

haemodirect®

kit for determining blood
haemoglobin levels

IVD

CE



General Information

haemodirect® is a kit for determining blood haemoglobin levels based on the AHD method⁽¹⁾. haemodirect® offers a number of decisive advantages over traditional methods (e.g. cyano-methaemoglobin) on account of the following properties:

- **Calibration with the help of a defined chemical control standard**
The defined chemical control standard puts an end to problems arising from the short shelf-life of biological controls (so called "whole blood controls"), which are essential to other methods.
- **Stability of the reagents and calibrators**
The substances remain stable over long periods under extreme climate conditions.
- **High level of accuracy**
Deviations from absolute value caused by serum lipids, serum proteins or corpuscles are extremely small.



- **Linearity of measuring range**
The linear measuring range of the AHD method enables precise and reliable estimates of haemoglobin concentrations ranging between 0.5 g/dl and 30 g/dl.
- **Covers all clinically relevant haemoglobin derivatives**
All clinically relevant haemoglobin species including foetal haemoglobin, sulphaemoglobin and carboxyhaemoglobin are measured.
- **Swift reaction time**
Results available fast - this will have a particular impact on the clinically relevant carboxyhaemoglobin.
- **Minimal toxicity of reagents and calibrators**
In their existing concentrations all the substances used are practically non-toxic and therefore do not require special storage and disposal. haemodirect® is not recognised as a dangerous product under EU-guideline 67/548/EWG and the German Hazardous Substances Act (Gefahrstoffverordnung).
- **Low cost**
Aside from its own reagent, the kit contains the calibrators required for calibrating and quality control. There are no added costs for biological controls ("whole blood controls").

Measuring principle

haemodirect® is based on the AHD method for quantifying haemoglobin. The reagent forms a coloured complex with haemoglobin and its variants, which can be detected photometrically. The colour intensity of the complex is proportional to the total haemoglobin concentration in the test sample. A 6-point calibration is used, in keeping with international guidelines (in particular those of the US Federal Drug Administration).

Applications

haemodirect® has been developed and certified for measurement of haemoglobin concentrations in blood tests as part of in vitro diagnostics. However, haemodirect®'s properties also make it suitable for determining haemoglobin concentrations in tests on other biological fluids (urine, aspirates, effluents). In routine medical diagnostics, for example, haemodirect® is used regularly:

- to detect anaemia or hyperglobulia
- to monitor the course and response to therapy of anaemia and hyperglobulia
- to screen groups at risk of iron deficiency (pregnant women, infants, blood donors, haemodialysis patients, diabetics, sportswomen)
- in point-of-care testing, on suspicion of acute bleeding and haemorrhaging
- to monitor the progress of diseases caused by infections or parasites
- to determine blood loss, e.g. in the case of paranaemia or on suspicion of occult bleeding

Properties

- 6-point calibration (6 standard solutions with different concentrations)
- Measuring range: 0.5 – 30.0 g/dl (5 – 300 g/l)
- Shelf-life of the reagents and calibrators: 1 year
- Comparison of methods:
Multicentric comparison (6 laboratories, 1107 samples) with the cyanmethaemoglobin method resulted in a correlation of $r = 0.983$ ($y = 0.98x + 3$)⁽²⁾
- Can be used with any photometer with adjustable wavelength

Bibliography

(1) Zander R, Lang W, Wolf HU (1989): The determination of haemoglobin as cyanhaemoglobin or as alkaline haematin D-575. Comparison of method-related errors; J Clin Chem Clin Biochem 27(4): 185–189.

(2) Moharram NMM, El Aouad R, Al Busaidy S, Fabricius A, Heller S, Wood WG, Wolf HU, and Heuck CC (2005), WHO Eastern Mediterranean Health Journal, in press.

Order information

Product: haemodirect®
Kit for determining haemoglobin levels
(400 tests)
Order no.: 25 010 0506

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