

# Best laboratory practices regarding POCT in different settings (hospital and outside the hospital)

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## ARTICLE INFO

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## ABSTRACT

Point-of-care testing is proliferating at an alarming rate as technological improvements in miniaturization coupled with the need for rapid diagnostics drive the market globally. This review highlights best laboratory practices that must be communicated to the diverse group of people employing POC testing in their respective settings both inside and outside the hospital setting so that reliable results can be obtained.

## INTRODUCTION

The COVID-19 pandemic highlighted the importance and versatility of point-of-care testing (POCT) in the triaging and management of disease <sup>1</sup>. This role, coupled with developments in miniaturization technology due to its appeal to the medical profession in monitoring of health has led to rapid proliferation of POCT. As such, POC testing has become an important component of healthcare maintenance across a wide spectrum of services from intensive care units, emergency rooms, skilled nursing facilities, outpatient clinics, physician offices, pharmacies, community wellness programs and direct-to-consumer testing. <sup>2</sup>The reliability of the test result is key in deciding the next step of a diagnostic, treatment or health maintenance plan, and hence requires best laboratory practices. As a result, responsibility extends from the manufacturer in the design and validation of the device, to the healthcare facility managing the service, to the ordering physician and/or personnel or consumer performing and acting on the test.

Best laboratory practices can be broken down into 4 areas of consideration <sup>2</sup>

A. Defining the roles and responsibilities of the personnel involved in the testing process

B. Ensuring the chosen POCT is appropriate for effective patient management. This comprises:

- a. Economic aspects
- b. Clinical aspects
- c. Validation studies
- d. Written procedures
- e. Training and competency testing staff

C. Developing a process to identify and mitigate errors

D. Ensuring there is accurate documentation of all aspects of laboratory testing

### *A. Defining the roles and responsibilities of the personnel involved in the testing process*

It is important to define the roles of the personnel involved in POC testing because it helps in managing the service. Who will train the personnel? Who will perform quality control (QC)? Who will perform and monitor quality assurance audits? Who will provide written procedures and available policies for staff? Who will investigate device data connectivity issues? These questions will help in the management as well as organizing root cause analysis and mediation of corrective actions. The POCT service should be supervised by a physician or doctoral-level scientist with training in laboratory medicine. They will be responsible for all aspects of the program, including giving or advising in the interpretation of test results. In a hospital setting, which is the most structured of settings, the laboratory director has to often delegate duties to others.

Here are some of the roles present in a hospital setting:

- (i) Laboratory director – this can be a physician or doctoral level scientist that is responsible for delivering all aspects of the testing service.
- (ii) Point-of-care coordinator – perform training, quality assurance audits, troubleshooting and is involved in daily communication with testing personnel.
- (iii) Point-of-care testing manager – these can be site specific or system-wide and have been delegated by the laboratory director to oversee day-to-day testing. They also write-up procedures and policies, perform device verification/validation studies, provide assistance with troubleshooting, audits, and training when necessary.

- (iv) Testing personnel – these are appropriately trained staff who will perform POC testing on patients.

### **B. Ensuring the chosen poct is appropriate for effective patient management**

To ensure the chosen POCT for monitoring a clinical condition is appropriate, the laboratory director must ensure the device and method is suitable for use in the diagnostic and clinical care algorithm. This can be further subdivided as follows:

#### **a. Economic aspects**

POC testing needs to be economically sustainable otherwise it will not be able to bring lasting benefit to the community it serves. Some questions that need to be considered are: How much will this test cost to perform? What is the cost for quality control, proficiency testing cost, maintenance and supplies? How much will the reimbursement be? Will someone need to be hired? Connectivity costs? How much does the technical support cost from the manufacturer and is it timely?

#### **b. Clinical aspects**

A POC test needs to improve patient management. Some questions that need to be asked are: What will be the workflow? How reliable is this test? Will a confirmatory test be required? The package insert and any available scientific literature on the test can help answer this with respect to sensitivity, specificity, negative and positive predictive values. Scientific literature on POCT correlations with other POC tests or core laboratory instruments should also be reviewed to determine the suitability of the POC test.

#### **c. Validation studies**

It is important to determine whether a thorough validation of test has been performed by

the manufacturer. This can be obtained from the package insert and any available scientific literature. The sensitivity, specificity, negative and positive predictable values need to be critically reviewed. A verification study should be performed to ensure the test performs as expected and the device has not been affected by the shipping process.

