IVD

CE en

# Hemoglobin

## Cyanohemiglobin Method
## According to DIN 58931 (modified)



## Intended Purpose

The haemoglobin reagent is used for the spectrophotometric determination of haemoglobin in blood with the cyanhaemiglobin method also called haemoglobin-cyanide method (= reference method). It is a ready-to-use reagent and is suitable for all standard photometers and laboratories.

## Principle

This reagent quantitatively converts hemoglobin derivatives (except verdoglobin) contained in the blood (erythrocytes) into hemoglobin cyanide.

This reaction is completed within 3 minutes. The formed dye (hemoglobin cyanide) is very stable and can be quantitatively measured in a photometer.

## Reagents

The reagent is ready for use and stable at +15 ... +25 °C until the stated expiry date. Always keep the bottle well closed and free of contamination after opening. Store the reagent protected from frost as well as direct light (sun, UV neon light).

### *Risks and Safety*

Please observe the necessary precautions for use of laboratory reagents and body fluids. Applications should be performed by expert personnel only. Follow the national and laboratory internal guidelines for work safety and infection control. Wear suitable protective clothing and disposable gloves while handling.

It is important to ensure effective protection against infection according to laboratory guidelines.

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For additional and general safety information please see details on the label and the corresponding Safety Data Sheet (SDS).

Download by QR code or link: www.sds-id.com/100033-5

### *Contents / Main Components*

| | | | |
|---|---|---|---|
| 004001-1010 | 1× | 1.0 l | Hemoglobin Reagent |
| 004001-1025 | 1× | 2.5 l | Hemoglobin Reagent |
| Cont. | 0.8 mmol/L cyanide, 0.61 mmol/L potassiumhexacyanoferrat(III), phosphat buffer pH = 7.40, detergent / lysis reagent / stabilizer. | | |

The above products are not approved for free hemoglobin (fHb).

Please only use the reagents designated for fHb for this purpose.

Additionally required or recommended materials

| | | | |
|---|---|---|---|
| 004623-0005/5 | 5× | 5.0 mL | Hemiglobincyanide Calibrating Standard |
| Cont. | c = 1:251 corresponds to 10.0 g/dL Hb = 1.55 mmol/L Hb | | |

## Sample Material

Capillary blood: Process immediately.

EDTA blood ($K_2$- or $K_3$-EDTA): Stability 7 days at +4 °C

### *Reference Ranges*

| | [g/dl] | [mmol/l] |
|---|---|---|
| Females: | 11.0 ... 16.0 | 6.83 ... 9.93 |
| Males: | 13.0 ... 18.0 | 8.07 ... 11.2 |
| Yearlongs: | 10.0 ... 14.0 | 6.21 ... 8.69 |
| Nurselings: | 12.0 ... 16.0 | 7.45 ... 9.93 |
| Neonates: | 14.0 ... 23.0 | 8.69 ... 14.8 |

## Procedure

Wavelength: ..... 540 nm, Hg 546 nm
Optical path length: ..... 10 mm
Temperature: ..... 20 ... 37 °C
Measurement: ..... against reagent

### *Dilution 1 : 251*

Please note that the precision decreases with the blood volume when pipetting manually.

| Dispense into tube/cuvette: | | Macro | Semi | Micro |
|---|---|---|---|---|
| R | Hemoglobin reagent | 5.0 ml | 2.5 ml | 1.25 ml |
| SA | Blood | 20.0 µl | 10.0 µl | 5.0 µl |

Flush pipette tip thoroughly by repeatedly filling with reaction mixture. Mix, wait at least 3 minutes, and then determine the extinction of the sample against Hb reagent.

## Analysis / Calculation

Hemoglobin concentration:

$E_{SA}$ × 36.77 = g/dL Hb

$E_{SA}$ × 367,7 = g/L Hb

$E_{SA}$ × 5,70 = mmol/L Hb

$E_{SA}$ × 22,82 = mmol/L $Hb_{(Fe)}$ *

* Unusual unit for Hb monomer.

