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BRIEF COMMUNICATION

Tweaking Internal Quality Controls for Cost Cutting in Resource Poor Settings

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Abstract

Commercial Internal Quality Control (IQC) materials are used regularly nowadays by most laboratories for ensuring that their test results are accurate, and the equipment used for analysis is functioning optimally. IQC may be procured from the company supplying reagents for a closed system or from an unrelated vendor who is not involved in supplying the equipment or reagents (third-party controls). Most IQC for Complete Blood Count have a short shelf life of up to three months and often the company further restricts the usage to 2-3 weeks after opening the pack or for few hours after reconstitution for coagulation-based assays. Some simple methods can go a long way in increasing the shelf life and enable substantial cost cutting, as we have succeeded in our laboratory for hematology and coagulation.

Key Words: *Internal quality controls; Accreditation; Cost cutting; Coagulation*

Introduction

Internal Quality control (IQC) does not have to be expensive certified reference material and can be easily prepared in-house [1]. Processing of IQC samples is usually done at the commencement of the day and again after specified samples have been processed is essential to ensure that an equipment is functioning satisfactorily and that patient sample results can be reported with confidence. The main objective of IQC is to ensure day to day consistency of results [2]. Most commercial companies provide a two-level commercial control which includes 'normal' and 'abnormal' controls that have limited shelf life. In-house 'normal' controls for coagulation assays can be easily prepared for prothrombin time, activated partial thrombin time, thrombin time and fibrinogen by collecting plasma from healthy volunteers.

Similarly, aliquots of known abnormal plasma and hemolysates from samples with haemoglobinopathies can be made and stored at -20°C or lower for a month. Most small and medium size laboratories in India do not have a -80°C so samples should not be stored beyond 2 months at -40°C unless the stability of the laboratory prepared IQC can be validated. Most laboratories procure commercial IQC either from the vendor supplying a given test kit for the sake of convenience and reliability e.g.,

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from Sysmex, Biomerieux, Tulip Diagnostics, and Stago Diagnostica while Bio-Rad labs is a popular third party IQC provider for many different tests.

Methods and Results

Haematology IQC are generally supposed to be stable for 2-3 weeks after opening the pack, though the shelf life may be more. In our laboratory we found that both proprietary and third-party controls stored at 2-8°C were stable for up to 10 weeks. Occasionally a non–reportable parameter reticulocyte-haemoglobin or platelets detected by fluorescence-optical analysis, which is useful for low platelet counts, did go out of range by <5% without affecting the quality of reporting. Aliquot preparation for storage (Figure 1) helped to augment the stability of a proprietary and one third party IQC for up to two months with minimal change of values for the reportable parameters. Aliquots of smaller volume may have further prevented deterioration, because loss in stability is due to the fact that the preparation needs to be kept outside the refrigerator for up to 20 minutes until it comes to room temperature, prior to running the IQC. This was observed for all three level (low, normal, and high) controls.

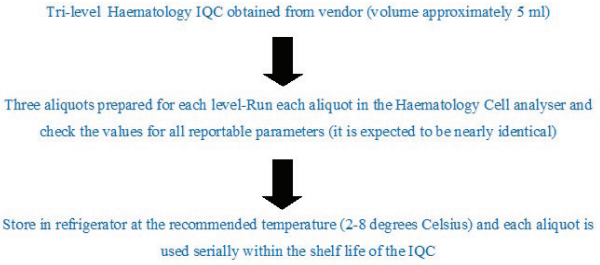

Figure 1) *Flow diagram showing method for extending shelf life of commercial IQC.*

In addition to extending the shelf life of commercial IQC, a laboratory can prepare normal controls for simple coagulation tests such as prothrombin time (PT) and activated partial thromboplastin time (APTT). Plasma samples can be collected from volunteers in blue top citrate vacutainers, centrifuged to make it platelet poor and then pooled after which PT and APPT is tested thrice and small aliquots of 200 µL are stored at ≤ -20°C. The frozen plasma was found to be stable for up to six weeks in our laboratory and is used as normal control for the tests. It is proposed to make similar aliquots of plasmas with high INR and check the stability under similar storage conditions. It is critical that the process of collection, testing, aliquot preparation, and storage should be done within minimum time and if the aliquots show prolongation of clotting time they should be discarded, and fresh in-house controls be prepared.

Discussion

IQC procedures ensure that factors determining the magnitude of uncertainty remain constant during the routine use of an analytical method and reagents over prolonged periods [1]. It is mandatory for a lab to perform 2-3 level IQC once or more depending on the workload. As per National Accreditation Board for Testing and Calibration Laboratories (NABL), India IQC is required to get a quantitative estimate of the uncertainty of measurement [3]. Small and medium sized laboratories with up to samples from 500 patients (as categorized by NABL) find it difficult to spend to pay for commercial IQC which are expensive and have a short shelf life for both vendor-driven and 3rd party controls. Therefore, if a laboratory can adequately and correctly validate that IQC material's stability for reportable parameters, it can be used for such time the results of reportable parameters are within range. It is well worth for the labs to do some research and adapt the IQC as mentioned above to augment the shelf life and thus cut down of the cost incurred substantially. This will not be objected to by any of the auditors who visit the lab for processing/extending its accreditation application. Preparation of in-house controls for coagulation-based assays results in significant cost cutting as commercial controls are stable for less than six hours. This

is very important for laboratories in resource poor settings and accreditation bodies must provide their approval after verification for use in-house IQC and use of commercial IQC beyond the documented shelf life of 2-3 weeks after opening the vial.

Conclusion

Simple procedures like making aliquots of commercial IQC and preparing normal controls from plasma can lead to significant cost cutting for laboratories in resource poor settings and this must be accepted by accreditation bodies if adequately validated by the user.

Disclaimer: The laboratory recommends that the suggested methods be properly validated prior to introduction in routine practice. In this hospital the practice is not carried out on regular basis.

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