

QC Explained 1.0 - Quality Control for Point of Care Testing

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Background

Point of care testing (POCT) refers to testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient. Over the past few years, the popularity and demand of POCT has been growing rapidly. This should come as no surprise as there are many advantages to POCT, for example, the added convenience of being able to obtain a rapid result at the patient's bedside, thus allowing immediate action, saving time and improving the potential outcome for the patient.

Although there are many benefits of using POCT devices in terms of their convenience, these benefits are only true if the results produced are both accurate and reliable. Ensuring accuracy and

reliability is the primary responsibility of Quality Control.

Quality control is composed of two key elements; internal quality control (IQC) and external quality assessment (EQA). IQC involves running quality control material that contains analytes of known concentration to monitor the precision of the analytical process over time. Whereas EQA involves running blind patient-like samples, comparing your results to peer results, in order to retrospectively monitor the accuracy of reporting. EQA samples should be treated as if they were a patient sample and therefore *must* be run by personnel who would be using the device. This provides confidence in the reliability of patient test results.

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1.0 Importance of Quality Control for POCT Devices

ISO 15189 states that **“Quality Control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result” (1)**. Therefore, when implementing a QC strategy for POCT devices the risk of harm to the patient should be the foundation of the plan: where and why do errors occur and what are the consequences of an erroneous result to the patient? It is important to balance the risk of harm to the patient with the stringency of the QC procedure applied. Inaccurate results can have serious implications for the patient including misdiagnosis and/or inappropriate or incorrect medical procedures being carried out unnecessarily, resulting in monetary implications for the hospital.

POCT procedures have been previously shown to be less stable than those run

within the laboratory. For example, a study undertaken by the Ontario Laboratory Accreditation body found that POCT is the largest source of error in the laboratory when compared to other sources of error (2) (see figure 1). This demonstrates the definite need for a well-designed QC procedure in a point-of-care (POC) setting to minimise the risk associated with POCT devices. Furthermore, another recent study found that the most common phase for errors in POCT was analytical, with 65.3% of errors occurring during this phase. (3) Conversely, in laboratory based testing the analytical phase is the least common source for errors (4) thus, highlighting the importance of QC procedures for POCT devices while also outlining how the potential risk of harm to a patient may be greater for POC tests compared to those performed on laboratory based analysers. This study also revealed that the potential impact of quality control error on a POCT device having a moderate adverse impact

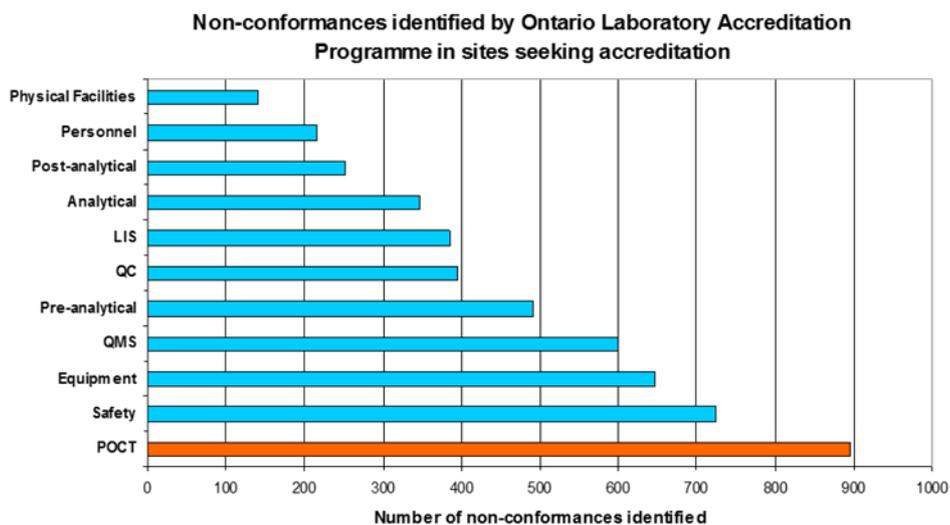


Figure 1: Ontario

on patient outcome was 14.7% (3), demonstrating that for POCT devices there is larger room for error and a greater need for quality control.

