Hb DRABKIN

IVD CE

mtd DIAGNOSTICS

Quantitative determination of Hemoglobin in whole blood. Drabkin (Cyanmethemoglobin) method.

REF **CC1075** R1: 4x100 mL

METHOD AND PRINCIPLE

The red blood cells are broken down to get the hemoglobin into a solution. The free hemoglobin and hemoglobin derivates are transformed into hemoglobin cyanide by potassium hexacyano ferrate (III) and potassium cyanide. The intensity of the color is directly proportional to the hemoglobin concentration and can be determined photometrically.

CLINICAL SIGNIFICANCE

Hemoglobin is the protein molecule in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues to the lungs. The iron contained in hemoglobin is responsible for the red color of blood. Several methods exist for measuring hemoglobin.
Low hemoglobin is referred to as being anemic. There are many reasons for anemia. Some of the more common reasons are loss of blood (traumatic injury, surgery, bleeding colon cancer), nutritional deficiency (iron, vitamin B12, folate), bone marrow problems (replacement of bone marrow by cancer, suppression by chemotherapy drugs, kidney failure), and abnormal hemoglobin (sickle cell anemia).
Higher than normal hemoglobin levels can be seen in people living at high altitudes and in smokers. Dehydration produces falsely high hemoglobin which disappears when proper fluid balance is restored. Some other infrequent causes are lung disease, certain tumors, a disorder of the bone marrow known as polycythemia rubra vera, and abuse of the drug erythropoietin (Epogen) by athletes for blood doping purposes.

REAGENT COMPOSITION

Reagent (R1)

Potassium hexacyano ferrate	0.607 mmol/L
Potassium cyanide	0,767 mmol/L
Potassium hydrogen phosphate	1.030 mmol/L
Surfactant	0.05 %

REAGENT PREPARATION AND STABILITY

Liquid and ready to use Reagent, stable up to the end of the expiry, if stored at +18° to +25°C, protected from light and contamination is avoided. Do not freeze the reagents.

Discard if appear signs of deterioration:
- Presence of particles and turbidity.
- Failure to recover control values within the assigned range.

SPECIMEN

Capillary or venous blood. Venous blood should be anticoagulated with EDTA and mixed immediately. Hemoglobin is stable for 48 h at 2° - 8ºC and for 24 h to 15° - 25° C. Discard contaminated specimens.

PROCEDURE

Wavelength:	546 nm
Temperature:	20 – 25 °C / 37 °C
Measurement:	against Reagent Blank

Pipette as follow:

	Macro	Semi Micro	Micro
R1 Reagent	5000 µL	2500 µL	1000 µL
Sample, Std / Cal	20 µL	10 µL	5 µL

Mix well and read the Absorbance after minimum 3 minutes against the Reagent Blank. The colour remain stable for 30 minutes.

CALCULATION

Calculation Factor (reading at 546 nm in 1 cm cuvette):

	Macro	Semi Micro	Micro
Hb (g/dL) = Abs Sample	x 36.8	x 36.8	x 29.4
Hb (g/L) = Abs Sample	x 368	x 368	x 294
Hb (mmol/L) = Abs Sample	x 22.8	x 22.8	x 18.2

Calibrator:

Calculate a specific factor using a certificate calibrator:

Calculated Factor = Conc. Calibrator / Abs Calibrator
Hb = Abs Sample x Calculated Factor

Conversion Factor:
Hb (g/dL) x 10 = Hb (g/L)
Hb (g/dL) x 0.6198 = Hb (mmol/L)

QUALITY CONTROL

For internal quality control the use of control blood is recommended. Each laboratory should establish corrective action in case of deviations in control recovery.

EXPECTED VALUES

The normal ranges for hemoglobin depend on the age and, beginning in adolescence, the sex of the person. The normal ranges are:

Hemoglobin		g/dL	g/L	mmol/L
In fetal blood				
18-20 weeks		11.5 +/- 0.78	115+/- 7.8	7.13 +/- 0.48
21-22 weeks		12.3 +/- 0.89	123+/- 8.9	7.63 +/- 0.55
23-25 weeks		12.4 +/- 0.77	124 +/- 7.7	7.69 +/- 0.48
26-30 weeks		13.4 +/- 1.17	134 +/- 12	8.31 +/- 0.75
In cord blood		13.5-20.5	135-205	8.37-12.7
In Total blood				
0-5 months		13.4-19.8	134-198	8.31-12.28
1 months		10.7-17.1	107-171	6.63-10.6
2 months		9.4-13.0	94-130	5.83-8.06
4 months		10.3-14.1	103-141	6.39-8.74
6 months		11.1-14.1	111-141	6.88-8.74
9 months		11.4-14.0	114-140	7.07-8.68
12 months		11.3-14.1	113-141	7.01-8.74
1-2 years		11.0-14.0	110-140	6.82-8.68
2-5 years		11.0-14.0	110-140	6.82-8.68
5-9 years		11.5-14.5	115-145	7.13-8.99
9-12 years		12.0-15-0	120-150	7.44-9.3
12-14 years	M	12.0-16.0	120-160	7.44-9.92
	F	11.5-15.0	115-150	7.13-9.3
15-17 years	M	11.7-16.6	117-166	7.25-10.29
	F	11.7-15.3	117-153	7.25-9.49
18-44 years	M	13.2-17.3	32-173	8.18-10.73
	F	11.7-15.5	117-155	7.25-9.61
45-64 years	M	13.1-17.2	131-172	8.12-10.66
	F	11.7-16.0	117-160	7.25-9.92
65-74 years	M	12.6-17.4	126-174	7.81-10.79
	F	11.7-16.1	117-161	7.25-9.98

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the Hemoglobin results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

PERFORMANCE

Precision

Intra-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	11.1	0.09	0.77
Sample 2	13.9	0.16	1.13
Sample 3	17.6	0.16	0.93

Inter-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	6.0	0.41	6.75
Sample 2	12.6	0.15	1.20
Sample 3	18.4	0.26	1.39

Method Comparison (Accuracy)

A comparison of **MTD Diagnostics** Hb Drabkin (y) with a commercially available test (x) using 60 samples gave following results:

y = 1.001 x – 0.289 r = 0.967

The analytical performances have been generated using an automatic instrument. Results may vary depending on the instrument.

Linearity: 25 g/dL.
Sensitivity: 0,5 g/dL.

SPECIFICITY / INTERFERENCES

No interference was observed by ascorbic acid up to 50 mg/dL, bilirubin up to 20 mg/dL and lipemia up to 200 mg/dL triglycerides. For further information on interfering substances refer to Young DS.

NOTES

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PRECAUTIONS

R1 contains Potassium cyanide - (CAS No) 151-50-8 - (EC no) 205-792-3 - (REACH-no) 01- 2119486407-29 - Xn; R20/21/22 - R52/53
R20/21/22 – (H301+H311+H331) Harmful by inhalation, in contact with skin and if swallowed
R52/53 (H412)- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
The products do not contain dangerous substances or mixtures, according to the EC Regulation n ° 1272/2008 or their concentrations are such as not to be considered persistent, bioaccumulative or toxic (PBT). The product is classified and labeled in accordance with EC directives or respective national laws. Sodium azide, less than 0.1%.
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.
FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY

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Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.