Characteristics:

#### Linearity:

This method is linear up to a concentration of 20 g/dl.

Samples with haemoglobin values > 20 g/dl, should be diluted 1+1 with deionised water, re-assayed and the result multiplied by 2.

#### Interferences:

Falsely elevated values are found in lipaemic samples and those containing abnormal plasma proteins. Numerous drugs exert an in vivo effect to decrease haemoglobin in the sample.

#### Reference Range:

Adult Males	13.0 – 18.0 g/dl
Adult Females	11.0 – 16.0 g/dl
Children	10.0 – 14.0 g/dl
Newborns	14.0 – 23.0 g/dl

Each laboratory should establish its own mean reference range according to the population.

#### Application for Automated systems:

This reagent is suitable for use only on semi-automated systems and photometric systems. Not intended for automated systems.

### Quality Control and Calibration Material:

It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.

### Note:

The result from this test should not be used as the sole criteria for the diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

### References:

- Eilers R.J Am J Clin Path., 47: 212 (1967)
- Tietz N.W.Fundamentals of Clinical Chemistry 2<sup>nd</sup> Ed., W.B Saunders., Philadelphia, p 411 (1976).

REF	Catalogue number	LOT	Temperature limitation
REF	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	Y	Use by Date
Manufacturer		Keep away from sunlight	