Some POCT device manufacturers advise that QC procedures similar to those found in the laboratory are unnecessary for POCT devices. However, this is not the opinion of the majority of laboratory professionals who believe a place undoubtedly remains for traditional IQC and EQA practices for

POCT. This view is supported by the introduction of the new ISO POC specific regulations. In 2006 a new ISO standard; ISO 22870 was released specifically for POCT titled: "POCT – Requirements for quality and competence" (5). ISO 22870 advises that where available, Internal Quality Control and participation in an External Quality Assessment scheme is required in the point of care setting. ISO 22870 is designed to be used in conjunction with ISO 15189.

2.0 Who is Responsible for QC in POC Testing?

According to ISO 22870:2006 a POCT management group should be set up with responsibility for managing and training staff using the equipment. This group should be responsible for the quality management strategy and implementation of a staff training programme which includes quality control, for all personnel performing POCT and interpreting results from a POC device.

Additionally, running of QC samples on POC devices should be performed by those who are using the devices regularly, as QC samples should be run as if they were a patient sample and therefore must be performed by personnel who are responsible for and undertake patient testing.

3.0 Choosing an Appropriate QC Procedure for your POCT Devices

3.1 Balancing risk with the stringency of your POCT quality control procedure.

There are many risk factors that should be considered when designing the stringency and frequency of any POCT QC strategy. The greater the risk, the more stringent

the QC procedure should be. When designing an appropriate QC strategy there are a number of risk factors that need to be taken into consideration:

- high risk tests with large impact for the wrong result,

- tests used to support the clinician's decision in isolation,
- tests acted upon immediately, and
- tests performed on specimens that are difficult to collect.

The POCT strategy will depend on the POC device that is being used as POCT devices can be broadly split into three categories:

1. "High Throughput Analyser"- Full size instruments used at the point of care, e.g.: blood gas analysers.
2. "Cartridge Based Instruments"- For example HbA_{1c} and INR analysers.
3. "Strip Based Instruments" e.g.: electrochemical or reflectance strip based glucose meters and INR analysers.
4. "Manually read Tests" e.g.: urine dipstick test.

3.1.1 Choosing a QC procedure for a High Throughput Analyser Type POCT Instruments.

A high throughput analyser mirrors those found within the laboratory and therefore, the quality control procedure should mirror that seen within the laboratory. Multi-level true third party controls should be tested *a minimum* of once per day, each day a patient sample is tested; in line with ISO 15189 regulations. Depending on the test in question and the number of patient samples processed, quality control frequency may need to be increased.

Not all IQC material can be described as third party, as a third party control is one which has not been designed or optimised for use with a specific instrument or reagent, therefore providing an unbiased,

independent assessment of analytical performance. The accuracy and reliability of those results should be monitored over time to provide a true reflection of performance.

According to ISO 22870 EQA should be performed on all POCT devices. EQA is useful both as an assessment of the reliability of patient results and to help identify internal staff training needs.

3.1.2 Choosing a QC procedure for Cartridge Based Instruments.

For cartridge based instruments the technology differs from that found in standard laboratory type analysers. However the use of third party controls is still essential to ensure optimised performance and accuracy.

Cartridge based devices usually consist of two components: a cartridge based component, and an electronic reader based component. The cartridge based component contains all of the necessary "ingredients" for the analysis of the patient sample, while the electronic reader component is responsible for converting the result from the cartridge component into a numerical value for analysis.

There are many possible sources of error with cartridge based devices: the cartridge may have been damaged during transport, the on-board reagents may have deteriorated over time, the electronic reader may become defective or the operators of the devices may not be adequately trained to use the device appropriately.

Each time the laboratory receives a new batch of cartridges they should be evaluated using multi-level, third party controls to ensure that the cartridges have not been damaged during transport. It is also a good idea to periodically test quality control samples over the shelf life of a particular batch.

Ideally a third party control should be used every day of patient testing to ensure the stability of the on-board reagents and the accuracy of the results obtained, as recommended by ISO 15189. However, it's important to note that when using QC for cartridge based devices it is only the performance of that one cartridge being analysed at that particular time. In addition some cartridge based devices have their own inbuilt QC self-check function. Therefore, running QC daily may not be entirely necessary however, in doing so the laboratory is instilling confidence that reliable patient results are released.

On the other hand, for instruments without a built in QC function, multi-level third party controls should be used daily to ensure the reliability of results. In accordance with ISO regulations, EQA should be performed for all cartridge based devices.

