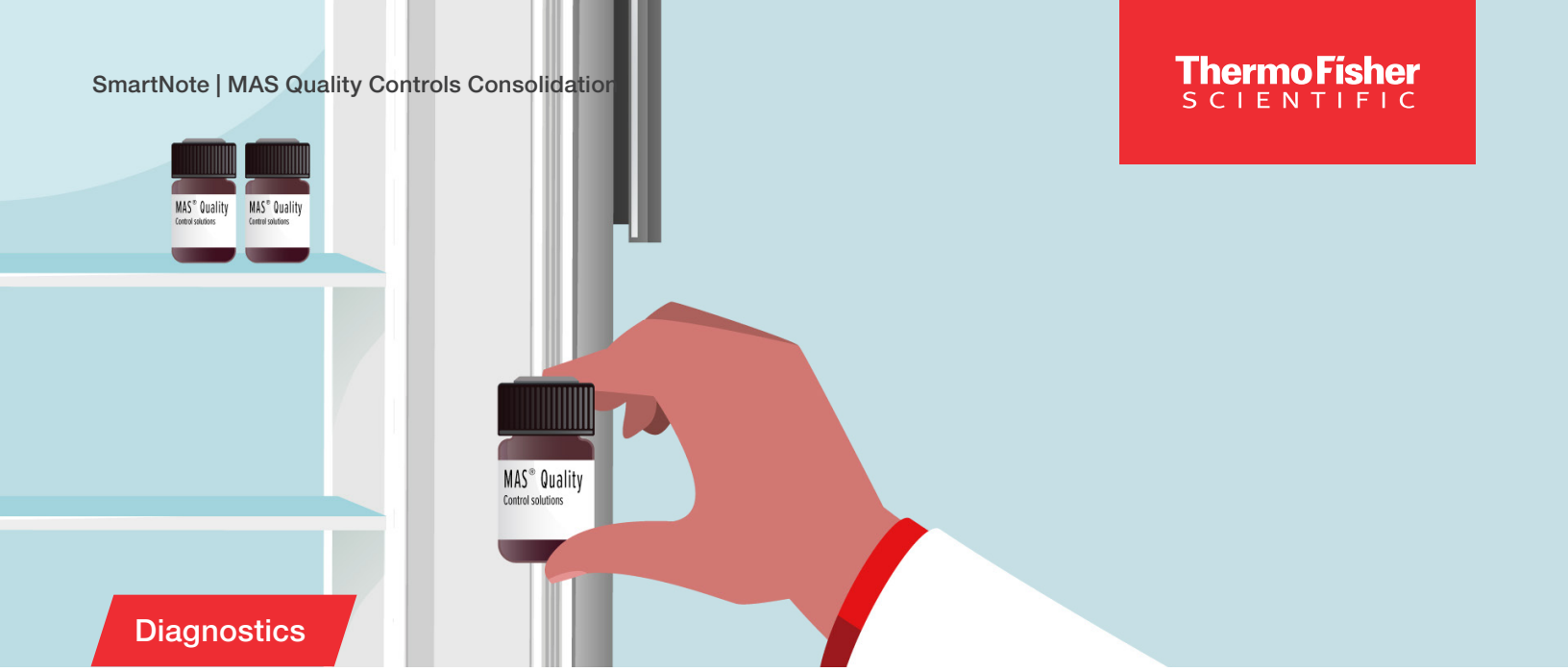


Diagnostics

Do more with Thermo Scientific MAS Quality Controls

How consolidation of QC references improve clinical laboratories' operational efficiency

