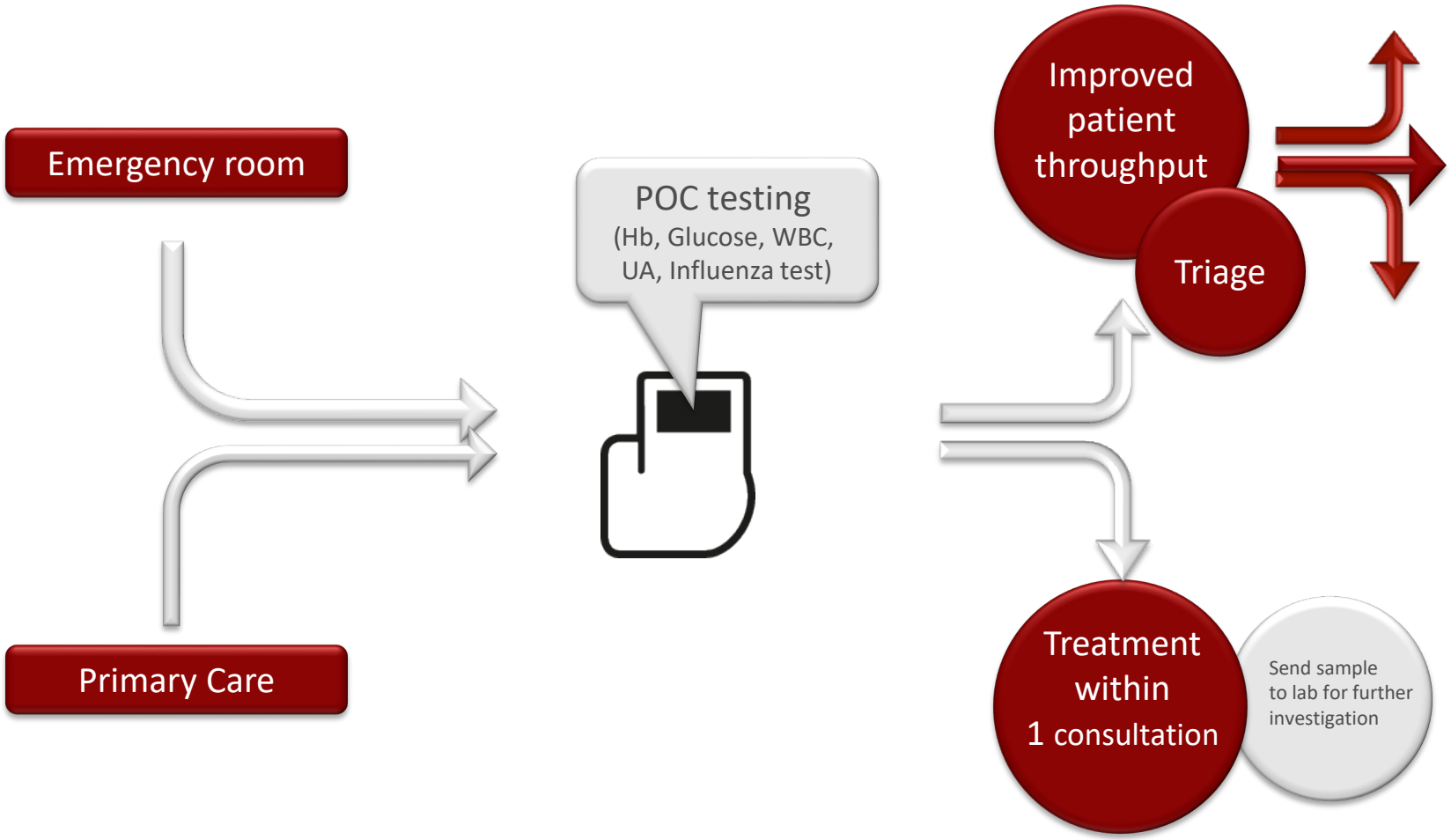
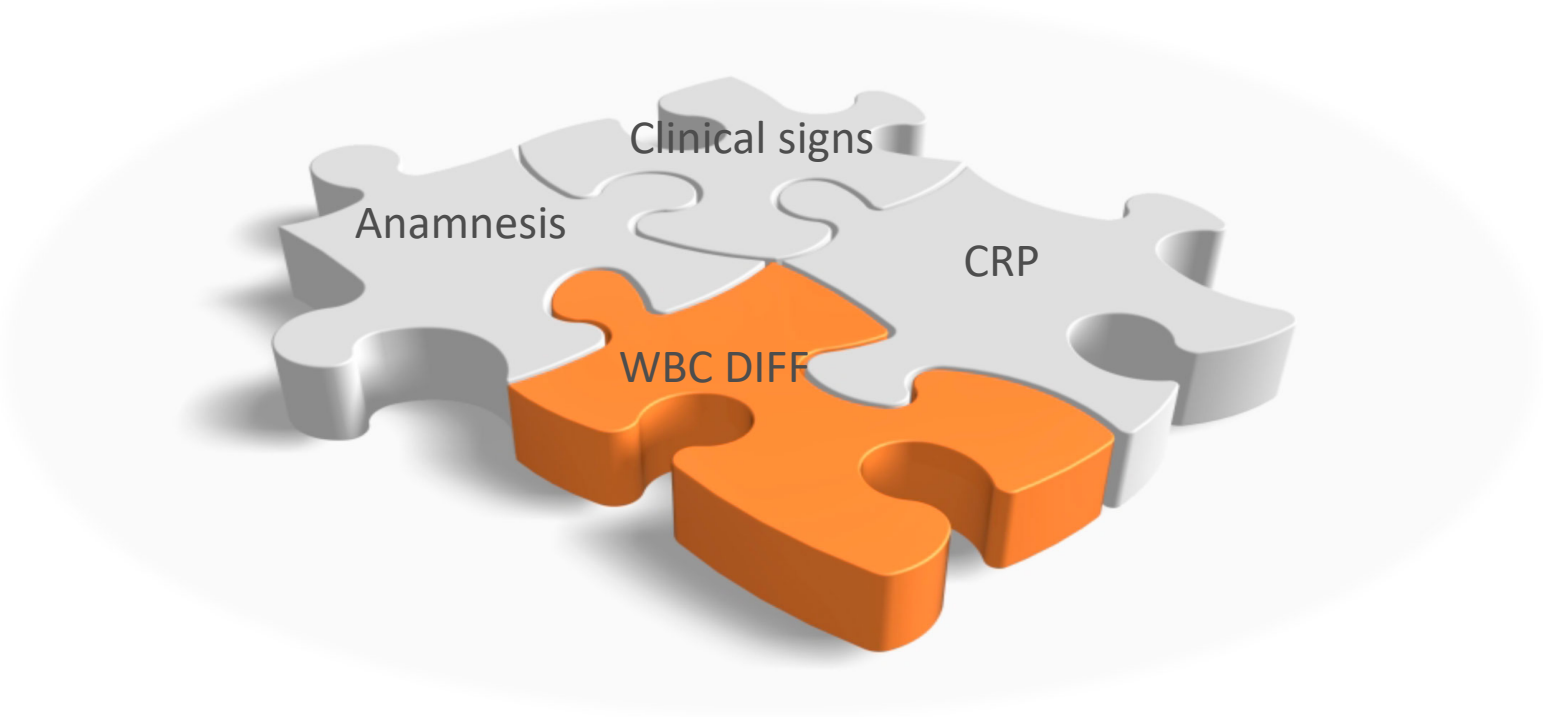
HemoCue® WBC DIFF System