3.1.3 Choosing a QC procedure for Strip Based Instruments.

Finally, strip based instruments are very similar in design to cartridge based

instrument. Like cartridges, the strips are responsible for the analysis of the sample however, unlike cartridge based devices the electronic component has no QC self-check feature and without this feature a faulty analyser could produce erroneous results which may remain undetected for some time. Due to this, QC processes should be more stringent for strip based devices than cartridge based devices to ensure the accuracy and reliability of the system. Strips should be checked on delivery using multi-level third party QC to ensure they have not been damaged during transit in addition to every day of patient testing. EQA should also be performed for strip based devices.

3.1.4 Choosing a QC procedure for manually read POC Tests.

It is essential to use both IQC and EQA for manually read tests, e.g.: the urine dipstick test. There is a higher degree of human error with manually read tests as results can vary depending on different interpretations and therefore there is a greater need for quality control. Using IQC and EQA will help to standardise results and ensure that reliable results are released.

4.0 Choosing IQC material and an EQA scheme that's appropriate for use with POCT devices

As discussed above, all POCT devices should run third party IQC samples and perform EQA. It is important to choose IQC material and an EQA scheme that fully meets the needs of the laboratory.

4.1 Choosing IQC material for POCT devices

When implementing an IQC strategy it is important to take into consideration the differing designs of the device and potential risk of harm of the patient. When choosing an appropriate QC material look for the following features:

- **Ease of use** – many samples are available in a 'liquid-ready-to-use' format which require no preparation. This format can be conveniently stored at +2 to +8°C meaning it can be stored safely on the ward rather than in a laboratory freezer.
- **A matrix similar to the patient sample** – choose samples that are as close to a human sample as possible, in-line with ISO15189 regulations.
- **Clinically relevant concentrations** – analytes should be available at clinically significant concentrations to accurately validate patient sample results.

- **Accurately assigned** - method/instrument specific target values and ranges should be accurately assigned.
- **Third party** – ISO 15189 recommends quality control material is from a third party source.

4.2 Choosing an EQA scheme for POCT Devices

EQA is strongly recommended for all point of care devices. ISO 22870:2006 states, ***"There shall be participation in external quality assessment schemes"***.

There are many EQA schemes available for POCT devices, it is important that you choose a scheme that offers:

- Frequent reporting to minimise the amount of time an error can go unnoticed.
- Quality material in a format suitable for use with POCT devices.
- Well-designed reports that allow for quick and easy troubleshooting of erroneous results at a glance.
- Multiple instrument registrations for each EQA sample provided, helping to save money and monitor performance across all POC instruments.

5.0 Additional Software Available

Perhaps a reason for the higher rate of error associated with a POCT device is due to a lack of responsibility on behalf of the staff performing the POCT. Ultimately, responsibility should lie within the laboratory but how can the quality of results released by POCT devices be managed when the people performing the tests are spread out in a hospital setting, and out of direct view of the laboratory QC Technician?

The review process can be facilitated by QC management software, which helps the laboratory monitor the reliability and accuracy of results released in the POC setting.

There are a number of QC management programs available, however the following requirements should be sought after:

- **Up to date peer group** – Ideally a QC management program should have a peer group functionality to enable the comparison of results to other laboratories worldwide using the same lot of control, method and instrument. Peer group monitoring should be in real time, and therefore, should be updated daily.
- **Multiple instrument registrations** – the ability to register multiple instruments is vital in POCT as there will be a number of POCT devices

through the POC setting that will need monitored.

- **Online access** – within a POC setting it's important that results can be entered online, anywhere at any time. This also means that the lab manager can remotely log onto the software to view the QC results entered for specific POC devices throughout the hospital or beyond.
- **Multiple user levels** - Different user level accounts should be available so that lab managers can track results. This also ensures that each POC operator is performing appropriate maintenance, instrument calibration and is adequately trained to use the device.
- **User defined acceptable limits** - to be applied to QC results, so that results can automatically be rejected or accepted.

Indeed major sources of error have been previously categorised to be commonly due to operator incompetence and a disregard for test procedures, and the use of uncontrolled reagents and testing equipment (6). Therefore, through using appropriate QC management software in the POC setting, the laboratory can reduce the level of risk and ensure accurate results are obtained.

6.0 Conclusion

It is important to remember that the benefits of using POCT devices are only true if the results obtained are accurate and reliable however given the large number of POCT devices available on the market choosing an appropriate quality control plan for your instrument can be

challenging. By following the guidelines outlined in this paper in addition to ISO 15189 and ISO 22870:2006 you can be assured that the management and overall results of your POCT devices will be of a higher and more reliable quality.

7.0 References

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