



Distributed by: **Test Yourself At Home™**
San Diego, CA 92121
tel 858-481-5031
toll free 888-882-7739
www.cliawaived.com

GB/US

For veterinary use of the HemoCue WBC system

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 system¹.

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.

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 μ 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 µg/g cuvette methylene blue, <500 µg/g cuvette saponin, <400 µg/g cuvette Surfynol 465, <400 µg/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. 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

Collect the blood sample according to normal procedures. Venous or capillary samples can be used. When collecting blood in tubes with anticoagulantia, make sure to fill the tubes with the correct amount of blood, and mix the samples thoroughly.

Note: For canine blood only use blood without additives. Make sure to measure the sample directly in order to avoid coagulation.

Please read the Operating Manual for proper use of the system¹.

Limitations of the Method

- a) The measurement should be made as soon as possible, but within 40 seconds after the blood has been drawn into the microcuvette.
- b) Do not remeasure the filled microcuvette.
- c) Mixing samples for an extended period may affect the result.
- d) Results above the measuring range will be displayed as HHH. Results below the measuring range will be displayed as LLL.
- e) 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 Manual¹.

Bibliography

1. HemoCue WBC Operating Manual

Test Yourself At Home.com™

Symbols Used



Caution



CE mark



Temperature limits



Do not reuse



Date of opening



Use by
(Year Month Day)



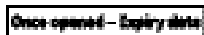
Consult instructions
for use



Catalog number



Batch code



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



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

HemoCue Distributor USA

Distributed by: **Test Yourself At Home™**
San Diego, CA 92121
tel 858-481-5031
toll free 888-882-7739
www.cliawaived.com

Manufacturer

HemoCue AB
Box 1204
SE-262 23 Ängelholm
Sweden

Phone +46 775 70 02 10
Fax +46 775 70 02 12
E-mail info@hemocue.se
www.hemocue.com



A General Diagnostic Company