Conversion:

g/dl Hb × 0,155 = mmol/L Hb

g/dl Hb × 0,621 = mmol/L $Hb_{(Fe)}$ *

* Unusual unit for Hb monomer.

Nomenclature

R = Reagent
SA = Sample
$E_{SA}$ = Extinktion/Absorption Sample

## Quality Control

To verify precision and accuracy of the method, use of a control or control blood with reference values for the cyanohemiglobin method (= basic reference method) is recommended



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## Capability Characteristics

### *Limitations*

This test can be used to determine concentrations up to 50 g/dL (up to 31 mmol/L).

Interferences

No significant interference of icteric samples up to 80 mL/dL bilirubin. Lipemic samples result in increased values.

### *Precision**

| Intra-assay n = 20 | Mean [g/dl] | SD [g/dl] | CV [%] |
|---|---|---|---|
| Sample 1 | 12.81 | 0.07 | 0.57 |
| Sample 2 | 18.34 | 0.12 | 0.67 |
| **Inter-assay n = 20** | **Mean [g/dl]** | **SD [g/dl]** | **CV [%]** |
| Sample 1 | 12.96 | 0.10 | 0.74 |
| Sample 2 | 18.36 | 0.14 | 0.76 |

### *Correlation**

When comparing this reagent (y) to another reagent used in the reference method *1) (x), the following result was obtained with n = 50 samples: y = 1.016 × + 0.057; r = 0.998.

* The results of precision and correlation were determined using the semi-micro method and dilution using automatic dilutor.

## Notes

For professional use only.

This product information exclusively pertains to the reagent described here. In particular, this product information cannot be applied to reagents from other manufacturers.

Simple photometers can be calibrated with our hemoglobin cyanide calibration standard 10.0 g/dl Hb; following the manufacturer's instructions/guidelines. This standard can also be used to run a function check on your photometer.

### *Drabkin's Reagent*

Drabkin's Reagent, which is mainly used in the U.S.A., can be replaced by this improved hemoglobin reagent. Drabkin's contains a low stable carbonate buffer system. The use is identical.

### *Classifications*

*EU: EDMA: 13 01 02 01 00; IVD (in vitro diagnostic medical device)*

### *Support / Information service*

For methodological and technical support, please contact us by E-Mail at support@bioanalytic.de.

Periodically check for updates of this product information on our website.

If a serious incident has occurred during or as a result of use, please report it to the manufacturer and/or its authorized representative and to your national authority.

### *Feedback*

Information from users can be reported to support@bioanalytic.de.

Suggestions for further developments will be considered.

### *Waste Management*

Please observe your national laws and regulations.

Used and expired solutions must be disposed of in accordance with your local regulations.

Inside the EU, national regulations apply that are based on the current, amended version of Council Directive 67/548/EEG on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Decontaminated packaging can disposed of as household waste or recycled, unless otherwise specified.

Unused Remains

These are usually hazardous wastes that must be recycled or disposed of. After consultation we take back such residual materials in the original container.

## Literature & Footnotes

Legends for the graphic symbols and tags used follow relevant norms or are available on our internet pages.


[1] Henry, R.J.: Clinical Chemistry, Principles and Technics, S.1134. Harper and Row, New York.

[2] DIN 58931:1995-2, Hämatologie - Bestimmung der Hämoglobinkonzentration im Blut - Referenzmethode.

[3] Williams, W.J., Beutler, E., Erslev, A.J., Lichtman, M.A., Hematology, 4. Aufl. McGraw-Hill, New York (1990: 9).

[4] Thomas, L. Labor und Diagnose, 4. Aufl. Med. Verlagsgesellschaft Marburg (1995: 597, 401)

[5] Rick, W., Klinische Chemie und Mikroskopie, 6. Aufl. Springer-Verlag, Berlin-Heidelberg (1972: 115)


*1) Reference method = Cyanhemiglobin-Method according to DIN 58931