prospect HAEMOGLOBIN Control HBT

Intended use

The Prospect Haemoglobin Control HBT is for professional use in the verification of the precision and accuracy of Prospect Haemoglobin Analysers and Prospect Haemoglobin Cuvettes. For in vitro diagnostic use only.

IVD Medical Device

The CE marked Prospect Haemoglobin Control HBT complies with the IVDD 98/79/EC directive and applicable US FDA regulations.

Summary and Principle

Prospect Haemoglobin Control HBT is a non-biological quality control material with a pre-determined optical density corresponding to assayed levels of haemoglobin in fresh whole blood. Please refer to local guidelines for recommended frequency of use.

Reagents

The Prospect Haemoglobin Control HBT is produced in three concentrations that correspond to three levels of haemoglobin in fresh whole blood. Each vial contains 1.9 ml of a solution of a red dye (Rhodamine) in purified water. The reagent does not contain any material of human or animal origin.

Warnings and Precautions

For in-vitro diagnostic use only. Do not use beyond the expiry date. This product contains chemical synthetic dye (concentration <0.2%). Although Prospect Haemoglobin Control HBT does not contain biological material, it must be handled according to good laboratory practice with the same precautions that would be used with blood samples. Avoid contact with skin and eyes, do not swallow. Dispose of all used material according to local guidelines. Consult local environmental authorities for proper disposal.

Storage and Stability

Unopened, stored at +2°C to +25°C (+35°F to +77°F), the product is stable until the expiry date shown on the label. Temperatures of –30°C to +70°C (-22°F to +158°F) are temporarily permitted during transport (24 hours max) as long as stored in the original package. Do not expose the vials to direct sunlight!
After opening and when properly recapped, the product is stable for 60 days stored at +2°C to +35°C (+35°F to +95°F).

Procedure and Instructions for use

Perform measurements according to the instructions for patient samples described in the Prospect Haemoglobin operating manual and the Prospect Haemoglobin Cuvettes package insert.

1. Allow the control solution to reach operating temperature of the Prospect Haemoglobin system.
2. Mix the control material by gentle inversion 5 times immediately before sampling.
3. Open the vial and discard the first drop.
4. Dispense a drop of the control to be measured onto a hydrophobic surface (e.g. Prowipe) and immediately fill the cuvette.
5. Place the cuvette in the cuvette holder of the Prospect Haemoglobin analyser and measure.
6. Wipe any excess material from the vial and cap with a prowipe and immediately recap the vial tightly.
7. If the measured value falls outside the expected range, verify that the test was performed correctly. Check the operator technique, expiry date and storage conditions for both the controls and cuvettes. Repeat the test. If the control still does not perform as expected, contact Prospect Diagnostics Ltd.

Expected results

The expected ranges provided are derived from replicate measurements on factory calibrated Prospect Haemoglobin analysers. Results obtained should fall within the expected range specified for the control and are only valid on Prospect Haemoglobin analysers.

For further information or technical assistance,
please contact Prospect Diagnostics Ltd on 01246 292955.

Symbols used:

CE	CE Mark		Consult instructions for use		**Manufacturer:** DiaSpect Medical GmbH Von-Canerin-Str. 1 D-63877 Sailauf Germany Phone: +49 6093 99668960 Fax: +49 6093 99668966 Email: service@diaspect.de
	Use by	LOT	Lot number		
REF	Reference number	IVD	In-vitro diagnostic device		