

Sunway Medical Laboratory Quality Control Plans Based on Six Sigma, Risk Management and Uncertainty



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KEYWORDS

• Analytical quality control • Six Sigma • Risk management • Uncertainty

KEY POINTS

- Measurement uncertainty, risk management, and Sigma metrics are often discussed as individual approaches, sometimes in conflict with each other. But in truth, these approaches can all be implemented together and provide complementary strength in assuring the quality of laboratory testing.
- Sustained effort and implementation of Sigma metrics result in continuous improvement of assay quality and reductions in costs and defective test results.
- Sigma metrics provide not only assistance in optimizing routine laboratory operation but also greatly assist in the selection of appropriate new instruments and methodology.
- Risk management allows laboratories to expand their quality assurance to cover the total testing process.
- Measurement uncertainty is an essential calculation for International Organization for Standardization 15189 certification, but often these figures are not routinely reported with patient test results and requires the greatest effort to educate laboratorians and clinicians about the meaningful use of these estimates.

INTRODUCTION

Any laboratory total testing process involves 3 major phases: the preanalytical, analytical, and postanalytical phases. All 3 areas can contribute to sources of errors resulting in poor patient care. Studies in the 1990s and 2000s led many to believe that about 80% of the errors are found in the preanalytical and postanalytical phases, whereas

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only 20% of the errors occur in the analytical phase. Thus, more support and improvements are focused on preanalysis and postanalysis, and less importance is given to analytical quality, which is assumed to be the least problematic area. Based on daily complaints from users, we noted preanalytical and postanalytical errors are obvious categories of errors, as they are easily detected by clinicians, in contrast to analytical errors in which clinicians depend totally on the laboratory for detection and correction of errors, unless the results are extremely divergent from clinical symptoms. If any test result has an error, the clinicians instruct the laboratory to perform repeat testing. Clinician voices are heard louder than any others, resulting in the perception that preanalytical and postanalytical errors are the bigger issues for laboratories. This finding leads to a misconception about which errors are bigger and need to be managed first. However, this triage might not be correct, as in a hospital laboratory all 3 phases carry equal weight and importance. If we can't get the patient specimen to the laboratory, if we can't perform the test correctly, and if we can't deliver the results back to the right patient, it leads to similar consequences of bad test results and poor patient care.

The core duty of a medical laboratory is to produce correct test results. Therefore, the interlinked 3 phases of the laboratory testing process need to be addressed concurrently and equally. Similar to US laboratories, Malaysian laboratories comply with regulatory requirements in implementation of quality control (QC) systems. Local standards, particularly Malaysian Standards (MS) International Organization for Standardization (ISO) 15189, have led medical laboratories to adopt uncertainty of measurement, "intended use" of clinical needs or requirements, and risk management to develop laboratory-specific quality control plans to reduce errors and enhance quality improvements and patient care. Similarly, international standards such as the Australian Council of Healthcare Standards (ACHS) and The Joint Commission International accreditations require health care sectors to adopt risk management in continuous quality improvement activities. QC is important in a health care setting to assure that a desirable quality standard is achieved. In a broad sense, QC is defined as processes, procedures, and techniques that are adopted to either prevent errors from occurring or to detect errors if they do occur.¹ Therefore, providing education, training, proper system in specimen collection, processing, analyzing correctly and reporting the test result to the right patient is part of the broad approach of QC. A more specific meaning of QC is statistical quality control (SQC), which focuses on monitoring and controlling the analytical phase of a laboratory testing process.¹ The biggest challenge faced by medical laboratories is to choose the right way of doing statistical QC and how much knowledge and skill the analyst has in applying the quality tools such as Six Sigma, measurement of uncertainty, and risk management to assure the quality of laboratory test results.