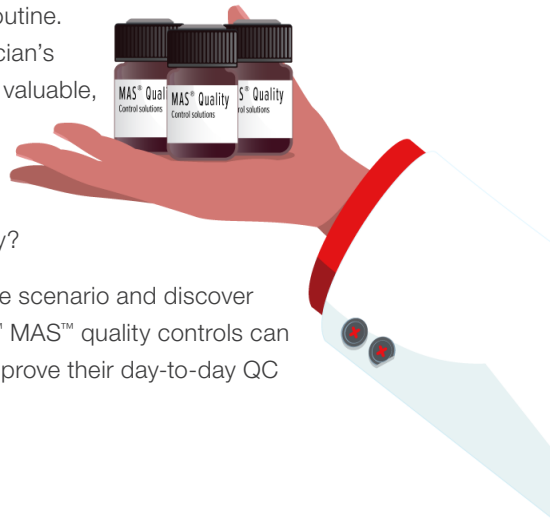
Introduction

Clinical laboratories around the globe, are facing staff shortages and are under pressure to reduce their annual spendings. This new reality impacts all aspects of the inner workings of the laboratory. Laboratory managers and supervisors must find creative solutions to maintain quality of testing and services, while improving productivity with more cost-efficient solutions.

One product line that can be overlooked when it comes to improve operation and cost efficiency is quality control.

Internal quality controls are a critical and sensitive topic for clinical laboratories as they act as the foundation and safeguard to ensure accurate testing results. Per clinical laboratory regulations, quality controls (QC) are mandatory for all analytes run on patient samples and often run every day, or several times per day depending on the amount of patient samples collected by the laboratory.

When clinical laboratories have been using the same quality controls for years, adding new QC for the expanding testing menu often results in a combination of QC from various vendors being used routinely. This variety of products comes with different instructions for use, storage conditions, open-vial stability, different purchasing processes, etc. It is not uncommon for laboratory technicians to spend one or two hours every day on their daily QC routine. Considering the technician's time being increasingly valuable, how can laboratories improve their daily QC routine and save precious time every day?



Let's explore a real case scenario and discover how Thermo Scientific™ MAS™ quality controls can support laboratories improve their day-to-day QC efficiency.

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Case study: QC reference consolidation

Consolidation

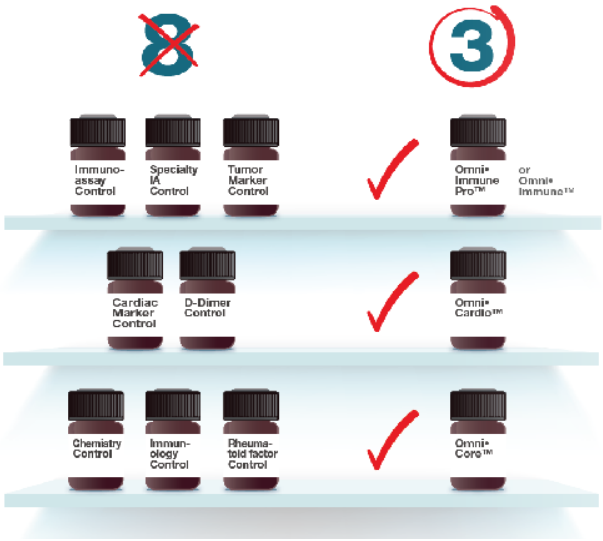
This laboratory, located in a large metropolitan area, is currently using routinely 18 different QC references purchased from two distinct vendors.

QC Manufacturer 1	Number of levels
Chemistry control	2
Immunoassay control	3
Anemia control	1
Urine Chemistry control	2
Immunology control	2
Lipids control	2
Pediatric bilirubin control	2
Diabetes control	2
Cardiac Markers Control	2
QC Manufacturer 2	**Number of levels**
Procalcitonin Control	3
PTH control	3
AFP Control	1
Anti-TPO Control	1
IgE Control	2
Methotrexate Control	3
NT-ProBNP Control	1
THC Control	3
Drugs of Abuse Control	2
Total: 18	**Total: 37**

Table 1: List of current quality controls and number of levels ran on a daily basis.

All QC references, even within the portfolio of one QC provider, can have different instructions for use. This means that the more QC references a laboratory is using, the more complicated it gets for the technicians' daily QC routine. They must follow numerous QC handling protocols, which leads to loss of time and increases the risk of potential errors. This grows exponentially when considering the different levels ran per QC references. Most clinical laboratories will run two levels or more per QC references. In this case, the laboratory runs a total of 37 different QC bottles every day.

