

Prospect Haemoglobin Cuvettes are only for use with the Prospect Haemoglobin Analyser, for the quantitative determination of haemoglobin in fresh whole blood. Please read the Operating Manual for the proper use of the analyser.

INTENDED USE

The Prospect Haemoglobin Analyser is designed for the quantitative determination of haemoglobin in whole blood e.g. for anaemia screening and monitoring in blood donor clinics. The Prospect Haemoglobin Analyser is for in vitro diagnostic use only and must only be used by properly trained personnel.

Summary and Explanation of the test

The Prospect Haemoglobin Analyser provides rapid and reliable quantitative measurements of total haemoglobin in a single drop of fresh whole blood. The analyser is based on spectrophotometric measurement of haemoglobin in unaltered whole blood and consists of a spectrophotometer and cuvettes. No active reagents are used, the haemoglobin concentration is calculated from the measured absorbances at multiple wavelengths. A patented method compensates for light scattering. Turbidity is measured and compensated for at infrared wavelengths. The Prospect Haemoglobin Analyser is standardised to the HiCN (cyanmethaemoglobin) reference method (ICSH). The analyser is factory calibrated and needs no further calibration.

In-Vitro Diagnostic Directive

The CE marked Prospect Haemoglobin Cuvettes comply with the IVDD 98/79/EC directive.

CUVETTE

Prospect Haemoglobin Cuvette

The Prospect Haemoglobin Cuvette is made of plastic (PMMA) and contains no active reagents. The disposable cuvette requires 10µL sample volume and serves both as a pipette and a measuring vessel. Cuvettes are ready for use upon removal from the package. The blood sample is drawn into the cavity by capillary action.

Storage and handling of the Prospect Haemoglobin Cuvettes

The Prospect Haemoglobin Cuvettes are packed in re-sealable pouches each contacting 100 cuvettes. Store between 0°C to +50°C. Temperatures of -30°C to +70°C are temporarily permitted during transport as long as stored in the original package. Use the Prospect Haemoglobin Cuvettes prior to the expiry date. Unused Cuvettes should be stored in the original pouch.

Warnings and precautions

The Prospect Haemoglobin Cuvettes are for in-vitro diagnostic use only. The Prospect Haemoglobin Cuvettes are for single use only. Always handle blood specimens as being potentially infectious. Consult local environmental authorities for appropriate disposal in compliance with local health and safety guidelines.

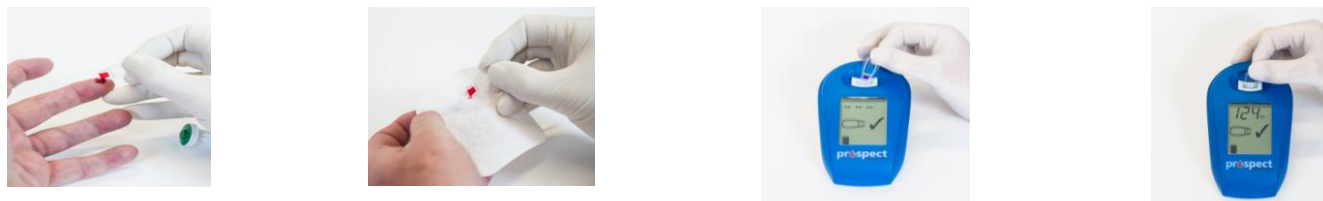
TEST PROCEDURE

Specimen collection and handling

Capillary, venous or arterial whole blood (EDTA and heparin) may be used. Sample tubes must be properly mixed.

Procedure and instructions for use

For full instructions, please refer to the Prospect Haemoglobin Analyser Operating Manual.



1. Take a cuvette out of the pouch.
2. Hold the cuvette at its rear end and bring the filling tip in contact with the blood. Avoid contamination of the outside of the optical 'eye'.
3. Fill the cavity of the cuvette completely. Do not refill the cavity of the cuvette. If visible air bubbles occur in the optical eye of the cuvette (due to inadequate filling) the cuvette should be discarded and another sample should be taken for the measurement.
4. When filled, wipe off the excess blood from the outside of the cuvette with a Prowipe.
5. Place the filled Prospect Haemoglobin cuvette into the cuvette holder of the Prospect Haemoglobin analyser.
6. Push the cuvette down into the cuvette holder for approx 1 second until a light appears and the analyser beeps.
7. Immediately remove the cuvette from the analyser. If you do not remove the cuvette, or hold/leave the cuvette in the analyser too long, the analyser will flash and you may see an E03 error.
8. The analyser will show the result on the display panel, along with a tick ✓. Make a note of the reading.
9. Dispose of the cuvette in a container for infectious waste.
10. The analyser can be re-set by holding down the cuvette holder for approx 1 second; Once again the tick ✓ symbol will appear.

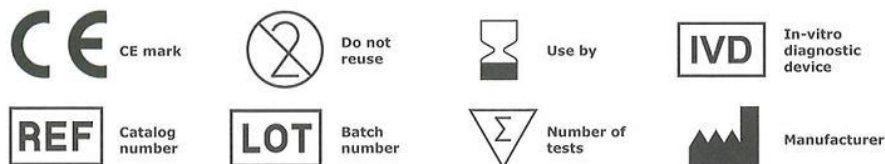
Limitations

The filled cuvette should preferably be analysed immediately and no longer than 1 minute after filling. Do not re measure a cuvette. Results deviating from the expected value should be confirmed with a laboratory reference method. WBC (439.8 x 10⁹), PLT (1096 x 10⁹/L), Microcytes (79 fl), Sickle Cells (439.8 x 10⁹), COHaemoglobin (16.9%), Haemolysis (40 g/L P-Hb), Triglycerides (27.7mM), Bilirubin (611 µmol/L), pH (7.2 – 7.7) have not been found to interfere, [highest tested concentration in brackets.] Slightly elevated values have been shown for Thalassaemia patients.

Performance Characteristics

The optical path length through the cuvette cavity, in combination with the Prospect Haemoglobin analyser, determines the precision and accuracy of the haemoglobin measurement. The Prospect Haemoglobin Cuvettes have a between-lot imprecision of ≤1 g/L haemoglobin. For details on the analyser performance, refer to the operating manual.

Symbols used



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