CompoLab TM Cuvettes

Catalog No. 9034050

Intended use
The CompoLab TM Cuvettes are designed for quantitative total hemoglobin determination in human blood donation settings, using capillary samples. The CompoLab TM Cuvettes are disposable microcuvettes for use only with a specially designed analyzer, the CompoLab TM Analyzer.
For in vitro diagnostic use only.

In-Vitro Diagnostic Directive
The CE marked CompoLab TM Cuvettes comply with the IVDD 98/79/EC.

Summary and Explanation of the test
The CompoLab TM System provides rapid and reliable measurements of total hemoglobin in one drop of blood. The system is based on photometric measurement of hemoglobin in unaltered whole blood and consists of a photometer and microcuvettes. The disposable microcuvette requires 10 µL sample volume and serves both as pipette and measuring cuvette. Cuvettes are ready for use upon removal from the package.

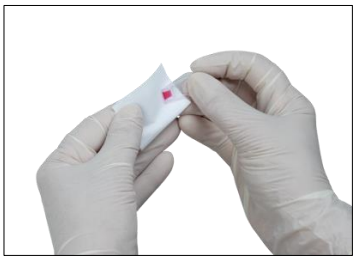
Principles of method/procedure
The system consists of an analyzer together with microcuvettes. A blood sample of approximately 10 µL is drawn into the cuvette by capillary action. The measurement takes place in the analyzer. The hemoglobin concentration is calculated from the measured absorbance at multiple wavelengths. A patented method compensates for light scattering. Turbidity is measured and compensated for at infrared wavelengths. The CompoLab TM System is standardized to the HiCN reference method (ICSH)[2]. The system is factory calibrated and needs no further calibration. The CompoLab TM Cuvette is made of Poly(methyl methacrylate) (PMMA) and contains no active reagents.

Warnings and precautions
The CompoLab TM Cuvettes are for in-vitro diagnostic use only. The CompoLab TM Cuvettes are for single use only. Always handle blood specimens as potentially infectious. Consult local environmental authorities for proper disposal.

Storage and handling of the CompoLab TM Cuvettes
The CompoLab TM Cuvettes are packed in re-closeable bags of 100 piece, 5 bags per box.
Store at 0°C to +50°C. Temperatures of -30°C to +70°C are temporarily permitted during transport (24 hours max.) as long as stored in the original package**.**
Use the CompoLab TM Cuvettes prior to expiry date (same expiry date for unopened or opened bag). Unused cuvettes should be stored in the original bag.

Specimen collection and handling
Capillary blood samples are used.

Procedure and instructions for use
For full instructions, please see the CompoLab TM System operating manual[1].

1. Take the cuvette out of the bag.
2. Hold the cuvette at the rear and bring the filling tip in contact with the blood. Avoid contaminating the outside of the optical eye.
3. Fill the cavity of the microcuvette completely. Do not refill the cavity of the microcuvette. If visible air bubbles occur in the optical eye of the cuvette (due to inadequate filling) the cuvette should be discarded and another sample be taken for the analysis.
4. When filled, wipe off excess blood outside of the microcuvette with a dry tissue. Do not touch the tip of the microcuvette!
5. Place the filled CompoLab TM Cuvette in the cuvette holder of the CompoLab TM Analyzer within 1 minute of filling. The cuvette fits with any side up.
6. Press the cuvette holder gently down until you feel a "click". The hemoglobin value will be displayed instantly.
7. Pull the cuvette out quickly after result appeared. Record the test result as soon as the check mark is shown.
8. Dispose the used cuvette according to local instruction for hazardous waste.
9. If the display should show an error code, please refer to the CompoLab TM System operating manual.

Limitations
A filled cuvette should be analyzed no longer than 1 minute after filling. A filled cuvette should be kept in a horizontal position. Do not re-measure a cuvette. Results deviating from the expected value should be confirmed with a laboratory reference method. WBC > $100x10^9$/L (21-$110x10^9$/L), Triglycerides > 10 mM (3.0-11.1 mM), PLT > 750 $x10^9$/L (598-794 $x10^9$/L), Microcytes < 80 fl (63-79 fl), Hb in Plasma > 10 g/L (1.0-11 g/L), COHb > 7 % (2.2-7.2 %), Bilirubin > 50 µmol/L (57-357 µmol/L), sO_2 (Oxyhemoglobin) < 40% (40-80%) have not been found to interfere (tested range in brackets).

A limited number of samples from individuals with sickle cell have been tested, the results were not influenced.

Performance characteristics
The light path length through the cuvette cavity, in combination with the CompoLab TM Analyzer, determines the exactness of the Hb measurement.
The CompoLab TM Cuvettes have a between lot imprecision of <0.1 g/dL (< 1 g/L) hemoglobin.
For details on the system performance, see CompoLab TM System operating manual[1].

Bibliography

1. CompoLab TM System operating manual.
2. Reference and Selected procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard NCCLS Document H15-A.

Symbols used

CE **CE mark**
Do not reuse
Use by
IVD **In-vitro diagnostic device**
REF **Catalog number**
LOT **Batch number**
Number of tests
Manufacturer
Storage-temperature
Read document-ation
Attention

Manufacturer:
Fresenius Kabi AG
61346 Bad Homburg
Germany

The soft copy of the Instructions for use / Operational Manual (ENG/FRE) is available at www.fresenius-kabi.ca
La copie électronique du mode d'emploi / manuel opérationnel (ENG / FRE) est disponible sur www.fresenius-kabi.ca