Introduction

Clinical Value of WBC Diff POC

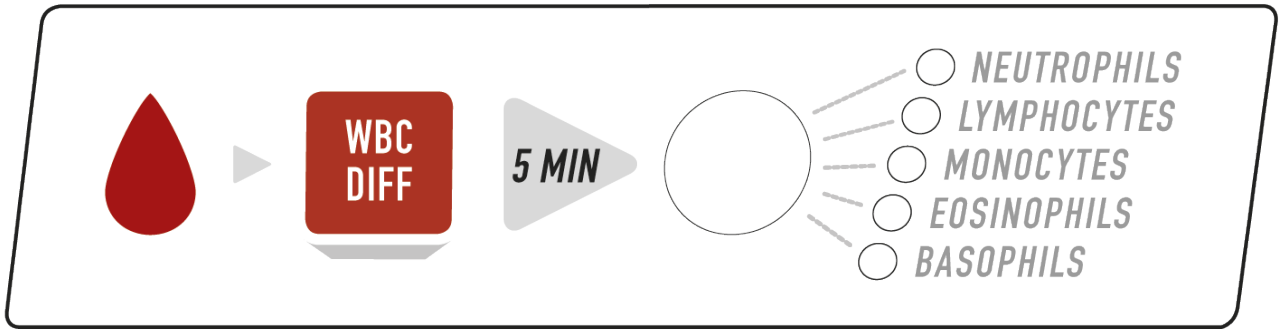


HemoCue® WBC DIFF System – an important part of the clinical puzzle

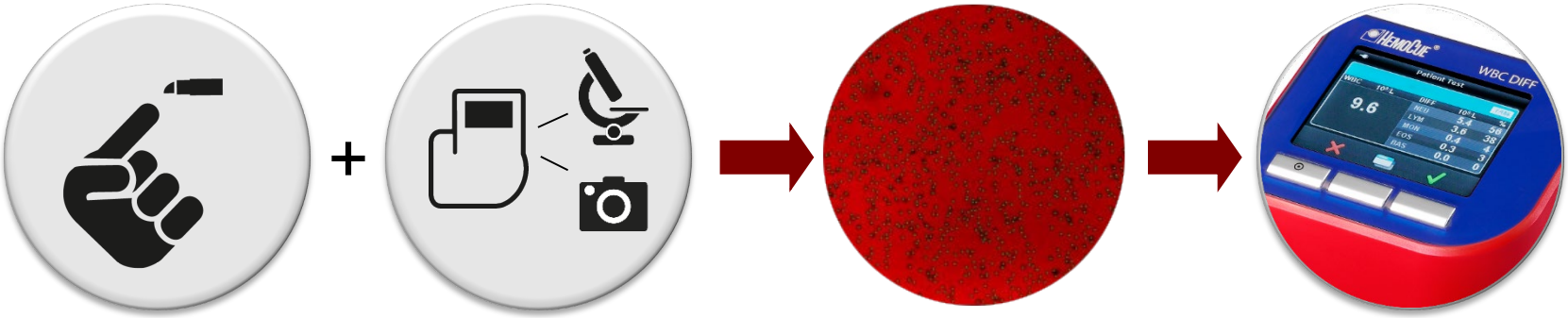


Introduction HemoCue® WBC DIFF System

The HemoCue WBC DIFF is a point-of-care testing system for quantitative determination of total white blood cell count and a 5-part differential count.