ANALYTICAL QUALITY CONTROL PLANS WITH SIX SIGMA QUALITY MANAGEMENT SYSTEM AT SUNWAY MEDICAL LABORATORY

In addition to assuring compliance with regulatory requirements, the goal of quality management is to satisfy stakeholders, such as doctors and patients, for reliable laboratory test results. Quality must meet the predetermined requirements to the satisfaction of the users for a particular substance or a service. Quality assurance is sum of all activities that are undertaken to ensure generation of reliable and accurate results or data.² An integral part of any analytical quality system is SQC.¹ QC in the medical laboratory is defined as a statistical process used to monitor and evaluate the analytical process that produces patient results.³ It is essential and crucial for the medical laboratory to select the right QC procedures.

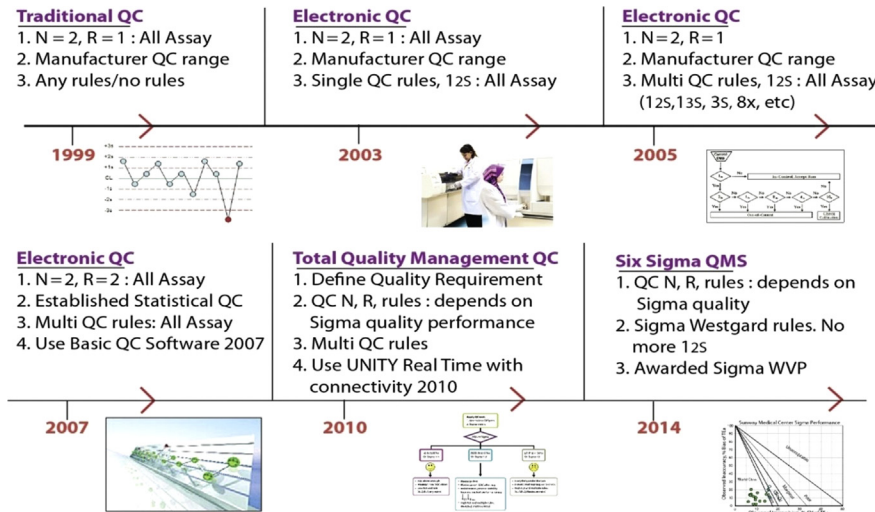


Fig. 1. SunMed journey on best QC practices.

For the last 2 decades, the QC practices of Malaysian medical laboratories have undergone constant evolution and change to provide the best practices and cost-effective monitoring of analytical processes. Traditional QC practices have been the heart of quality systems; however, now they have been expanded to develop a more comprehensive plan for managing analytical quality that will cover all the potential risks or errors and monitoring of the residual risks.¹

Fig. 1 shows how the laboratory in one of the private hospitals in Malaysia, Sunway Medical Center (SunMed), evolved in their QC practices since the inception of the hospital in 1999.

Initially, SunMed adopted default QC of 2 levels once per day with no QC rules in place. We have been using electronic QC even as early as 2003. The manufacturer ranges were used instead of establishing our own mean and standard deviation. SunMed implemented a single “1:2s” rule for all assays and realized that this “one size fits all” QC rule was not enough for good error detection. Thus, in 2005, we further expanded to implement the multirule (Westgard Rules) for all assays. In 2007, statistical QC and basic QC software was used to monitor the QC performance. Eventually in 2010 the QC software was upgraded to a real-time quality data management system while also defining the quality requirement and running QC according to individual assay performance. SunMed laboratory realized that the use of electronic QC checks are not sufficient; therefore, the need for a quality system is essential to effectively monitor and control the error sources in the total testing process. While the laboratory was in the midst of being verified for a Sigma Verification Program, we implemented the Six Sigma Quality Management System (6 σ QMS), the new Westgard Sigma Rules, and selected QC runs and rules according to the respective assay performance. One of the reasons that triggered our turning point in QC plans in 2014 was the lack of QC knowledge and awareness among laboratory personnel. Without a sturdy understanding and knowledge about the total testing process and basic QC, it would have been a challenge to sustain good quality in the laboratory. The implementation of 6 σ QMS enabled us not only to look into the performance of our analyzers, but also take into account the preexamination steps on specimen collection, transportation, and sorting and the postexamination steps on test interpretation and transmission. This resulted in

the need for preventive techniques and control mechanisms to prevent sources of errors and improve the current workflow to preserve the level of quality of laboratory test results. SunMed laboratory, while achieving status as a Sigma-verified laboratory, still felt that single QC procedures were not able to monitor all the sources of errors in the total testing process. QC plans and quality management systems (QMSs) were enhanced with additional tools and techniques, some of those are as mentioned below:

- Policies and procedures are in place to describe the standard operating procedures and processes for producing test results.
- Local MS ISO 15189 guidelines are used for essential requirements on best laboratory practices.
- International accreditation such as ACHS looks at overall processes in the hospital where cross-functional teams will be necessary to the preanalytical and postanalytical portion of the total testing processes to mitigate sources of errors and satisfy the needs of doctors and patients.
- Inspection is done by the hospital internal quality audit team and on accreditation assessment by the external assessors on the weak points in the total testing process that requires further improvements.
- External monitoring is done of the analytical performances by comparison and participation in proficiency testing and external quality assessment.
- Quality indicators such as critical value reporting, turnaround time, and specimen rejection rates, give quantitative performance of the testing processes.
- SQC is established for monitoring the analytical performances of the laboratory testing process. The 2 important aspects related to statistical QC are quality planning and quality goals. Quality planning results in the selection and validation of new methods or instruments, whereas quality goals fulfill the ISO standard requirement on the phrase *intended use*. The need to define tolerance limits or total allowable errors is an essential part of 6 σ QMS. Sigma metrics enable us to quantify the performance of individual assays and indicate if the instruments are performing well in terms of measurable quantitative data. They also provide a benchmark to select QC protocols and target assay improvement.
- Analytical QC plans take into account the statistical (which is the SQC) and the nonstatistical elements of the procedures to mitigate potential risks or errors. The approach to the analytical QC plan began with the definition of the goal for intended use that complies with ISO 15189 regulatory requirements; total allowable error (TEa) from Clinical Laboratory Improvement Amendments were used. The calculation of Sigma metric takes into account the measurement procedure by assessing the precision (coefficient of variation) and inaccuracy (bias); these lead to validation of the QC design. The appropriate statistical QC procedure is designed by establishing the required control rules, total number of control measurements, and the frequency. Once the appropriate QC procedure is designed, strategies are developed by incorporating risk analysis and recommendations from the manufactures as part of the procedures.

SOME OF THE POSITIVE IMPACTS OF ANALYTICAL QUALITY CONTROL PLANS WITH THE SIX SIGMA QUALITY MANAGEMENT SYSTEM

1. Via the 6 σ QMS, we were able to quantify individual assay performances and compare them with those of previous years. With the QMS in place, not only did we manage to improve the Sigma quality of individual assays from preverification and postverification (2014 to 2015), we managed to reduce the number of assays

with $\leq 3\sigma$ and 4σ and increase number of assays with 5σ and $\geq 6\sigma$ (Figs. 2–4). We found more than 70% of the assays maintained a world class performance of Six

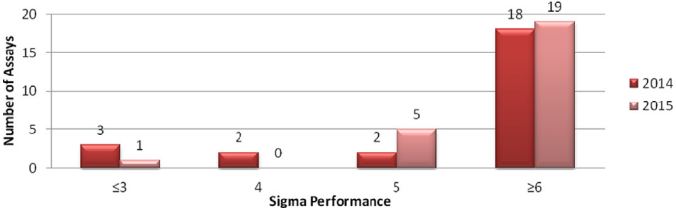


Fig. 2. Comparison of Sigma performance for chemistry assays—2014 and 2015 (level 1).

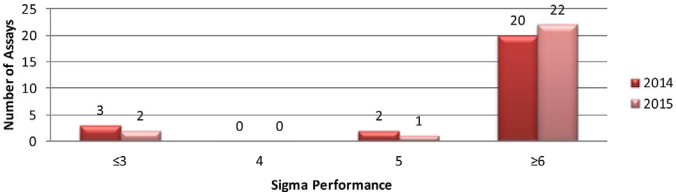


Fig. 3. Comparison of Sigma performance for chemistry assays—2014 and 2015 (level 2).