When performing a comparison analysis, with the Thermo Scientific MAS QC portfolio, we were able to cross-reference each reference from QC manufacturers 1 and 2, resulting in two proposals: One with the legacy MAS QC products, and one with the most recent Thermo Scientific MAS Omni products.



The classical MAS QC products would reduce by half the number of QC references run daily, whereas the MAS Omni products would offer 61% reduction in the number of QC reference with only seven QC products.

	Thermo Scientific MAS quality controls	
QC Manufacturer 1	**Classical MAS products**	**MAS Omni products**
Chemistry control	MAS ChemTRAK™ H	MAS Omni•CORE™
Lipids control		
Immunology control	MAS Immunology	
Immunoassay control	MAS Liquimmune	MAS Omni•IMMUNE-PRO™
Anemia control		
Urine Chemistry control	MAS UrichemTRAK	MAS UrichemTRAK
Pediatric control	MAS Bilirubin	MAS Bilirubin
Diabetes control	MAS Diabetes	MAS Diabetes
Cardiac Markers Control	MAS CardioImmune™ XL	MAS Omni•CARDIO™

	Thermo Scientific MAS quality controls	
QC Manufacturer 2	**Classical MAS products**	**MAS Omni products**
Procalcitonin Control	MAS Omni•IMMUNE-PRO	MAS Omni•IMMUNE-PRO
PTH control		
Anti-TPO Control		
AFP Control	MAS Liquimmune	
IgE Control	MAS Immunology	MAS Omni•CORE
Methotrexate Control	MAS ChemTRAK H	
NT-ProBNP Control	MAS CardioImmune XL	MAS Omni•CARDIO
THC Control	MAS DOAT	MAS DOAT
Drugs of Abuse Control		

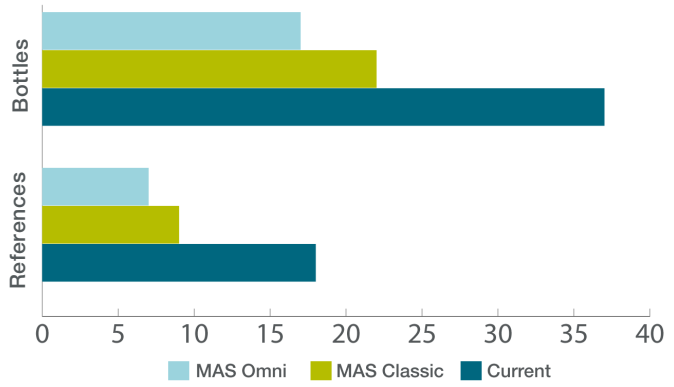
Total References		
18	9	7

Table 2: Cross-reference of current QC menu with the Thermo Scientific MAS QC portfolio

Laboratories run several levels for each QC reference resulting in a multiplied number of vials used every day. The present laboratory uses 37 different QC bottles for their daily QC routine every morning. With the Thermo Scientific MAS classic products, the number of daily QC bottles would decrease by 41% with 22 bottles. With the Thermo Scientific MAS Omni products, the laboratory would achieve a 54% reduction in the number of daily QC bottles.

	Current QC solution from other vendors	MAS classic		MAS Omni	
# of References	18	9	-50%	7	-61%
# of Bottles	37	22	-41%	17	-54%

Table 3: QC References and bottles comparison



Graph 1: Summary of cross-reference study displaying the numbers of QC references and QC bottles.

Lot-to-lot validation

Clinical laboratories, when switching to a new lot of QC material, must perform a validation commonly called lot-to-lot validation. Laboratories must run their current QC lot in parallel with the new QC lot for a certain amount of QC data point. The number of QC data points will vary upon each laboratory standard of operation. Though a largely adopted method is to run 20 QC points. Those QC points will allow the laboratory to establish their means, standard deviation, and coefficient of variation before using the new lot in routine.