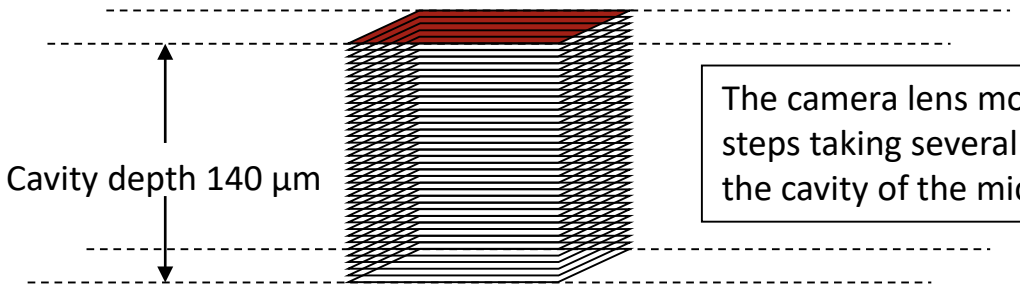


How the HemoCue® WBC DIFF System works

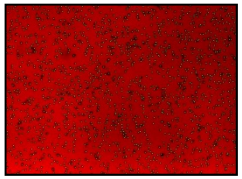


- When the microcuvette is filled with blood, the red cells are lyzed and white cells are coloured
- The analyzer contains a camera and a microscope
- Several images are taken
- The white cells are classified and the results are presented

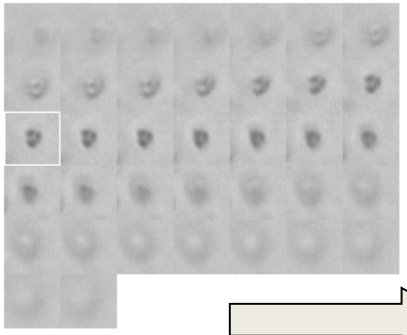
The microcuvette cavity is analyzed in separate layers to enable detection of cells at different depths



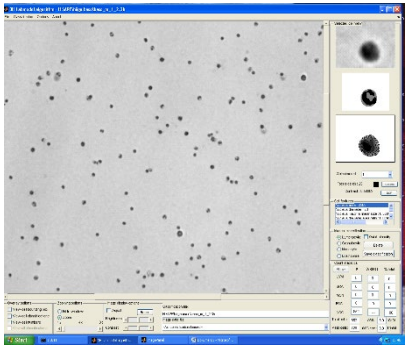
The camera lens moves in small steps taking several images through the cavity of the microcuvette



