**DiaSpect Hemoglobin Cuvettes**

Catalog No. 90C.0001

**DiaSpect Hemoglobin Cuvettes are for use only with the DiaSpect Hemoglobin measuring device, for quantitative determination of hemoglobin in whole blood. Please read the Operating Manual for proper use of the system.**

**INTENDED USE**
The DiaSpect Hemoglobin System is designed for quantitative determination of hemoglobin in whole blood for anemia screening and monitoring in blood donation settings. The DiaSpect Hemoglobin System is for in vitro diagnostic use only and must be used by properly trained personnel only.

**Summary and Explanation of the test**
The DiaSpect Hemoglobin System provides rapid and reliable measurements of total hemoglobin in one drop of blood. The system is based on spectrophotometric measurement of hemoglobin in unaltered whole blood and consists of a spectrophotometer and microcuvettes. No active reagents are used, the hemoglobin 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 DiaSpect Hemoglobin System is standardized to the HCN reference method (ICSH). The system is factory calibrated and needs no further calibration.

**In-Vitro Diagnostic Directive**
The CE marked DiaSpect Hemoglobin Cuvettes comply with the IVDD 98/79/EC.

### CUVETTE
**DiaSpect Hemoglobin Cuvette**
The DiaSpect Hemoglobin Cuvette is made of plastic (PMMA) and contains no active reagents.
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. The blood sample is drawn into the cavity by capillary force.

**Storage and handling of the DiaSpect Hemoglobin Cuvettes**
The DiaSpect Hemoglobin 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 as long as stored in the original package. Use the DiaSpect Hemoglobin Cuvettes prior to expiry date. Unused cuvettes should be stored in the original bag.

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

**TEST PROCEDURE**
**Specimen collection and handling**
Capillary, venous or arterial blood (EDTA and heparin) may be used. Sample tubes must be mixed properly.

**Procedure and instructions for use**
For full instructions, please see the DiaSpect Hemoglobin Measurement System Operating Manual.

1. Take the cuvette out of the bag.
2. Hold the cuvette at its rear end 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 wipe the filling slit of the microcuvette!
5. Place the filled DiaSpect Hemoglobin Cuvette in the cuvette holder of the DiaSpect Hemoglobin Analyzer. The cuvette fits with any side up.
6. Close cuvette holder by tapping it, the holder closes automatically and the measuring starts. The display panel shows an hourglass symbol.
7. After about 5 seconds the photometer will show the result on the display panel. Make a note of the reading.
8. Remove the measured cuvette from the holder and dispose it in a container for infectious waste.
9. If the display should show an error code, please refer to the operating manual.

### Limitations
The filled cuvette should preferably be analyzed immediately and 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 (439.8 x 10³), PLT (1096 x10³/L), Microcytes (79 fl), Sickle Cells (439.8 x 10³), COHemoglobin (16.9 %), Hemolysis (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 Thalassemia patients.

### Performance characteristics
The light path length through the cuvette cavity, in combination with the DiaSpect Hemoglobin analyzer, determines the exactness of the Hb measurement. The DiaSpect Hemoglobin Cuvettes have a between lot imprecision of < 1 g/L hemoglobin.

For details on the system performance, see operating manual.

### Symbols used
- **CE mark**: European conformity mark. The device is CE marked and complies with the IVDD 98/79/EC.
- **Do not reuse**: The device is for single use only.
- **Use by IVD diagnostic device**: The device is for in-vitro diagnostic use only and must be used in a device certified for in-vitro diagnostic use.
- **REF Catalog number**: Catalog number of the device.
- **LOT Batch number**: Batch number of the device.
- **Number of tests**: The number of tests that can be performed with the device.
- **Manufacturer**: DiaSpect Medical GmbH, Von-Cancrin-Str. 1, D-63877 Sailauf, Germany.

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