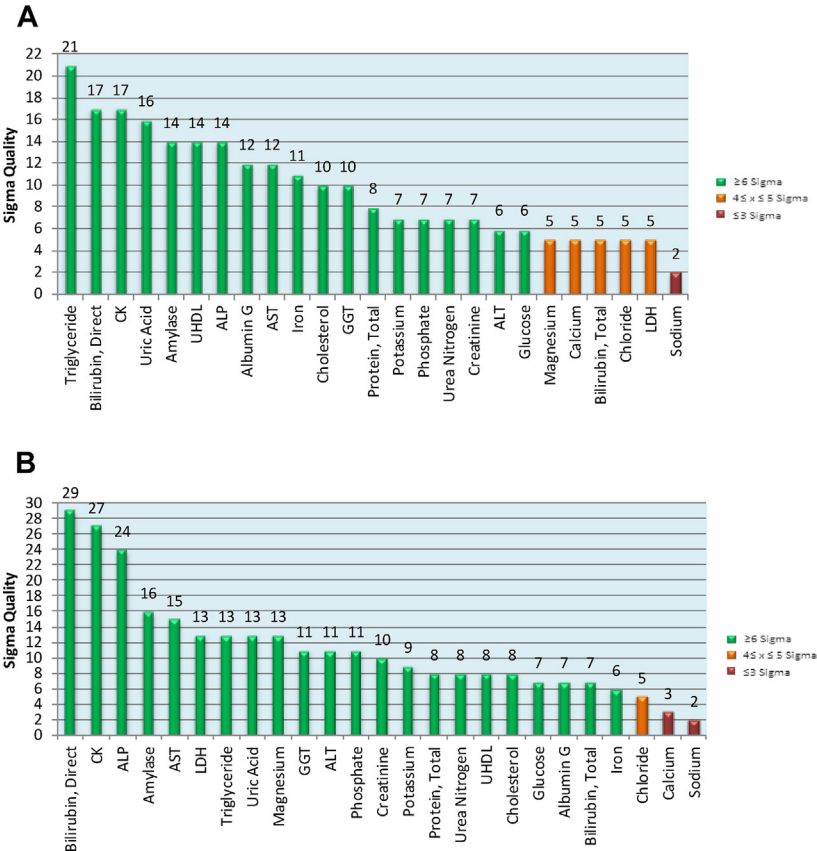


Fig. 4. (A) Sigma quality for architect ci8200 clinical chemistry assays (level 1)—Nov 2015. (B) Sigma quality for architect ci8200 clinical chemistry assays (level 2)—Nov 2015.

Table 1 Comparison of Sigma metric obtained by manual calculation using the Sigma metric equation for the 4 assays on 4 different analyzers						
Assay	Analyzer	TEa from Ricos Database	QC Mean	Coefficient of Variation, %	Bias, %	Sigma Metric
Sodium	EPOC blood	± 4 mmol/L	139.6	0.2	0.7	10.7
Potassium	gas	±0.5 mmol/L	4.1	0.5	2.5	19.4
Glucose	analyzer	± 6 mg/dL or ± 10% (greater)	5.5	1.0	10.0	<3
Hemoglobin		± 7%	10.9	0.4	10.0	<3
Sodium	I-STAT blood	± 4 mmol/L	141.4	0.2	1.4	14.2
Potassium	gas analyzer	±0.5 mmol/L	4.5	0.5	2.2	17.8
Hemoglobin		± 7%	10.2	0.4	7.5	<3
Sodium	Architect ci	± 4 mmol/L	141.6	0.8	0.7	<3
Potassium	8200	±0.5 mmol/L	3.9	0.8	0.1	15.5
Glucose		± 6 mg/dL or ± 10% (greater)	4.8	1.1	0.3	6.0
Hemoglobin	CD Sapphire	± 7%	12.2	1.8	1.6	3.0

Sigma. We investigated the 3 Sigma metric performing assays; looked into the pre-analytical issues on sample collection, transportation, and processing; ensured staff is aware of the available policies and procedures; and ensured training and education were performed to enhance staff knowledge on how to review the QC. Furthermore, the frequency of control testing is based on the recommendation and application of the Westgard Sigma Rules. Close monitoring of the assays has resulted improvement in the performances.

