

Technical letter no 24

Global Product Management, HemoCue AB

Advanced built-in Quality Control HemoCue® WBC System and HemoCue® WBC DIFF System

The ability to verify proper functioning of a system is a crucial part of point-of-care testing. The HemoCue® WBC and HemoCue® WBC DIFF Analyzers have an advanced built-in quality control system, ensuring a well-controlled measurement, while at the same time being easy to use. At start-up and between each measurement, the performance of the electronics, software and optics is automatically verified. In addition, during each measurement, the analyzer, the microcuvette and the sample itself are automatically checked to guarantee optimal performance. An error code will be displayed if any of the QC checks fail.

The built-in quality control consists of several steps:

1. "Self-test" at start-up

Test of electronics and software as well as a blanking test.

2. Blanking test between measurements

Checking light and optics.

3. During each measurement

By using state-of-the-art imaging technology, the system will detect user or handling errors such as incorrect filling

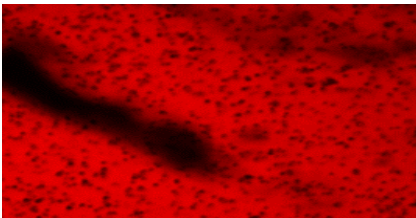
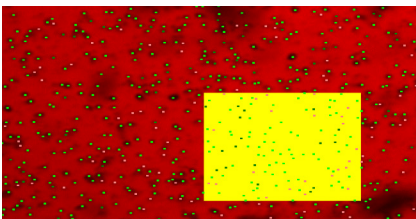
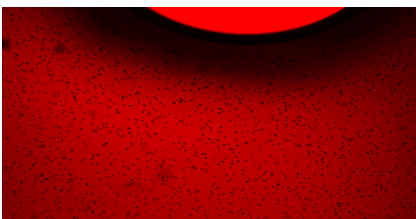
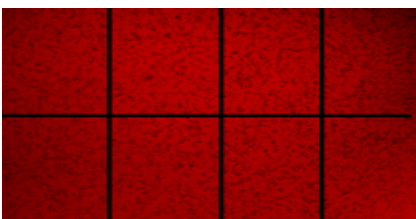
or position of the microcuvette, reagent functionality, impurities or blood outside the microcuvette, non-homogenous sample, air bubbles, etc. See list on next page for details.

4. White cell recognition (HemoCue® WBC DIFF)

Two different sets of algorithms are implemented in the software: one for differentiation of normal white cells and one for identification of pathological cells and abnormal patterns in normal white cells. For a normal sample, 1,000 white cells are counted and classified into cell types. If the sample contains any abnormalities, such as pathological, damaged or unrecognized cells, a warning symbol is displayed along with the result.

The cell recognition software is based on a number of cell characteristics e.g., shape, size and number of nucleons, where the system is programmed with more than 50,000 cell images. The warning symbol indicates that the system does not recognize the cell from the programmed library/software. This does not necessarily indicate a pathological condition of the sample. However, for patient safety it should always be verified with a suitable laboratory method.

During each measurement the following checks are performed.

Detection	Image	Built-in QC system
Bad area - Dirt or scratches on microcuvette - Blood smear outside microcuvette - Microcuvette not filled with sample - Microcuvette not completely filled		When the background is similar to the color of stained white cells, the area is eliminated from counting. If the eliminated area is too large, the sample is rejected and an error code is displayed.
Out of focus - Condensation on optical parts - Incorrect microcuvette position - Rough maintenance of optical parts - Abrupt movement of analyzer		If the cells are not sufficiently sharp, the area is eliminated from counting. If the eliminated area is too large, the sample is rejected and an error code is displayed.
Air bubble - Incorrect filling of microcuvette - Microcuvette not completely filled - Incorrect storage of microcuvette		When an air bubble is detected, the bubble and the area around it are eliminated from counting because of inaccurate distribution of cells. If the eliminated area is too large, the sample is rejected and an error code is displayed.
Poor light intensity - Optical parts dirty or scratched - Poor maintenance of optical parts - Malfunctioning of LEDs		When the measuring area is so dark that the light adjustment cannot compensate to detect the cells correctly, the sample is rejected and an error code is displayed.
Bad cell distribution - Non-homogenous sample - No even cell distribution		The image is divided into sub-parts and when the counted number of cells differs significantly in any of the parts, the sample is rejected and an error code is displayed.

No additional quality controls are required for functionality verification of the system. Local, state or other regulations may require additional external quality control testing. If so, R&D Systems liquid controls (R&D HC WBC/WBC Diff Controls) may be used for the HemoCue WBC/WBC DIFF system. Please refer to local guidelines for recommended frequency of use.