All cells in all images will be cut out



Identification when each cell is in focus



Mount the focused cells into one image

Total WBC and differential counting as final step

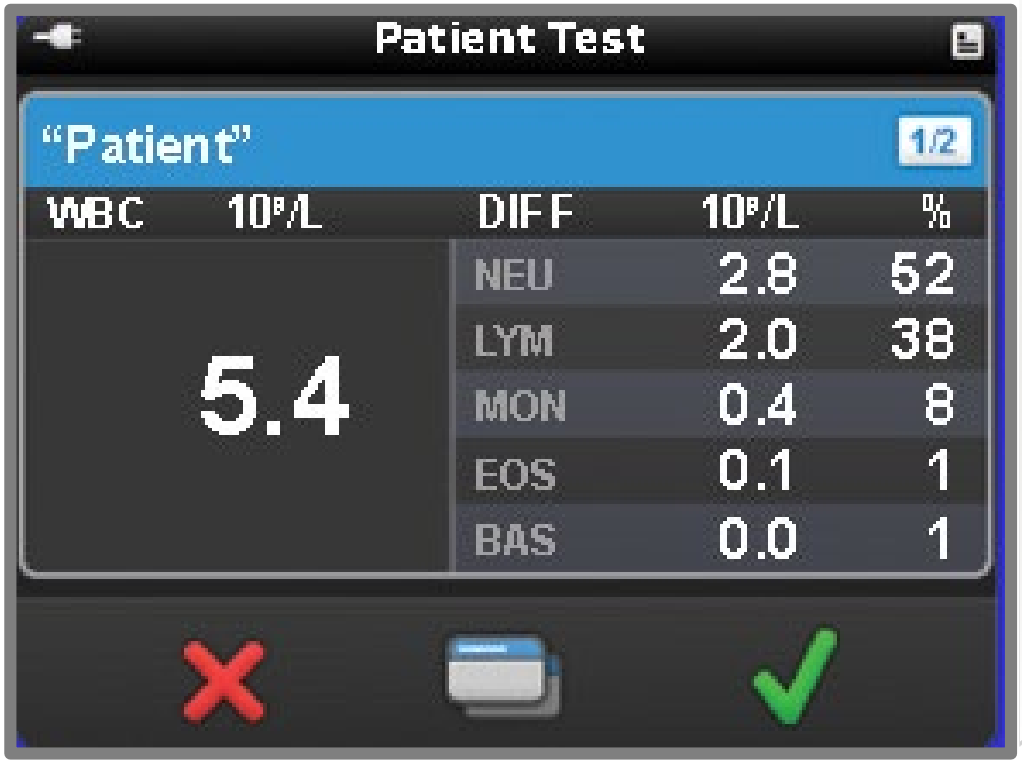
How to use the HemoCue WBC DIFF

1. Fill the microcuvette

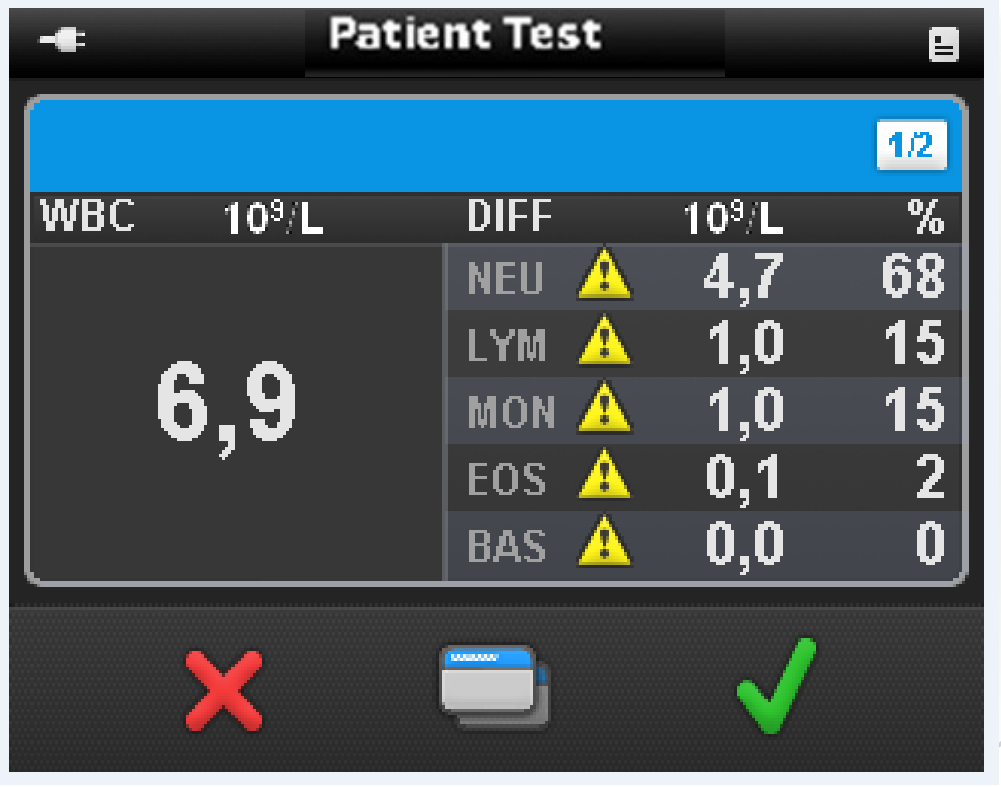
2. Push the button for patient test and place the microcuvette in the cuvette holder

3. The results will be displayed within five minutes

Displayed Results



Displayed Results –Unreliable DIFF*



* Sample could contain pathological cells and/or abnormal counts and should be verified with a suitable laboratory method.

HemoCue® WBC DIFF System Specifications

- Measuring range: 0.3–30.0 x 10^9/L
- The differential will be displayed when total WBC: 1–30 x 10^9/L
- Measuring time: <5 minutes
- Sample material: capillary or venous blood
- Sample volume: 10 µL
- Data management
- Data transfer through Ethernet
- Quality control: built-in self-test
- Power supply: 6 C (LR14/HR14) batteries or adapter

HemoCue WBC/DIFF Microcuvettes

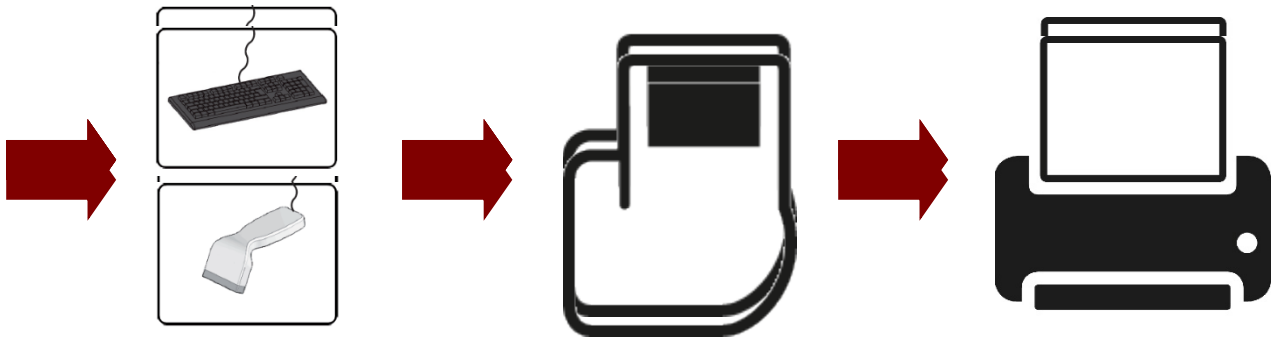
- HemoCue® WBC DIFF Microcuvettes:
  - Total WBC count and 5-part differential count
  - Individually packaged microcuvettes: 2x25 pcs

- HemoCue® WBC Microcuvettes:
  - Total WBC count
  - Microcuvettes packaged in vial: 4x40 pcs

WBC DIFF Data Management

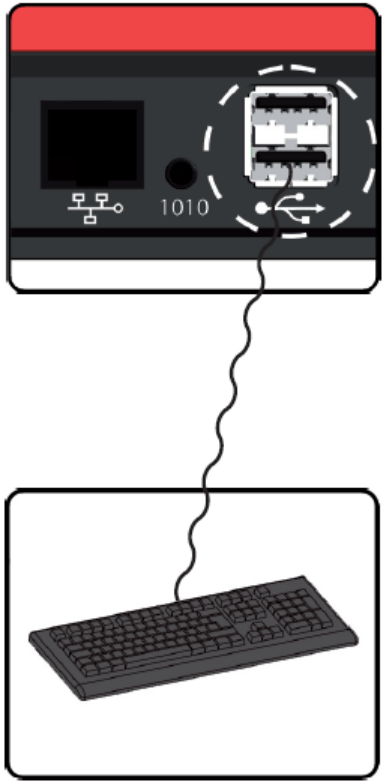
Patient ID
Site ID
Operator ID
QC ID
Lab ID

