

**GENESIS**

Instructions For Use

HEMOGLOBIN (Drabkin Reagent (9+1))

Cat no.	size
2101 301	2*20
2101 302	4*20

INTENDED USE

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

DIAGNOSTIC CHARACTERISTICS

Hemoglobin levels can be used to determine the severity of anemia or polycythemia. Higher than normal levels of hemoglobin may indicate dehydration or lung disease; low levels of hemoglobin are associated with iron deficiency, vitamin and mineral deficiencies, renal disease, liver cirrhosis or cancer affecting the bone marrow.

PRINCIPLE OF THE METHOD

Hemoglobin is first oxidized by potassium ferricyanide into methemoglobin which is converted into cyanmethemoglobin by potassium cyanide. The absorbance of the cyanmethemoglobin is monitored at 546 nm.

COMPOSITION

REAGENT(R)	
Potassium ferricyanide	0.6 mmol/L
potassiumcyanide	0.77 mmol/L
preservative	1%

STORAGE

Store at room temperature.

Reagent stable until the expiration date shown on the vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Working reagent: (9 Part d.w + 1 part Drabkin Reagent)

ADDITIONAL EQUIPMENT

1. Accurate pipetting devices
2. Test tubes/rack
3. Timer
4. Spectrophotometer able to read at 546 nm.

SPECIMEN

1. Whole blood with EDTA as an anticoagulant is recommended.
2. The specimens may be collected also with heparin, citrate or oxalate as anticoagulants.
3. If capillary blood is used, exercise care to avoid coagulation.
4. Hemoglobin in whole blood collected with EDTA appears stable for one week at room temperature (15 - 30°C).

Precautions and Warnings

Do not ingest or inhale. 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.

Symbols in Product Labeling	
EC	Authorized Representative
REP	For in-vitro diagnostic use
IVD	Catalogue number
REF	Lot number
LOT	Consult instructions for use
CE	Expiration date
	CAUTION, consult instructions for use
	Manufactured by
	Temperature Limit

PROCEDURE

1. Pipette into labeled test tubes:

	Sample
REAGENT(R)	5.0 ml
Sample	20 μ L

2. Shake vigorously and immediately, then leave the test for 10 min at 20° to 25°C

3. Measure absorbance of A specimen at 546 nm.

CALCULATIONS

Haemoglobin concentration (g/dL) = A specimen x 36.77

Haemoglobin concentration (mmol/L) = A specimen x 22.83

REFERENCE VALUES

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

-Factors such as age, race, exercise, season and altitude are reported to influence the values of normal ranges.

- The above range should serve only as a guideline.

- Each laboratory should establish its own range.

QUALITY CONTROL

The reliability of test results should be monitored routinely using suitable quality control materials (normal and abnormal) analyzed in the same manner as the Unknowns. Failure to achieve assayed values of freshly prepared control sera should be thoroughly investigated before patient values are reported.

METROLOGICAL CHARACTERISTICS 1. **Linearity:** 20.0 g/dL

2. **Comparison:** Studies conducted against a similar procedure yielded a coefficient of correlation of 0.992 with a regression equation of $y=0.985x + 0.098$ on samples with values from 8.7 to 18.2 g/dL (n=27) 3. **Precision:** Assays (n=25) of hemoglobin control material yielded a coefficient of variation of 1.1% at 8.9 g/dL and 1.4% at 12.6 g/dL.

- INTERFERENCES

1. Substances that cause turbidity will falsely elevate the hemoglobin value. These include lipids, abnormal plasma proteins (macroglobulinemia) or erythrocyte stroma.

2. A review by Young et al reveals the numerous drugs that exert an in vitro effect to decrease blood hemoglobin values.

BIBLIOGRAPHY

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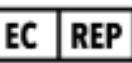
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