

IMPLEMENTING A NEW QC PROGRAM IN THE UK: DRIVERS FOR CHANGE

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Biography

Tony Dedman was first appointed as a junior in 1980, then qualified and became licenced to practice in the UK in 1983 with a Fellowship in Clinical Biochemistry at the Institute of Biomedical Sciences (IBMS) following in 1985. Tony has been a member of the LTG (formerly London Toxicology Group) since 1999, and Association of Clinical Biochemistry since 2000. For the past twelve years he has lectured in Pathophysiology and biomedical science at the University of Hertfordshire. He has contributed to the teaching profession as an assessor for the IBMS and Health Care & Professions Council (HCPC) for the award of Certificate of Competence and then HCPC registration and as an IBMS specialist portfolio examiner for immunology and clinical biochemistry. In addition, Tony was responsible for the implementation of CPA (UK) Ltd and later ISO15189 training programmes in a number of laboratories. Currently he is employed as Training Coordinator and Method Development Scientist at Homerton University Hospital. Tony is responsible for research and development and the incorporation of new methods into the routine laboratory such as teicoplanin, TB drugs, Fat soluble vitamins, antibiotics and antiepileptic's primarily by HPLC, LCMS or GCMS. His current role includes commissioning a new GCMS system complete with thermal desorption to examine the potential of breath analysis as a diagnostic/prognostic tool in both primary and secondary care. His experience with chromatography techniques is contributing to the research for novel early biomarkers for Alzheimer's disease for which he is currently completing a PhD at the University of Middlesex.

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Abstract

The use of independent third party internal quality control is now a major requirement of ISO 15189(2012). Laboratories in the UK headed by Tony Dedman have been using TechnopathCD Quality Control products since 2000 – a true third party control. Performance led to the subsequent implementation at other NHS laboratories. The Multichem™ range (TechnopathCD, 2015) is human based and mimics the performance of patient samples. Multichem™ also adheres to the integrated solutions trend witnessed throughout the automated chemistry platforms of today. Analyte range includes a full menu for both chemistry and immunoassay offering benefits with respect to cost, efficiency and performance.

The main driver for change was a mandate to consolidate and improve workflow efficiencies. Reduced physical cost coupled with a reduction in staff time proved significant. TechnopathCD allowed extended lot sequesters, reducing the frequency of target value establishment and associated costs. This paper will review storage and delivery schedules customized for the laboratory in addition to the superior technical support received from TechnopathCD.

Introduction

Clause 5.6.2 of the current ISO 15189(2012) standards refers to the use of internal quality control material. This recommends that the use of 3rd party/independent control material should be considered as well as or instead of reagent/instrument manufacturer. In the current economic climate this can be considered to read instead of. With a reduction in technical competence seen by recent biomedical science graduates the decision was made to abandon the use of lyophilised internal quality control material in favour of ready to use liquid material. Furthermore, by employing LEAN techniques unnecessary steps in the processing of internal quality control runs were removed as it was possible to greatly consolidate number of samples used. After assessment of material from Bio-Rad, Randox and TechnopathCD, the various Multichem™ products were chosen and have been the recommended control material of choice ever since.

Drivers for Change

The main drivers for change were regulatory compliance, a drive to reduce the number of laboratory errors, to improve workflow and finally cost improvements were considered. It is important to realise throughout the assessment and decision making processes that quality always overrode cost.

Regulatory Compliance

The current laboratory environment within the UK means that the maintenance of accreditation status via Clinical Pathology Accreditation (CPA (UK) Limited, 2010) succeeded by ISO 15189:2012 is now fundamental to maintaining an independent laboratory service within an NHS Trust. Clause 5.6.2 of the current ISO 15189:2012 standards refers to the use of control material which is independent from the reagent/instrument manufacturer. The use of TechnopathCD Multichem™ products therefore ensures that laboratories comply fully with this standard.

Consolidation

The author has experience of employing the use of Multichem™ internal quality control material on analytical systems supplied by Olympus (now Beckman Coulter), Roche and Abbott Diagnostics. Regarding the Roche configuration TechnopathCD controls ensured that the number of individual routine internal quality control levels used were reduced considerably from 26 to 7 as shown in table 1.