Date and time



- To enter data in the HemoCue WBC DIFF – a barcode scanner or a keyboard
- The HemoCue® WBC DIFF Analyzer can be connected to a printer
- Data transfer through Ethernet

Connect to Keyboard



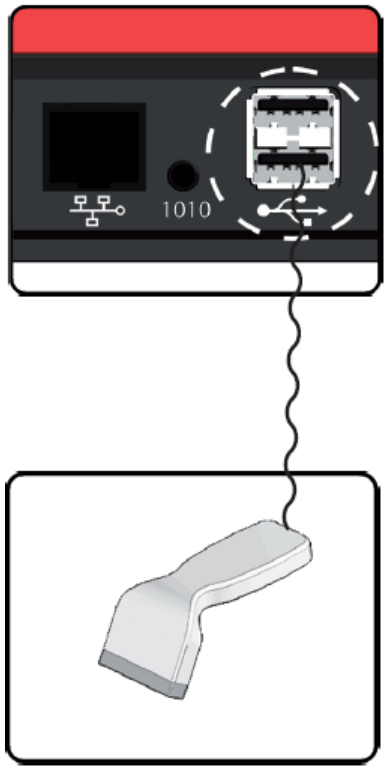
The keyboard can be used for data entry of:

- Patient ID
- Operator ID
- Lab ID
- Control ID
- Site ID

To navigate use F1 for left, F2 for up/down, F3 for right.

Connect the cable from the keyboard to the USB port connection on the analyzer before performning analysis.

Connect to Barcode Reader

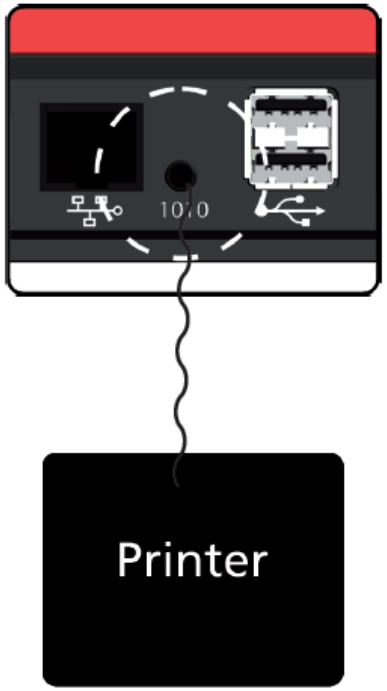


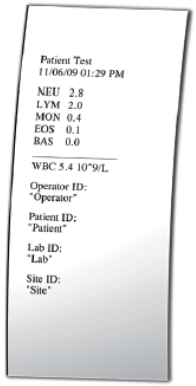
The barcode reader can be used for data entry of:

- Patient ID
- Operator ID
- Lab ID
- Control ID
- Site ID

Connect the cable from the barcode reader to the USB port connection on the analyzer before performing analysis.

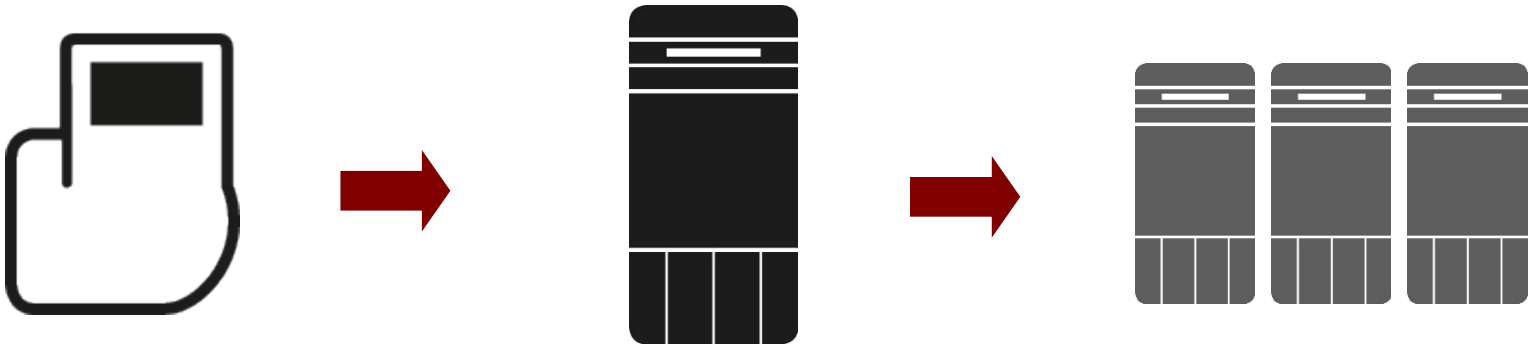
Connect to Printer





- Connect the cable to the analyzer and ASCII printer before performing the analysis.
- The result is shown on the display and will be printed automatically.

