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Consolidation of quality control material improves patient safety and supports sustainability

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Abstract

Objectives: Quality control measurements are a keystone in daily routine laboratory workflows. This study evaluated the use of a consolidated quality control material for increasing efficiency while also reducing costs.
Methods: Quality control materials from two different manufacturers were chosen to evaluate efficiency in a test setting. A total of 23 clinical chemistry tests and 15 immunoassays were performed twice each day under routine conditions over a 10-day time period using an Abbott Alinity system.
Results: The data obtained showed a saving of between 40 and 100% depending on test criteria. The cost savings in waste reduction ranges between a factor of 5.4 for dead volume to 19.8 for consumables. No difference in quality performance were found.
Conclusions: Choosing a consolidated quality control material resulted in a higher efficiency, greater cost savings and higher sustainability while maintaining the same level of performance.

Keywords: cost and labor reduction; efficiency; performance; quality control; sustainability.

Introduction

Quality control (QC) is essential within medical laboratories for providing highly reliable test results and, therefore, for contributing to patient safety requirements. There are many proposals, guidelines, and laws describing how to run QC procedures – including the Westgard rules, CLIA and RiliBÄK [1–5] – which aim to deliver dependable results and, ultimately, support patient safety.

To date, no studies have been undertaken to improve and describe efficiency in daily routine work in regard to QC protocols. Our lab made the decision to evaluate the impact of using a highly consolidated QC material vs. the currently used material, which is a mixture of lyophilized and liquid. Regardless of the QC material we use, the performance should not change.

Using fewer bottles/vials of QC material and reducing handlings steps contributes to a higher level of patient safety. The likelihood of errors decreases when using liquid QC material, as pipetting and sampling mistakes are less frequent. Therefore, we evaluated in this study if running a highly consolidated QC material has a positive impact on efficiency and sustainability, while maintaining high performance over 10 days.

Additionally, the issue of sustainability is now becoming a focus in healthcare, so our intention was to reduce the use of consumables as well as waste production in the lab, which also lowers the costs to the lab [6, 7].

Materials and methods

This study was performed at the University Hospital Ramón y Cajal in Madrid, Spain. The hospital has about 900 beds and its laboratory runs approximately 13.5 million tests per year (10,000,000 in biochemistry, 2,250,000 in hematology, 438,000 in microbiology and 458,000 in immunology). The lab is currently using a mixture of liquid and lyophilized QC material and plans to change over to a highly consolidated purely liquid QC material. Study goals were to improve the efficiency of the lab as well to contribute to the concept of sustainability, covering two main aspects:

- To analyze the efficiency performance of QC materials in use, such as:
  - Cold storage space requirements – calculate the volume in cm^3.
  - Handling time – using a stopwatch to measure all steps in minutes.
  - Dead volume – what is left in the cup or vial after each QC sampling event that cannot be used. The manufacturers state that this is a minimum of 50 µL per Alinity sample cup or 100 µL per Technopath Multichem Alinity vial.
  - Consumables waste – measured on a balance in *g*. The costs were calculated by counting the number of consumable components (tips, cups and vials) multiplied by their individual weight, and finally multiplied by the costs of waste disposal as provided by the hospital administration.
- To compare the analytical performance of current independent QC materials from Bio-Rad (Irvine, USA) and Technopath

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(Ballina, Ireland) on an Alinity system (Abbott, Wiesbaden, Germany).

The aim was to generate at least 20 results per method per QC material for both clinical chemistry (CC) tests and immunoassays (IAs), representing two measurements per day over a period of 10 days. Twenty-three CC tests and 15 IAs were carried out (Figures 1 and 2). The study was limited to 38 tests only.

A range of QC materials were selected to cover all the assays mentioned above: Lyphochek Assayed Chemistry Control (2 levels), Liquichek Immunology Control (3 levels), Liquichek Immunoassay Control (3 levels), Lyphochek Tumor Markers Plus Control (3 levels), Liquichek Cardiac Marker Plus Control LT (3 levels), and Liquichek Specialty Immunoassay (3 levels) all from Bio-Rad, and Multichem S Plus (3 levels) and Multichem IA Plus (3 levels) (Table 1) both from Technopath. The Alinity system was run according to the manufacturer's instructions.

We used all three levels of Technopath QC material as it was new to us and as well as we wanted to evaluate concentrations of the analytes at relevant clinical levels, near or above the higher and near or under the lower limits and within range values. The lyophilized CC Bio-Rad QC material we are using is available only in two levels, and three levels for IA. Additionally, our interest was to compare the current lyophilized QC material in use vs. the new liquid QC material.

We measured and calculated the space required in the cold storage the QC materials, the handling time and the dead volume in the vial or cup, as well as the consumable materials used (vials + stoppers, tips, cups). The results from the Alinity system were used to calculate the coefficients of variation (CVs) to describe and compare analytical performance. Dead volumes were determined after processing the Bio-Rad controls in the instrument by measuring the volume remaining in the Alinity cup. For the Technopath controls, dead volume was calculated based on the remaining volume of the Alinity barcoded vials once this became insufficient to continue using them.

