Why standardization in hematology is so special

Effective patient care requires comparable results regardless of which lab or country the patient sample is recorded in, as physicians focus on parameter ranges that indicate disease.
Harmonization and standardization, on the other hand, are based on traceability to either certified reference materials, either with defined International Units (SI) or any arbitrary WHO units or reference methods.

The best standardized parameters are displayed in SI units, as they are available for distance measurements, for example. One of the oldest reference systems is the UR meter in Paris. Anyone can compare their meter at any time to ensure correct readings over years.

Is there an SI base unit and a reference material in hematology?

In hematology, the subject of SI is quite complicated. There are parameters such as water content, light scattering, lyses shrinkage or cell shape that are used to differentiate cells such as erythrocytes, leukocytes or blood platelets. Cell differentiation and measurement by a hematology analyzer therefore depends on a large number of non-SI parameters. Since these parameters are not measured in SI units only a few parameters are traceable and comparisons are feasible. For most parameters these options are not available.

The best reference material currently available is the calibration and control material consisting of stabilized but still living cells. An artificial material, consisting of beads and colors, does not reflect the composition of the blood and therefore does not exist. The absence of cells in the calibrator and control material would not allow the function of lyses of e.g. erythrocytes to be tested. Also the lack of leukocytes with different granularity would not support the unambiguous reading of a scatter diagram. The quality control of a correct measuring system can only be achieved by measuring a control material with standardized living blood cells. This control material, as it is composed of living cells, which die sooner or later, can only be used as a reference for a relatively short period of time - one month for the calibrator and several months for the control material.
There are basically two types of control materials: manufacturer controls and external controls.

Manufacturer calibrator and controls

The use of a manufacturer quality control ensures the daily consistency of the analytical processes. This procedure ensures the reliability of patient results as it controls the functionality of the analyzer. The quality of the laboratory can also be monitored and documented by a quality control. In most countries, the use of quality controls is required by national guidelines or regulations.
The manufacturer‘s calibrator and controls is strictly linked to the instrument and the associated reagents. The target values therefore only apply to this specific setting and provide only in this combination reliable results. They cannot be used with instruments from other manufacturers because each analyzer operates differently and uses different amounts of reagents. Thus, only the manufacturer‘s control can demonstrate the full functionality with all parameters recorded by the system.

External Quality Assessment System (EQAS)

In addition, independent, external quality controls are required to verify accurate values at a national or global level for the calibrator and the controlled manufacturing system. They also ensures that a system consisting of instrument, reagent, manufacturer control and calibrator, as well as the operator and laboratory environment, using the same material, produces comparable values with other systems.
Companies like ESfEQA or HuQAS offer external hematological controls that can be used on analyzers from different manufacturers to allow a comparison of results between laboratories, even if the instruments are not identical. Typically, normal and pathological samples are provided. To achieve a good comparability the samples should be treated in the same way as patient samples. The specified target values are valid for all analyzers but limited to a number of common and traceable parameters. For hematological systems, WBC, RBC, HGB, HCT, MCV and PLT are usually available, but e.g. not the WBC Diff parameters.

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A limitation is that external quality assessment samples are manipulated to prolong shelf life and reduce sensitivity to transport conditions such as temperature variations and vibrations.
A direct comparison with the patient results is therefore not possible. Laboratories should use the results of EQAS to compare their results with (inter)national consensus or reference results. They also serve to improve their quality and harmonize their hematology analyzer with a consensus group on a global level.

Round Robin tests with fresh blood

There are also external quality assessment providers (e.g. INSTAND e. V.) who offer interlaboratory comparisons with fresh blood samples. These samples, consisting of fresh pooled blood samples, have the advantage that they cover many parameters and can be fully compared with the patient‘s results.

The ring test is a blind trial. No target values are provided for the material. The results determined by the respective system are transferred to the assessment provider. The collected data is evaluated and the performance of the system is compared with other instruments of the EQAS.

However, the transport conditions and handling of the fresh blood samples must be taken into account. The test material must be measured within a short time (24 hours) in order to obtain valid results. A repetition of the measurements is not possible due to the limited stability. Therefore, this type of external quality control only works at the national level, but not at the global level.

Summary and conclusion

A stable reference system, as available for SI-based parameters, is except for hemoglobin, not available in hematology. To provide reliable and accurate test results, laboratories must continuously monitor and evaluate their performance.

This can only be achieved by the daily use of a manufacturer control and the regular use of an external QC. Control materials need to consist of intact cells in order to test chemical reactions and the hardware function of a hematology analyzer. Only the manufacturer‘s control and fresh blood offer the possibility to test all measured parameters. As a manufacturer, we ensure that all laboratories have access to the necessary controls for our analyzers through our distributors.

The operation of both types of controls is a must in hematology because the SI units of the measurement system of a hematology analyzer are missing.

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