

QUALITY CONTROL IN POCT

Patient testing is increasingly being carried out at the point of care; how can accuracy be ensured?



By Sarah Kee

The variety of point-of-care tests (POCT) has evolved significantly in recent years. Whilst these instruments bring undisputed benefits in obtaining rapid results at the patient's bedside, these benefits are only true if the results are accurate and reliable. Quality controls (QC) exist to ensure accuracy and reliability.

For many of the healthcare workers using POCT instruments, QC will be unfamiliar territory. Many of the standard QC procedures applied in laboratories cannot be applied to POCT devices. However, it is essential that both primary and community care settings apply well-structured QC procedures to ensure the accuracy and reliability of results, minimizing risk to patients and improving patient outcomes.

In recognition of this, there is now an international standard for POCT, namely ISO 22870, which, in conjunction with ISO 15189, lays out the requirements for quality and competence. However, there is no "one-size-fits-all" solution.

Developing an Appropriate QC Plan

First, the actual design of the POCT device needs to be factored in. These broadly fall into three categories:

Laboratory type instruments — full size instruments, for example blood gas analyzers. Similar to instruments you might find in a laboratory, the QC procedures for these types of analyzers should follow full laboratory QC protocol. Multi-level QC samples should be run on these instruments

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every day a patient test is performed and the accuracy and reliability of those results should be monitored over time by participating in a frequent PT scheme.

Cartridge-based instruments — for example HbA1c and INR analyzers. These are usually very different from those found in a standard laboratory, consisting of a cartridge-based component and an electronic reader, which may have a self-check system built in. The cartridge contains all the necessary components for the analysis of the patient sample while the electronic reader is responsible for converting the results from the cartridge component into a readable numerical value.

The difficulty with QC on cartridge-based instruments is that you can only ever test that one particular disposable cartridge and the electronic functioning of the instrument. However, for such devices QC is still essential. The cartridge may have been damaged during transit or the onboard reagents ►►

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may have deteriorated over time. It is therefore recommended, as a minimum, to run QC when changing cartridge lot and periodically throughout the lifespan of the lot to ensure the stability of the onboard components. It would also be beneficial to participate in a frequent PT scheme to monitor the accuracy of reporting over time.

Strip-based instruments — for example, electrochemical or reflectance strip-based glucose meters. These are similar to cartridge-based instruments in that the strips are responsible for the analysis of the



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sample. However, unlike cartridge devices the electronic component has no self-check feature and without this a faulty analyzer could be producing erroneous results for some time undetected. This makes QC even more important for these types of instruments. Strips should be checked using multi-level QC on delivery and every day of patient testing. Liquid-ready, multi-analyte third party quality controls available from some QC manufacturers are ideally suited for this, as they require no advance preparation and are easy for non-laboratory staff to use.

Regular proficiency testing is also important for these devices to ensure accuracy of reporting over time.

Who is Responsible for POCT?

Responsibility for QC on POCT instruments, although located in the clinical setting, should ultimately lie with the laboratory. However, it should be a team effort involving the staff who are using the actual equipment. Training of staff to use the POCT equipment, including QC, and the ongoing competency of operators should be documented and governed as part of an overall quality management program.

Training staff who are using the POCT equipment to perform QC will give them a better understanding of how the equipment works and, in doing so, will help them to see for themselves when errors occur. However, ultimately the responsibility of quality control should lie with the laboratory. ■

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