HemoCue WBC DIFF Connectivity

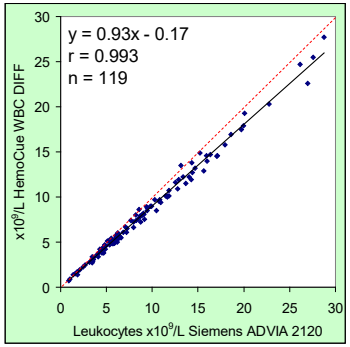
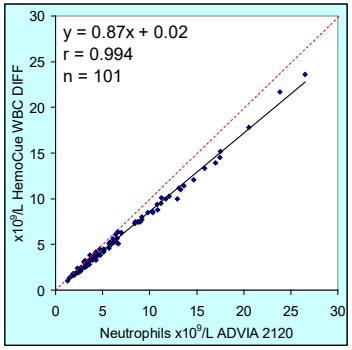
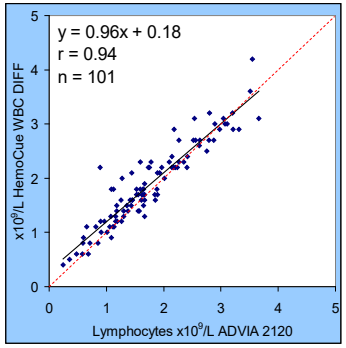
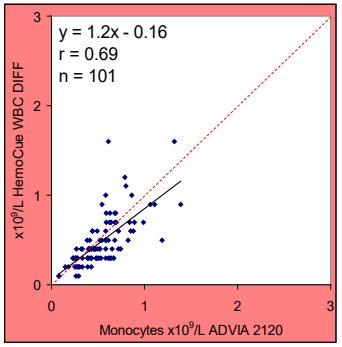
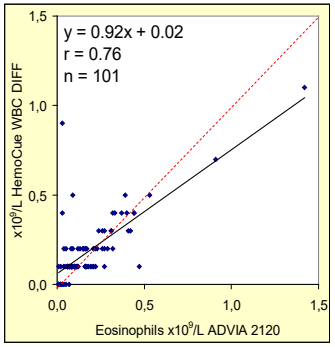
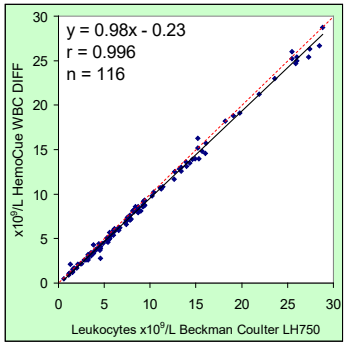
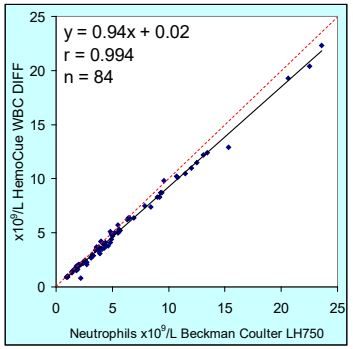
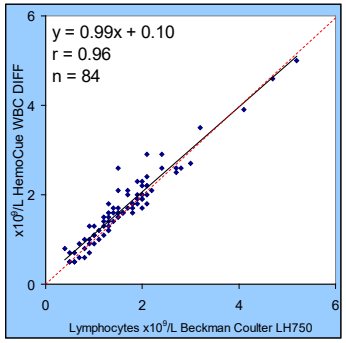
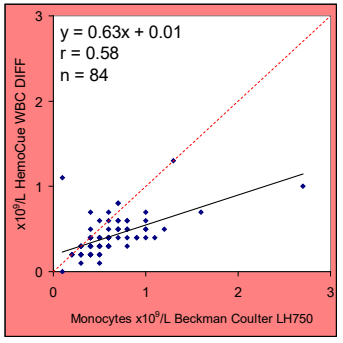
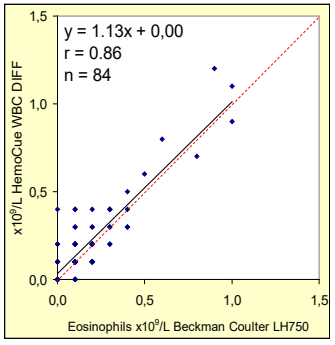
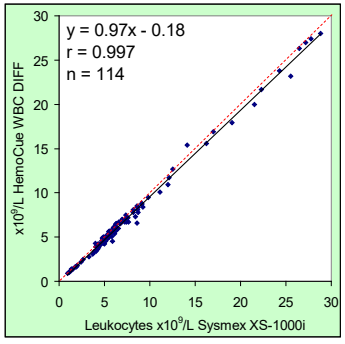
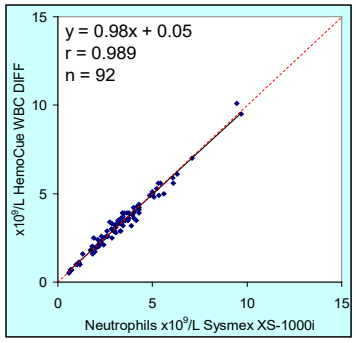
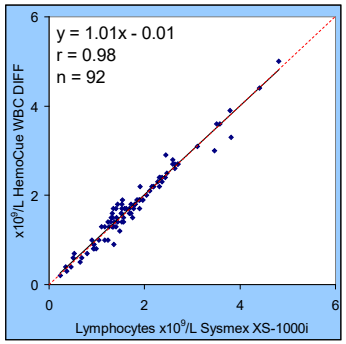
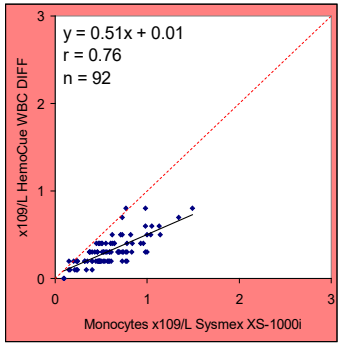
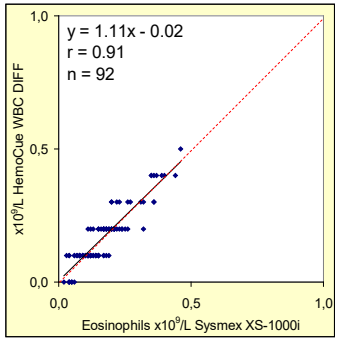