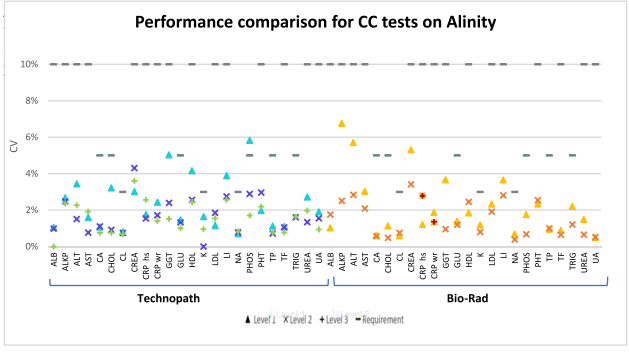

Figure 1: Performance comparison for 23 CC tests on the Alinity analyzer using QC materials from two different manufacturers, Technopath and Bio-Rad. CV=coefficient of variation. The limits used are based on results from several consensus meetings between the medical laboratory and the medical doctors from our hospital. They may be different from other recommendations but they follow the Milan hierarchy as we have the clinical evidence (8). ALB, albumin; ALKP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CA, calcium; CHOL, cholesterol; CL, chloride; CREA, creatinine; CRP hs, C-reactive protein high sensitive; CRP wr, C-reactive protein wide range; GGT, gamma-glutamyl transferase; GLU, glucose; HDL, high-density lipoprotein cholesterol; K, potassium; LDL, low-density lipoprotein cholesterol; LI, lithium; NA, sodium; PHOS, phosphorous; PHT, phenytoin; TP, total protein; TF, transferrin; TRIG, triglycerides; UREA, urea; UA, uric acid.

Results

Cold storage

Cold storage space requirements for CC and IA QC materials were 7,997 and 4,886 cm^3 for Bio-Rad, respectively, and 776 and 2,328 cm^3 for Technopath, resulting in a space savings of between 52% (IA) and 90.3% (CC).

Handling time

Handling time based on 20 test events – which includes reconstituting controls, labeling cups, pipetting into cups, and loading them into racks – was calculated to be 269.9 min for Bio-Rad QC materials, and 2 min for Technopath. This demonstrated a saving in handling time of 99.8 and 99% respectively. We estimated that the time savings could be up to 7.8 days/year/instrument if the lab ran three QC events per day or up to 10.2 min/shift/instrument, depending on the specific QC protocols used.

Dead volume

Dead volumes for IA QC materials were 11.63 mL for Bio-Rad and 2.49 mL for Technopath, saving 9.14 mL or up to 79%. For CC we found 3.29 mL for Bio-Rad and 0.0 mL for Technopath which makes savings of 100% (Table 2).

Consumable waste

As Technopath QC material was pipetted directly from the barcoded vial by the Alinity system, no additional cups and pipette tips were used. The Bio-Rad QC material had to be transferred from the vials into cups to be placed on the instruments, and therefore we needed 340 cups and 350 pipette tips. In regard to total vials used in the study, there was a 50% saving by using Technopath QC materials for IA and 40% for CC. Results are summarized in Table 1.

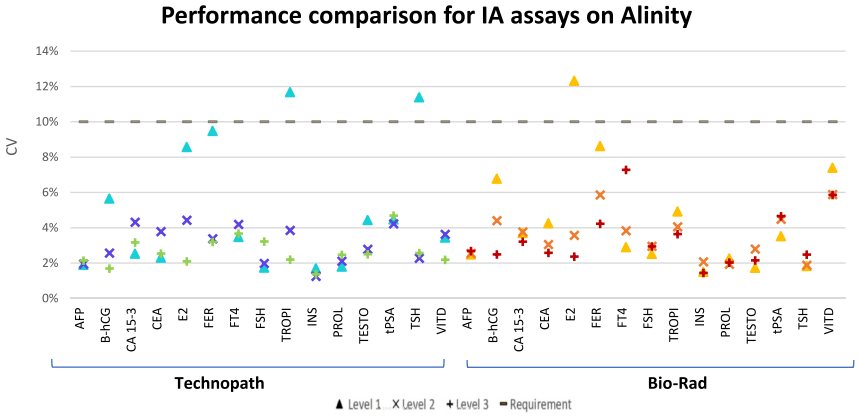

Figure 2: Performance comparison for 15 IAs on the Alinity analyzer using QC materials from two different manufacturers, Technopath and Bio-Rad. CV=coefficient of variation. The limits used are based on results from several consensus meetings between the medical laboratory and the medical doctors from our hospital. They may be different from other recommendations but they follow the Milan hierarchy as we have the clinical evidence (8). AFP, alpha-fetoprotein; ß-HCG, beta human chorionic gonadotropin; CA 15-3, cancer antigen 15-3; CEA, carcinoembryonic antigen; E2, estradiol; FER, ferritin; FT4, free thyroxine; FSH, follicle-stimulating hormone; TROPI, troponin I; cardiac high-sensitive; INS, insulin; PROL, prolactin; TESTO, testosterone; tPSA, prostate specific antigen; TSH, thyroid-stimulating hormone; VITD, vitamin D.

