

# DiaSpect Control HBT



## Intended Use

The DiaSpect Control HBT may be used by professionals in the verification of the precision and accuracy of DiaSpect hemoglobinometers and DiaSpect Hemoglobin Cuvettes. For in vitro diagnostic use only.

## IVD Medical Device

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

## Summary and Principle

DiaSpect Control HBT is a non-biological quality control material with pre-determined optical density corresponding with assayed levels of human hemoglobin. Please refer to local guidelines for recommended frequency of use.

## Reagents

The DiaSpect Control HBT is produced in three concentrations that correspond to three levels of human hemoglobin. 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 expiration date. This product contains chemical synthetic dye (concentration <0.2 %). Although DiaSpect Control HBT does not contain biological material, it must be handled according to good laboratory practice with the same precautions used with patient blood samples. Avoid contact with skin and eyes, do not swallow. Dispose of all used material in a suitable way. 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 bottles to direct sunlight!

After opening, 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 instructions for patient samples described in the DiaSpect hemoglobinometer operating manual and DiaSpect Hemoglobin Cuvettes package insert.

1. Allow the control solution to reach operating temperature of the DiaSpect hemoglobinometer 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. parafilm) and immediately fill the cuvette.
5. Place the cuvette in the cuvette holder of the DiaSpect hemoglobinometer and measure.
6. Wipe any excess material from the vial and cap with a clean tissue and recap the vial tightly, immediately.
7. If the measured values fall outside the expected range, verify that the test was performed correctly. Check operator technique, expiration date and storage conditions for controls and cuvettes. Repeat the test. If the control still does not perform as expected, contact DiaSpect or local representative.

## Expected results

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

For further information or technical assistance, please contact DiaSpect or local representative.

Symbols used:

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

(label)