The validation period implies extra work and expenses by the laboratory personnel:

- Consumption of additional reagent
- Additional QC bottles to prepare and run every morning
- Additional QC data to gather
- Time needed for the final statistical analysis

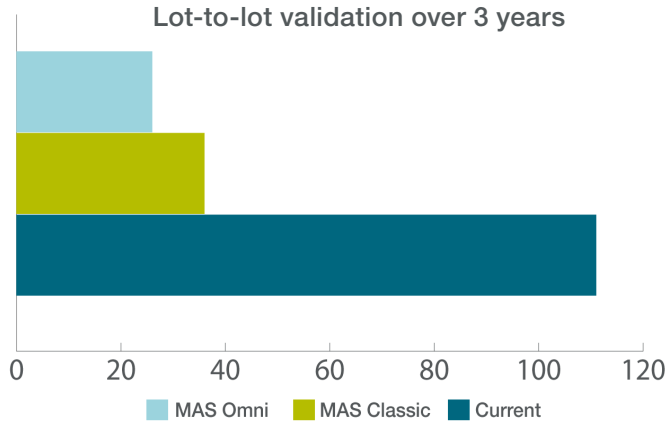
Changing a QC lot is also a sensitive period because the new lot might not perform similarly to the previous lot, or the values might be different and not in the ranges needed by the laboratory anymore. This is why laboratries try to stay on the same lot as long as possible, to reduce the frequency of lot-to-lot validations. Not all vendors can offer laboratories to stay on the same lot until expiry. Some vendors proceed with annual inventory orders, which results in the laboratory switching lot every year.

In the laboratory situation we are analyzing here, they are switching lot every year with their current vendor. This results in 111 lot-to-lot validation over three years when counting each level for each QCs.

This number would be reduced to 36 with the fewer references needed to cover the same list of analytes in parallel with the ability to stay on the same lot until the expiry date with Thermo Scientific MAS classic products.

The amount of lot-to-lot validation will shrink to 26 with the higher consolidation of QC references offered by the MAS Omni portfolio, which is a 77% reduction in lot-to-lot validation periods.

Another benefit brought by the MAS Omni control solution is the long lot shelf life. It allows facilities to save time and anxiety with less lot-to-lot validation periods. It also allows for long-term QC management, which brings easier and faster troubleshooting.



Graph 2: Lot-to-lot validation over a three-year period

Discussion

Changing a well-established routine can be time consuming and stressful, especially when it relates to something as fundamental as quality controls. Though, after running the same mix of QC for so many years, clinical laboratories can sometimes not realize that more innovative and efficient solutions are available in the market.

In this example, switching to Thermo Scientific MAS Omni QC will greatly increase productivity and efficiency in the laboratory. Decreasing the number of daily QC bottles used by more than half will dramatically improve the laboratory efficiency. It will also simplify processes on many levels:

- **Technician time:** The MAS Omni solution offers a 54% reduction in the number of QC bottles run everyday. The time saved every day will allow technicians to perform other duties in the laboratory.
- **Purchasing:** Fewer references to order.
- **Storage:** Fewer references to organize in the fridge and freezer.
- **Lot management:** Fewer QC references means fewer lot numbers and fewer lot expiry dates to track.
- **Troubleshooting:** With fewer references and less QC bottles used every day, potential risk of errors is greatly reduced.
- **Customer support and service:** Instead of having 2 or sometimes more support teams to contact, a single provider team will take care of your requests.
- **Waste:** With fewer QC references every day comes fewer dead volumes thrown in the trash every day, resulting in less waste and financial savings.
- **Environment:** Fewer references ordered from fewer vendors, means less shipments, fewer boxes, less microcups in the trash.

Conclusion

When facing financial constraints and staff shortages, Clinical laboratories will look for avenues to improve productivity and efficiency, ensuring an operational status of their patient sample testing systems. One solution to consider is a review of the quality controls used in the laboratory. This can result in significative time saving and increased efficiency.

Thermo Scientific MAS Omni controls are a modern and innovative solution to do more with less QC products.

Learn more at **thermofisher.com/morewithMASQC**

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