Roche QC Product	Analytes	TechnopathCD QC Product
Alcohol, ammonia, bicarbonate Levels 1 & 2	Alcohol, bicarbonate	Multichem S Levels 1, 2 & 3
Precinorm CKMB	CK & CKMB	Multichem S Levels 1, 2 & 3
Precinorm Lipids	HDL Cholesterol	Multichem S Levels 1, 2 & 3
Precinorm Protein	CRP, Immunoglobulins	Multichem S Levels 1, 2 & 3
Precinorm U	Routine chemistry	Multichem S Levels 1, 2 & 3
Precipath CKMB	CK & CKMB	Multichem S Levels 1, 2 & 3
Precipath HDL/LDL-C	HDL Cholesterol	Multichem S Levels 1, 2 & 3
Precipath Protein	CRP, Immunoglobulins	Multichem S Levels 1, 2 & 3 Multichem P
Precipath U	Routine chemistry	Multichem S Levels 1, 2 & 3
TDM I Levels 1, 2 & 3	Paracetamol, salicylate, antiepileptic's, gentamicin, vancomycin	Multichem S Levels 1, 2 & 3
TDM II Levels 1, 2 & 3	Amikacin	Multichem S Levels 1, 2 & 3
Precicontrol Bone Levels 1 & 2	PTH	Multichem IA Levels 1, 2 & 3
Precicontrol Haematinics Levels 1 & 2	Vitamin B12, Folate, Ferritin	Multichem IA Levels 1, 2 & 3
Precicontrol Troponin Levels 1 & 2	Troponin I	Multichem IA Levels 1, 2 & 3
Precicontrol Tumour Marker Levels 1 & 2	PSA	Multichem IA Levels 1, 2 & 3
Precicontrol Universal Levels 1 & 2	Routine immunoassays	Multichem IA Levels 1, 2 & 3

Table 1: Comparison of Roche and TechnopathCD Controls at Ealing Hospital 2007 –2012

Error Reduction

This reduction in the physical numbers of internal quality control (IQC) vials required led to a reduction in transposition errors made by laboratory staff. Regular audits occurred which involved reviewing the internal quality control review sheets for each analyser. These demonstrated that at least once a week a member of the staff would mix up at least two levels. This ultimately led to unnecessary repeats having to be run which not only incurred additional IQC and reagent costs but meant that the instrument concerned was effectively out of commission for an unavoidable period consequently affecting turnaround times. Audits post implementation of TechnopathCD revealed no further errors.

Improved Workflow

The marked reduction in the number of IQC materials pipetted and the reduction seen in transposition errors led to less time being spent reviewing IQC, a vast reduction in the volume of IQC wastage and analyser downtime. The reduction in staff time amounted to approximately 3½ hours a week which in fiscal terms led to savings of approximately £3000 to £4000 pa (Dedman, 2015). Ordering is reduced as it is possible to place a single order every two years but more importantly the risk involved in such a large order remains with TechnopathCD. With deliveries being made once a quarter, if the freezer malfunctions then the laboratory will only lose three months' worth of IQC material but if the freezer at TechnopathCD malfunctions then it is the company's loss.

Product Quality

The quality of the product was assessed initially over a period of three to six months. During this time the stability of all the analytes were reviewed. Throughout this period the standard deviations for TechnopathCD material were significantly smaller than those observed for the equivalent material from Bio-Rad and Randox. This data was further supported at the IFCC World Lab meeting in Istanbul and Chicago (Brault, et al., 2014).

Storage and Stability

Ideally the frozen quality control material should be stored at -20oC or colder and each box thawed prior to being brought into use with an open vial shelf life quoted as 10 days. In practice however, it was found that all analytes, including alcohol, are stable for minimum of 5 days once the vial has been thawed and opened. Although experience has shown that this does not meet the stability quoted in the package insert, this is only due to the department using a vial after 5 days.

Six months after introduction, the Biochemistry Department at Ealing Hospital observed an under recovery with ALT and amylase. Standard troubleshooting protocols failed to resolve this issue and the low levels

were seen on both Roche c6000 analysers (Dedman, 2015). The only change identified which may have been a cause was that new boxes of Multichem™ S entered use. TechnopathCD Customer service, after reviewing the data, supplied the laboratory with fresh samples of the same and different lots. These were then run alongside freshly thawed samples from the laboratories stock. The final resolution was identified to a storage issue within the department and the affected boxes of stock material were replaced with crucially no fiscal penalties.

Conclusions

As a user of TechnopathCD Internal Quality Control Material since early 2000, the Multichem™ product range has proved to be reliable and stable, allowing for tighter limits and therefore reduced measurements of uncertainty for all of the analytes. The range allows for significant consolidation, together with an observed reduction in errors compared to manufacturer's material. The use of Multichem™ ensures that laboratories maintain ISO15189:2012 accreditation and good laboratory practices can be maintained with the use of this fully independent material.

Having used TechnopathCD Multichem™ on multiple analytical platforms from a variety of manufacturers for an extended period of time confirms that this is a truly independent quality control material. The quality is such that no longer does the laboratory have to maintain a stock of manufacturer's internal quality control material for troubleshooting purposes. Not only is this a direct financial benefit but the use of refrigerator and freezer space for the storage of manufacturers material becomes redundant and so reduces the laboratories carbon footprint.

Signed:



Tony Dedman

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