#### **d. Written procedures**

Procedures need to be written for each test derived from information in the package insert as well as any other relevant information specific to the workflow at the facility. They must be available for the testing staff for reference. Therefore, the package insert needs to be critically inspected for methodology, specimen requirements, causes of interference, quality control and reagent storage requirements, procedures for trouble shooting when QC is incorrect/out of range, analytical measuring range of the instrument, interpretation and documentation of results. The package insert needs to be retained and be available as a reference. Periodic POCT updates by the manufacturer will be reflected in the package insert.

#### **e. Training and competency testing of staff**

Training of staff on the correct techniques is important and preferably by the same person or group so that there is standardization of how the test is performed. For example, if “3 drops of diluent” are required then adding 2 or 4 drops could lead to under saturation or over saturation effects that could give a false result. Likewise, where a reading after a defined period is required, reading the result before or after this period could lead to a false negative or a false positive. Staff should also be tested for color blindness as some tests are based on a color change. For example, urinalysis by dipstick employs reagent pads on the dipstick that produce a color change when they react with

a particular biomarker in the urine. The resulting color correlates with the concentration of the biomarker. Finally, training needs to be assessed periodically - at least annually to ensure skills are maintained and staff are kept abreast of manufacturer updates.

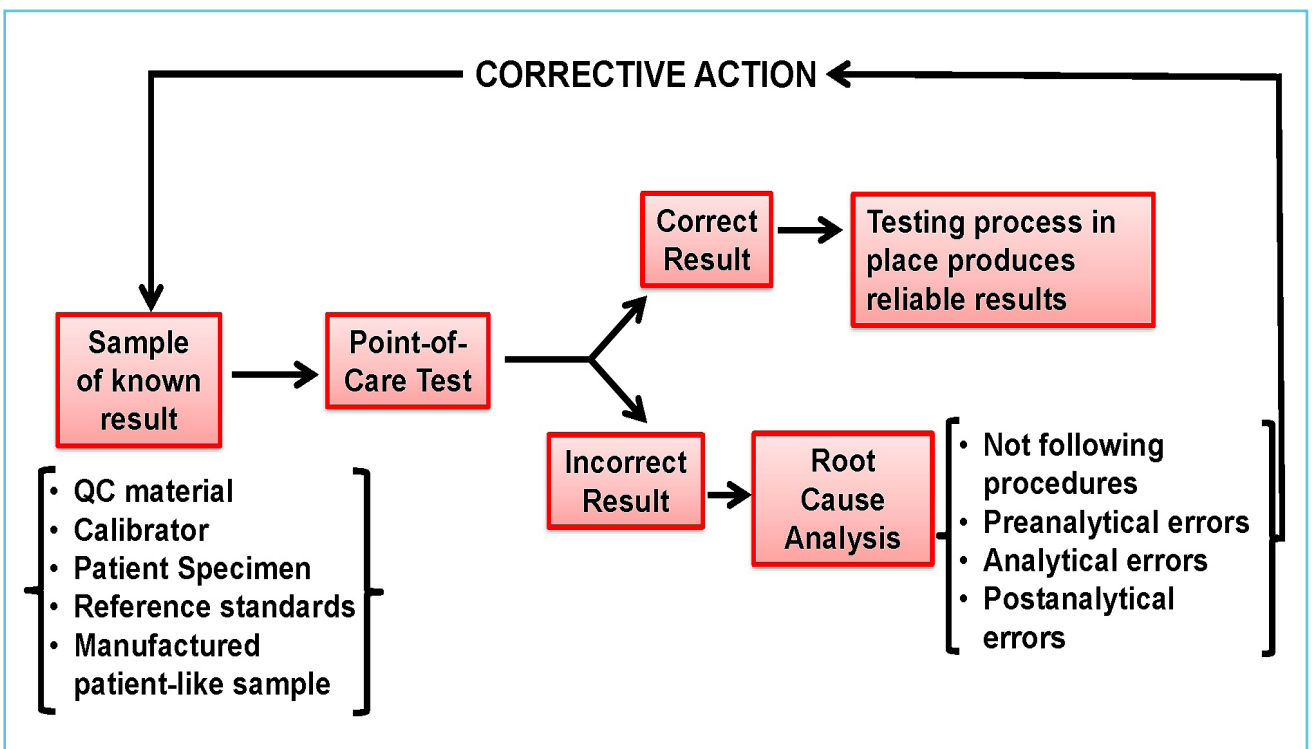
**C. Developing a process to identify and mitigate errors**

Errors in the pre-analytical, analytical and post-analytical stages of testing can affect the result and lead to misdiagnosis and incorrect management of the patient. Proficiency testing also known as external quality assessment (EQA) is an important tool to identify these errors because the test sample provided is treated like a patient specimen. Hence participation in an external EQA program is strongly recommended (Figure 1) and has shown to reduce errors.<sup>3</sup> In particular, EQA programs:

1. Identify if healthcare workers are adequately trained.
2. Identify if there are procedural deficiencies mentioned in the product insert but omitted in the final procedure.
3. Identify procedural deficiencies not mentioned in the product insert.

