QUALITY CONTROL / QUALITY ASSURANCE

Quality involves accuracy, reproducibility and reliability; thus, performing quality control testing gives assurance that the test device, consumables and procedure/techniques are performed correctly, which ensures a reliable test result on which a clinical decision may be made.\textsuperscript{1,2} Quality control testing should be a mandatory component of a Point of Care Testing (PoCT) program.\textsuperscript{3}

In general, the quality control testing is done on artificial samples provided either by the manufacturer of the PoCT device (internal QC) or by a registered external provider of quality assurance programs (external QA).\textsuperscript{3}

1. INTERNAL QUALITY CONTROL TESTING

Consistent high quality testing depends on the optimal performance and interaction of the electronic, mechanical and chemical processes that comprise the test system. Sub-optimal performance of any part of the analytical process may be sudden or slow in onset, and can cause major or subtle deterioration in result quality.

Running quality control (QC) samples is used to detect such occurrences. QC testing uses a large pool of the same material to allow regular testing over a period of several months. The composition of this pool should be as similar as possible to the patient specimens.

QC pools are generally produced with several levels to cover the ranges that might be encountered clinically. PoCT suppliers or manufacturers usually supply this material in the form of single use vials. Each lot number of QC material is usually supplied with a mean value and a result target range. If a result falls within that target range then the result is considered to be within acceptable limits.

A QC result falling outside the acceptable range is suggestive of a process problem (e.g. Specimen, instrument, reagents, and operator). A decision is made on whether to accept or reject the QC result as determined by the rules located in the quality manual.

It is mandatory to record all results on the QC Log Sheet, comparing them to the expected results.\textsuperscript{2}

A patient result cannot be reported if a QC result has been rejected.

The individual responsible for PoCT must regularly review QC results, and record any explanations or actions taken as a result of rejected QC results.

The Australasian Association of Clinical Biochemists (AACB) Position Statement on PoCT states A QC sample must be tested:
- With every new delivery of reagents
- One QC sample per month must be tested as a minimum requirement. In this case, it is recommended that the sample tested has a value in the pathological range.
• The patient result does not fit the clinical presentation
• When a major maintenance or repair procedure has occurred.
• If no suitable quality control material is available, patient specimens must be substituted and results compared with those from a local accredited pathology laboratory.

2. EXTERNAL QUALITY ASSURANCE PROGRAMS

QC testing does not detect all types of analytical problems that can have clinical significance e.g. Calibration errors. Therefore, the ability to compare actual analytical performance with the same method as used elsewhere provides a valuable check as to whether the test is performing in the same way as its peer group.

The External quality assurance program is a peer review activity and provides long-term monitoring of the analytical performance. This can allow the detection of trends or problems that could otherwise slowly develop unnoticed.

An external quality assurance program (QAP) distributes samples of the same pool to all QAP participants, who then run the samples as if they were patient samples. The results are returned to the QAP office, where the results are collated. The program reports on the range of results received which are generally grouped by method and / or instrument. The report will identify if a participant’s method is generating results that are significantly different compared to those from the same method used elsewhere.

Other useful information concerning the accuracy and precision of the participant’s results is also provided. An example of such a program is RCPA Quality Assurance Programs RCPA QAP). [www.rcpaqap.com.au](http://www.rcpaqap.com.au).

The RCPA QAP produce a range of external quality assurance programs, including programs designed for PoCT / Near Patient Testing. The interim reports during each cycle are returned to the participant. They show the results submitted by the participant in relation to all participants on a histogram.

This shows the range and distribution of all the results as well as where the individual participants results for each sample lie.
They also group together all the participants using the same instrument. The participant should be looking to ensure that their results fall into the acceptable range. In this example, there are 127 participants in the program, with 93 using the Roche CoaguChek XS.

This is visually demonstrated on a Levy-Jennings plot of each pair of results showing the deviations from the target value in allowable limits of performance (ALP). If the results are within the acceptable limits and are similar to their peers, then the participant can continue testing with the knowledge that the performance of their instrument is within specifications.
Some of the QA programs have an interpretation section where participants are required to make an interpretation as to whether the results, as in this example, are within, above or below therapeutic range. Again, each participant’s results are indicated with a small arrow.

If an interim report indicates that the results are not in the acceptable range for their peers, then further investigation is required to determine why. Actions on the part of the participant would include a review of QC and maintenance records. Other sources of errors can be transcription of results or mishandling of the testing material. On review of the interim report, all investigations should be recorded as a record of the corrective action taken.

An alternative to the formal QAP testing is ‘split’ or ‘parallel’ patient sample testing in which the same patient sample is tested by PoCT and by the laboratory.

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<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tr>
<td>Rapid external check of quality</td>
<td>Testing a limited range of concentrations</td>
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<tr>
<td>Testing uses the same sample matrix</td>
<td>Lack of peer comparison</td>
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<td>Cost effective external assessment of quality</td>
<td>Need to define appropriate acceptability criteria</td>
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<td>Can check pre-analytical component of testing</td>
<td>that recognize measurement uncertainty.</td>
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<td></td>
<td>Problems associated with delivery and</td>
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<td>transport to the laboratory, especially in</td>
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<td>isolated rural and remote areas.</td>
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3. QUALITY ASSURANCE

A quality system comprises the organizational structure, policies, procedures and practices that together define how the practice operates its’ PoCT services. These are all brought together in a single folder, whether it be electronic or paper based, and issued under the authority of the person responsible for PoCT. These documents form the working guide of how PoCT is organized and performed in the practice.

The quality manual should include a statement from the practice principal supporting the quality system and the policies and procedures comprising the quality manual. Minor revisions of the document can be made with hand written notes appropriately signed and dated.

All the policies and procedures should carry the dated signature of the person responsible for PoCT.

4. QUALITY AUDIT

Quality audits assess how well the quality system is working for the PoCT service. Regular audits of compliance with PoCT policies and procedures are undertaken. Audits should be performed on an annual basis and a record kept of this by the person responsible for PoCT.

5. REFERENCES