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## HemoCue® WBC Microcuvettes

The system consists of the HemoCue WBC Analyzer together with HemoCue WBC Microcuvettes. Please read the Operating Manual for proper use of the system<sup>1</sup>.

### Intended Purpose/Intended Use

The HemoCue WBC system is indicated for use for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC system is for *In Vitro* Diagnostic use only. The HemoCue WBC Analyzer is only to be used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for use in clinical laboratories and for point-of-care settings.

### IVD Medical Device Directive

The HemoCue WBC system complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

### Principles of the Method/Procedure

#### *Principle of the Method*

A hemolyzing agent lyses the red cells in the microcuvette and a staining agent colors the white cells. An image is taken of the stained white cells and the number of cells is counted by image analysis in the analyzer.

#### *Principle of the Procedure*

The microcuvette serves as a sample container and reaction chamber. The microcuvette is for single-use only. A blood sample of approximately 10  $\mu\text{L}$  is drawn into the cavity by capillary action. The microcuvette is placed in the analyzer. The result is obtained within 3 minutes. The system was designed and developed to establish agreement with the manual light microscopy method for white blood cell count. The system is factory calibrated and needs no further calibration.

### Composition

The microcuvette is made of polystyrene plastic and contains the following reagent: <20  $\mu\text{g/g}$  cuvette methylene blue, <500  $\mu\text{g/g}$  cuvette saponin, <400  $\mu\text{g/g}$  cuvette Surfynol 465, <400  $\mu\text{g/g}$  cuvette Triton X-100.

### Warning and Precautions

The microcuvettes are for *In Vitro* Diagnostic use only. Always handle blood specimens with care as they may be infectious. Consult local environment authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvettes are for single-use only.

### Storage and Handling of the HemoCue WBC Microcuvettes

The microcuvettes are to be stored at 15–35 °C (59–95 °F), < 90 % non-condensing humidity. Once the seal of the vial is broken, the microcuvettes are stable for 3 months. An unopened vial of microcuvettes can be stored for a shorter period of time (4 weeks) outside the specified storage conditions down to 0 °C (32 °F) and up to 50 °C (122 °F), < 90 % non-condensing humidity. Allow the microcuvettes to reach 15–35 °C (59–95 °F) before use. Use the microcuvettes prior to the expiration date that is printed on the package. Keep the vial properly closed. All unused microcuvettes should remain in the original package.

### Specimen Collection and Preparation

Capillary or venous whole blood may be used. EDTA anticoagulant may be used, preferably in solid form to avoid dilutional effects. Mix all specimen tubes thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 10–20 times by hand.

The specimen can be stored at room temperature (15–35 °C, 59–95 °F), or in a refrigerator (2–8 °C, 35–46 °F) for 48 hours. If the specimen has been stored in a refrigerator, it will be viscous and the blood should be allowed to warm up to room temperature before mixing.

## Procedure

Please read the Operating Manual for proper use of the system<sup>1</sup>.

## Limitations of the Method

- The measurement should be made as soon as possible, but within 40 seconds after the blood has been drawn into the microcuvette.
- Do not remeasure the filled microcuvette.
- Mixing samples for an extended period may affect the result.
- Results above the measuring range will be displayed as HHH. Results below the measuring range will be displayed as LLL.
- Studies have shown that patient samples with > 2 % nucleated red blood cells (NRBCs) may give falsely elevated white blood cell count.

For specific performance characteristics, please refer to the Operating Manual<sup>1</sup>.

## Bibliography

- HemoCue WBC Operating Manual

## Symbols Used



Attention, see instructions for use



CE mark



Catalog number



*In Vitro* diagnostic medical device



Date of opening



Batch code



Do not reuse



Temperature limits



Use by  
(Year Month Day)

**Once opened – Expiry date**

Open vial expiry date.  
Must not exceed the  
“Use by” date.

**PATENTED OR  
PATENT PENDING**

The product is  
protected by the  
following patents  
(or Patent Pending)

## Manufacturer

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