In Finland, Nissinen and co-workers<sup>4</sup> used an EQA program for evaluating group A streptococcal (GAS) antigen test in the hands of laboratory and nursing staff. Specimens were either GAS-negative, weakly positive or strongly positive. For GAS-negative samples, no significant difference in performance was observed between the laboratory and nursing staff (99.5% vs. 95.1% respectively). In contrast, laboratory staff performed statistically better for both strongly positive and weakly positive samples, with correct identifications being 98.9% vs. 95.1% and 79.3% vs. 65.3% respectively.<sup>4</sup>

**Figure 1** Summary of the external quality assessment program showing how results can be used to identify errors in the testing process



The difference most likely was because laboratory technicians ensured they had a better understanding of the principle and showed exact compliance with test instructions (e.g. timing) and exposed to similar quality assurance processes as part of their routine work compared to nurses that work primarily with patient care issues. This experience enables them to make a better decisions when a test is weakly positive.<sup>4</sup>

Furthermore, this study showed that environment illumination could affect results and because this was not mentioned in the product insert, its importance was revealed through participation in the EQA and illustrated the usefulness of participation in EQA schemes. In another study, Skurtveit et al.,<sup>5</sup> evaluated physician office laboratories that used serological POC tests to identify infectious mononucleosis. Laboratories that were enrolled in an EQA scheme that had outdated test kits or kits close to their expiration date, did poorly in the assessment. This information helped them in establishing a quality assurance program that removed kits when they were close to their expiration date so that patient results were not misleading.

In situations where an EQA program is not available, an in-house scheme can be developed using split patient samples. Here, a patient specimen can be sent for testing with another instrument or using another operator to test the sample.<sup>6</sup> Acceptability criteria for sample correlation can be obtained from published guidelines<sup>7</sup> or using  $\pm 2$  or 3 standard deviations from the mean from quality control data for quantitative assays.<sup>6</sup>

In order to identify and mitigate errors an individual quality control plan (IQCP) can be developed. Traditional QC refers to daily running a sample that contains a normal or abnormal concentration of the analyte to be tested before patient testing. The frequency is tied to

the stability of the analyzer's measuring system. However, with advances in technology, some measuring systems are stable for weeks or months.<sup>8</sup> The traditional quality control processes that were originally designed for large analyzers in centralized laboratories have become insufficient to address all the quality issues in POC testing. For instance, in certain point-of-care tests, the "analyzer" or measuring system, is often disposed-off soon after the test. As a result the Clinical Laboratory Standards Institute (CLSI) published the EP23-A, Laboratory Quality Control Based on Risk Management in October 2011.<sup>9</sup>

This guideline proposed that each test should have an IQCP and recommended a risk assessment approach to quality control, mapping out the testing process through the pre-analytical, analytical and post-analytical phases, to identify weak points in the process. Control mechanisms could then be placed at these points where there was a high probability of error to either prevent or monitor them and to take corrective action accordingly to maintain quality testing.<sup>10</sup>

This approach takes into consideration advances in technology by manufacturers for point-of-care instruments. In an attempt to continuously improve instrumentation several mechanisms have been put in place for POC tests by manufacturers to prevent reporting of unreliable results. Some examples of these quality assurance mechanism are:

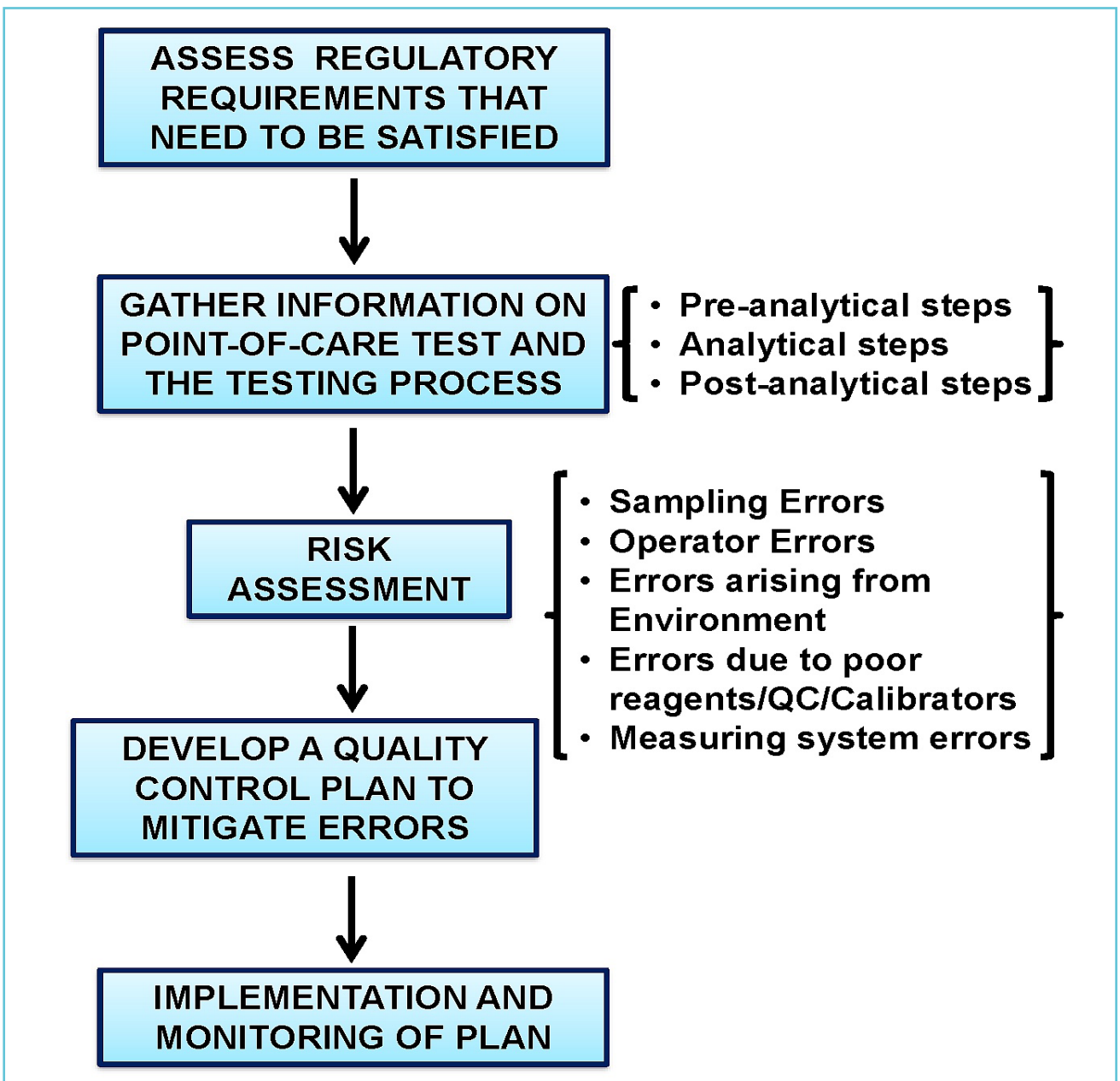
1. Reagents have barcoded expiration dates that prevent their usage if employed past this date.
2. Instrument lockout features prevent operator usage if the QC has failed or has not been run.
3. Instrument usage requires an operator-specific code ensuring qualified operators are testing patients.

4. Sensors in the instrument can detect air bubbles or clots and will not run patient samples unless this has been corrected.
5. For qualitative tests (e.g. pregnancy kit), a correct QC run is confirmed by the development of a strongly visible line.

1. Assessing any regulatory or accreditation requirements that need to be satisfied.
2. Gathering information about the instrument and the testing process for the analyte (s) from the manufacturer.
3. Risk Assessment - mapping the process to identifying procedural weaknesses.

The development of the IQCP involves the following steps (Summarized in Figure 2):<sup>11</sup>

**Figure 2** Schematic showing the thought process in developing an IQCP (11)



4. Developing a Quality Control Plan to mitigate errors identified in the risk assessment.
5. Implementation and monitoring the Quality Control Plan to ensure that it is always appropriate, making adjustments as necessary.

#### **D. Ensuring there is accurate documentation of all aspects of laboratory testing**

Accurate documentation is important in ensuring the correct result is associated with the correct patient but with respect to QC, EQA, instrument maintenance, and performance improvement exercises instills a culture of accountability and therefore is an important aspect of any quality management system. It also helps provide potential metrics for service assessment and performance improvement.

#### **CONCLUSION**

Best laboratory practices are the cornerstone of diagnostic testing and essential for patient care and therefore important whether testing is performed inside or outside a hospital setting. Following best laboratory practices have highlighted problems in workflow and/or diagnostic processes that would have otherwise been missed. Furthermore, because the nature of POC testing involves a diverse personnel with different educational backgrounds, it is essential to educate healthcare professionals in these best laboratory practices to keep up pace with the extensive proliferation of POC testing and their increasing reliance as integral components of the patient's treatment.

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