Patient ID
Lab ID
Site ID
Operator ID
Control Lot

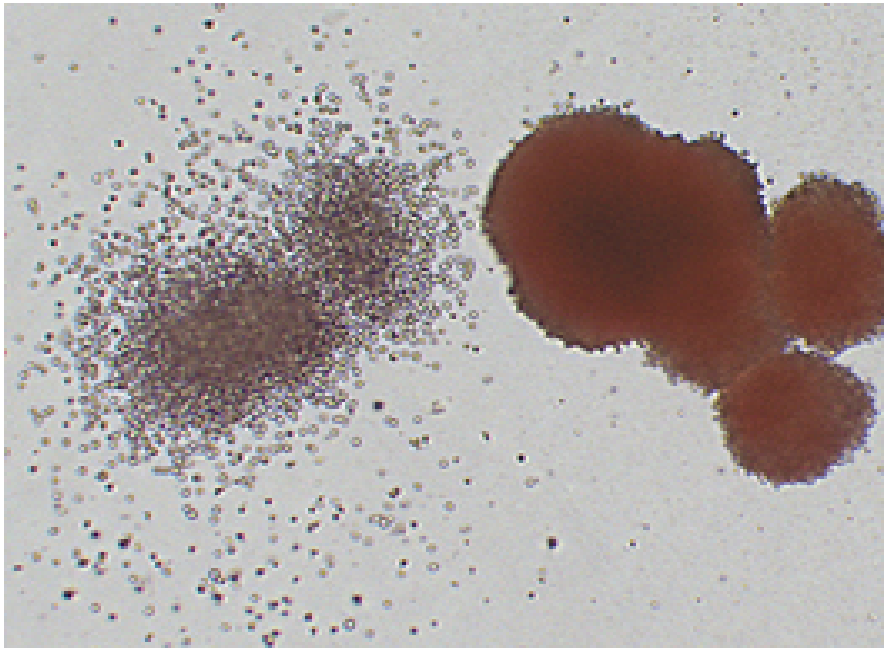
Observational Reviewer
(Data Management Server)

LIS
HIS

Validation Studies
HemoCue® WBC DIFF System

	Total Leukocytes	Neutrophils	Lymphocytes	Monocytes	Eosinophils
Siemens ADVIA® 2120					
Beckman Coulter® LH750					
Sysmex® XS-1000i					

HemoCue® WBC DIFF System -Advanced Internal QC System



HemoCue WBC DIFF

Advanced Internal QC System

At power up (the "self-test"):

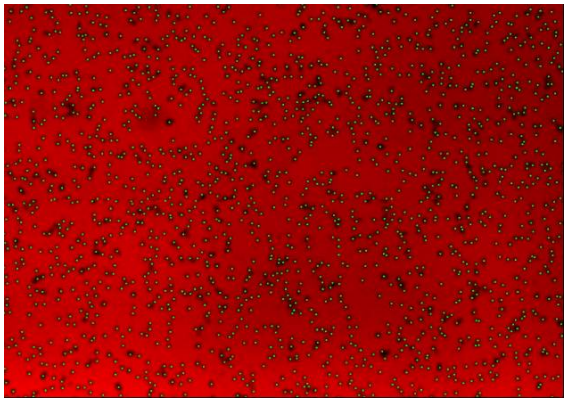
- Test of electronics and software
- Blanking test
  (Quality of light, check for dirt in the optics)

Between samples:

- Blanking test

For each sample:

- Bad area detection
- Out of focus detection
- Air bubble detection
- Poor light intensity
- Bad cell distribution

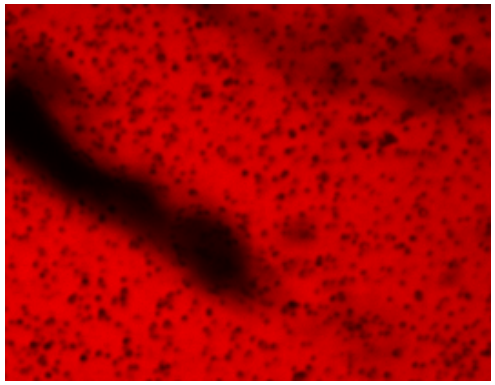


HemoCue WBC DIFF

Bad area detection (Error codes: E01, E33)

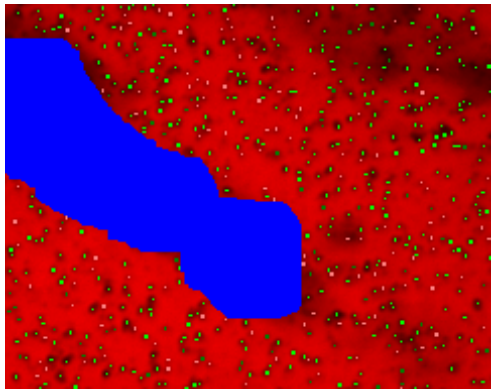
Identified risks due to human factors:

- Measurement area dirty
- Blood on the outside of the microcuvette
- Empty cuvette
- Microcuvette not completely filled



Technical description:

- When the background colour approximates the colour of stained cells, the area is eliminated from counting
- If the eliminated area is too large, the sample is rejected



HemoCue WBC DIFF

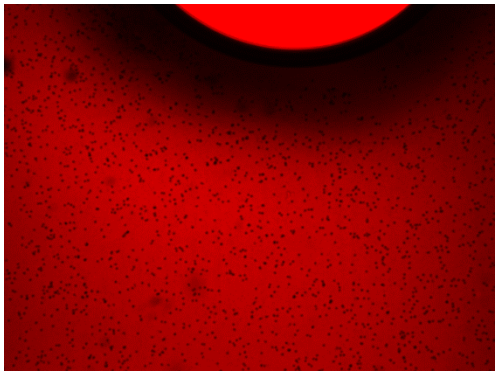
Air bubble detection (Error codes: Err 01)

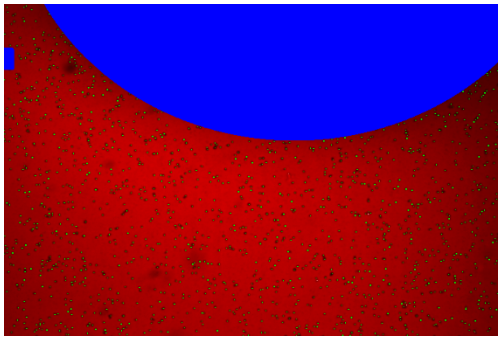
Identified risks due to human factors:

- Incorrect filling
- Cuvette not completely filled
- Incorrect storage of cuvette

Technical description

- If an air bubble is detected, the bubble area and the area around it is eliminated from counting
- If the eliminated area is too large, the sample is rejected





HemoCue WBC DIFF

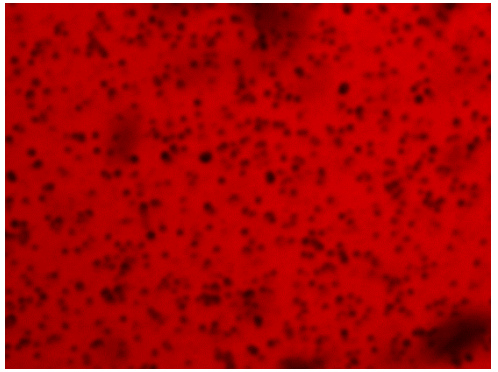
Out of focus detection (Error codes: E03)

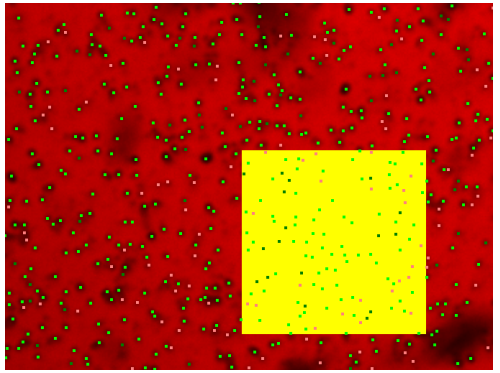
Identified risks due to human factors:

- Condensation on optical parts
- Incorrect positioning of cuvette holder inside the analyzer
- Brutal maintenance of optical parts
- Abrupt movement of analyzer

Technical description

- If the sharpness of the cell edges are not clear enough, the area is eliminated from counting
- If the eliminated area is too large, the sample is rejected





HemoCue WBC DIFF

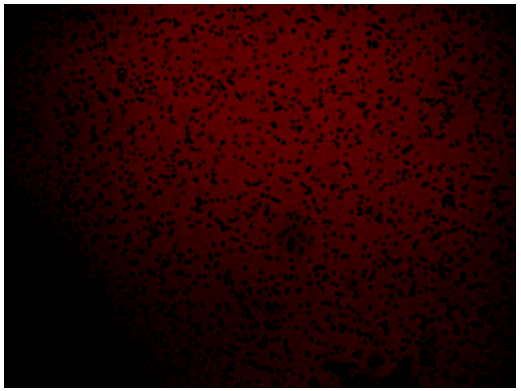
Poor light intensity (Error code: Err 04, 30)

Identified risks due to human factors:

- Optical parts dirty or scratched
- Poor maintenance of optical parts
- The LEDs are malfunctioning

Technical description

- The measuring area is so dark that the light adjustment cannot compensate to get a clear image



HemoCue WBC DIFF Internal QC System

- No additional quality controls, such as liquid controls, are required on a daily basis for verification of the system functionality
- However, liquid controls may be required by local, state or other accreditation agencies
- WBC DIFF has a separate QC Channel which should only be used to run QC test

HemoCue WBC DIFF – Maintenance

- No preventative maintenance is needed for the electronic components of the analyzer
- Clean the cuvette holder each day of use, or more frequently if needed, using alcohol or mild detergent. Dry the holder completely before re-inserting into the analyzer
- For cleaning of dirty optical parts (displays an error code) use the cleaner recommended by HemoCue

Why HemoCue?

- First 5-part differential at the POC
- Accurate lab quality results within minutes
- Easy to use, no laboratory training required
- Portable, can be used at bedside
- Venous/capillary blood can be used
- Small amount of blood needed
- Minimum of maintenance needed
- Allows for earlier treatment of patient

Because when it comes to caring for people, we refuse to compromise.

hemocue.com