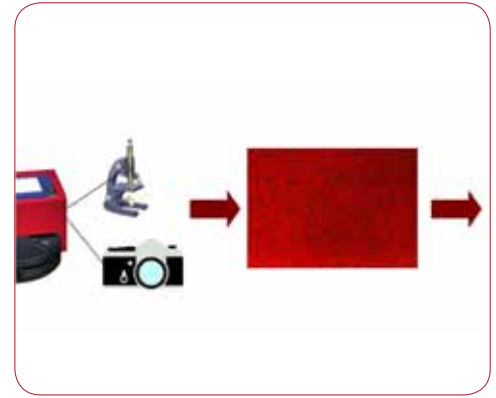


# Point of care diagnostic device for total WBC

Country of origin | Sweden

## Health problem addressed

Measuring white blood cells (WBC) can provide information which may aid in the diagnosis of infection, inflammatory diseases or leukemia and aid in judicious prescription of antibiotics. A WBC POC will be beneficial in rural settings to increase access of a vital test. The system is designed as a portable device to be used in rural settings or where near patient testing for WBC is of benefit. As only a small blood volume is needed it is useful also for small children and anemic patients.



## Product description

The system consists of an analyzer and single use cuvettes. One drop (10 $\mu$ L) of capillary or venous blood is drawn into the cuvette by capillary action. The portable analyzer consists of a microscope and a camera and the cells are counted by image analysis.

## Product functionality

The microcuvette serves as pipette, mixing and reaction chamber and the correct specimen volume is obtained by capillary action.

## Developer's claims of product benefits

No similar system exists which can be used by the intended user/environment. Automated cell counters or manual microscopy technologies are available at laboratories but requires laboratory educated staff and requires specimen to be transported. The suggested solution is performed as near patient testing. The WBC system will provide rural areas with increased availability to one of the most frequently used lab parameters. Instant results of the white blood cell count will facilitate more well informed decisions in several clinical situations and facilitate monitoring of diseases and treatment (for example in infections, HIV, inflammatory diseases etc.). Making the WBC more rapidly accessible to rural settings will improve healthcare as well as save costs and transportation time.

## Operating steps

1. Fill the cuvette. 2. Place it in the analyzer. 3. Result is available < 3 min.

## Development stage

The device is CE-marked and FDA 510(k) cleared. Besides internal evaluations, the accuracy of the device has been validated in 2 published studies: a study by Osei-Bimpong et al (Osei-Bimpong; Int Journal of Laboratory Hematology; 2008) and a study by Casey et al (Casey et al; Clinical Pediatrics, 2009).

## Future work and challenges

The company will use its well established distribution network to make the system available to the intended user. Through an extensive network the hemoglobin systems have been made widely available in developing regions, and has proved experience in bringing POC tests to rural settings including set up and local training. The main challenge lies in introducing and getting local acceptance of a new test and challenges regarding local decision making policies.

## User and environment

**User:** Physician, technician, nurse, midwife

**Training:** Required; provided by device distributors

**Maintenance:** Minimal; cleaning

## Environment of use

**Settings:** Rural, urban, ambulatory, primary (health post, health center), secondary (general hospital), tertiary (specialists hospital)

**Requirements:** Power supply

## Product specifications

**Dimensions (mm):** 120 x 135 x 183

**Weight (kg):** 0.6

**Consumables:** Yes

**Life time:** >7 years

**Shelf life:** >7 years

**List price (USD):** 624.50

**Other features:** Portable, single use consumables and reusable device

**Year of commercialization:** 2008

**Currently sold in:** US, Europe

Contact details Lena Wahlhed | Email lwa@live.se | Telephone +46 43 148 1311 | Fax +46 43 148 1225

[http://www.who.int/medical\\_devices](http://www.who.int/medical_devices)