Table 1: Summary of savings in an efficiency study on different QC materials.

		Immunoassays				Chemistry			
Metric	**Unit**	**Bio-rad**	**Technopath**	**Difference**	**Saving, %**	**Bio-rad**	**Technopath**	**Difference**	**Saving, %**
Cold storage space requirements	cm^3	7,997	776	7,221	90	4,886	2,328	2,558	52
QC sample handling time	Hours	3.44	0.03	3.41	99	1.06	0.0025	10.56	99.8
Dead volume	mL	11.63	2.49	9.14	79	3.29	0	3.29	100
Waste from vials	Vials	24	12	12	50	10	6	4	40
Waste from cups	Cups	240	0	240	100	100	0	100	100
Waste from pipette tips	Tips	246	0	246	100	104	0	104	100

Performance

The imprecision data over 10 days are shown as CVs in Figures 1 and 2 [8]. They ranged from 0.0 to 6.8% for CC, and from 1.3 to 12.3% for IA.

Costs

The waste costs for consumables are over 19.8 times higher with the current solution compared to the consolidated QC material. Remarkable savings were also found while using ready-to-use vials, due to reduction of the QC material dead volume, 118.12 € for Bio-Rad vs. 20.64 € for Technopath. Details are given in Table 2.

Discussion

Independent QC material is recommended by ISO 15189 (4) and the IVDR [9] to evaluate the performance of the analytical process. So far, neither the practicality and efficiency of certain QC materials, nor the advantage of using of a consolidated QC material, have been studied. Furthermore, many authors have described the risk of using only in-kit control material, especially in the case of reagent lot changes [10–14].

QC in integrated systems are still a challenge. In our short term study we have done a limitation for a 10 days period in order to evaluate the performance and the sustainability of a highly consolidated QC material. Further studies are needed to evaluate the long term use.

Table 2: Summary of calculation of costs from efficiency study on different QC materials over 10 days. (For calculation of the costs, one has to consider that depending on the location and contracts, different pricing may occur, so we are reporting the prices listed for the QC material as well as for the consumables).

Waste		Weight per unit, g	n	Weight total, g	Costs of waste, €
Bio-rad					
Empty vials + stoppers		19.67	34	668.78	0.21[a]
Yellow tips		0.33	220	72.6	0.07[b]
Blue tips		0.8	130	104	0.11[b]
Cups		1.74	340	591.6	0.60[b]
Total				**1,436.98**	**0.99**
Technopath					
Empty vials + stoppers		9.11	18	163.98	0.05[a]
Total				**163.98**	**0.05**
Dead volume	**Source**	**Dead volume, mL**		**Price per 1 mL[c], €**	**Costs, €**
Bio-rad	IA	11.63		8.29	96.41
	CC	3.29		6.60	21.71
Total					**118.12**
Technopath	IA	2.49		8.29	20.64
	CC	0		6.60	0.00
Total					**20.64**

[a]Waste costs for vials: 0.3148 €/kg (no VAT included). [b]Waste costs for consumables (tips and cups) (special biohazardous waste): 1.0152 €/kg (no VAT included). [c]For fairness reasons we have taken the same price per mL regardless of the manufacturer and contract conditions (no VAT included). The bold values are the sum of each type of control.

We reduced cold storage space by 52% for CC analysis and 90.3% for IA, handling time by 99.8%, dead volume by up to 100%, and consumables by between 40 and 50% for vials, and 100% for both cups and tips. This was because we were able to use original Technopath Multichem Plus barcoded Alinity vials directly on the instrument.

The performance of the QC materials was comparable between both suppliers and within the expected CVs, as defined by our laboratory-based on, long-term observations.

Overall, Technopath Multichem Plus consolidated control materials deliver the same high performance on the Alinity instrument as the Bio-Rad Liquichek/Lyphochek QC materials. In regard to efficiency (costs, cold storage space, handling time, dead volume, and waste), we found savings of between 40 and 100%. The costs of waste are over 19.8 times higher with current solution than with the consolidated material. It is remarkable that the reduction of dead volume by using ready-to-use vials on the Alinity system is high, resulted in a factor of 5.4. As sustainability becomes a prominent issue [6, 7] it is important to check all areas of the medical lab for ways to reduce waste while saving money. Our study clearly showed the savings in costs and the reduction of waste, even if it was a 10 days study only.

We are fully aware that the study was limited to one lab, 10 days, 38 analytes, one analyzer, one lot of QC material and one lot of reagent. An extended study is needed to get more details.

Finally, we believe by using less vials of barcoded QC that is sampled directly by the instrument could contribute to patient safety as delays due to levels mix up and pipetting errors into wrong sample cups could be eliminated. These manual errors can cause delays in releasing of patients results which can effect patient diagnosis and treatment especially for urgent STAT samples. So, it would be a potential benefit of QC consolidation.

Conclusions

We have been able to demonstrate that selecting highly consolidated control materials and ready-to-use vials from Technopath will yield important savings in terms of time and costs, while providing a comparable analytical performance. This is a step forward toward running QC procedures in a very smart and efficient way.

The savings of consumable and waste is also remarkable.

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