Medical laboratories can use the Sigma metric to make decisions about method quality when a new analytical system is in place. In addition, we are able to monitor the method quality throughout the lifetime of the system.⁴ When purchasing new equipment and instruments, it is a requirement to verify those instruments against current method using correlation, impression study, and linearity (Table 1). By only looking at correlation and impression studies, we cannot truly determine whether assays are providing world class performance. However, by converting the data into Sigma metrics, it is practical to determine if the instruments are performing well. At SunMed, we aimed to verify and select an acceptable blood gas analyzer based on precision data, correlation coefficient of selected assays, and Sigma performance of the assays carried out in 2 portable blood gas analyzers, EPOC and I-Stat, in the intensive care unit, against the laboratory analyzers, Architect ci8200 and CD Sapphire. EPOC and I-Stat showed excellent precision for all parameters except for P_{CO}₂ in EPOC. As for the slope of regression, sodium, potassium, glucose, and hemoglobin showed a correlation coefficient of more than 0.900. The 3 analyzers showed variable Sigma performances, and not all assays met the minimum performance goal of 3.0 Sigma. This study enabled us to select the acceptable method based on precision, correlation coefficient, and sigma performance and at the same time establish a proper QC plan for poor performing assays.

- 2. With a good QMS in place, patients and doctors have confidence in the test results. Accurate and reliable results are vital to assist doctors in providing the best

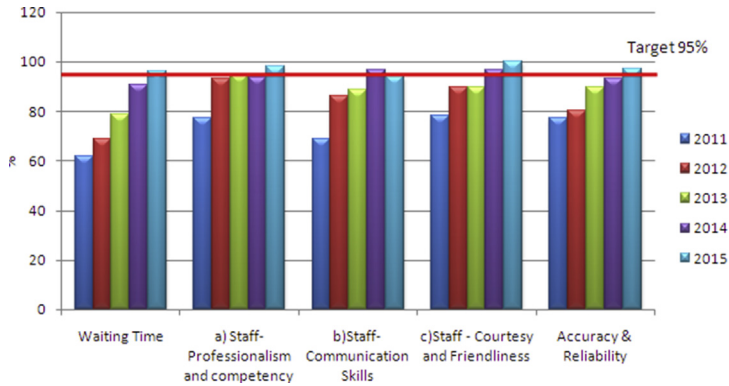


Fig. 5. Internal customers' satisfaction rate.

diagnosis and treatment to the patients. The application of Westgard Sigma Rules has helped reduce QC rework and costs caused by reduction in false rejection. These rules also improved the turnaround time of the test allowing us to provide timely and quality laboratory results to doctors and patients while also improving customer satisfaction toward our services (Fig. 5).

- Initially, when we started our Six Sigma journey, our aim was reducing operational costs. It was discovered that the Sigma metric helps significantly in reducing the cost of QC materials and cost of failures annually with improved performance characteristics on most assays. Thus, patient safety is not compromised. We have been monitoring analytical performance based on Sigma metrics, and the QC procedures vary according to assays, resulting in a reduction in cost (Fig. 6).

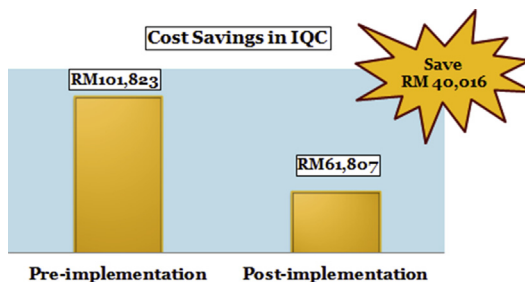


Fig. 6. Cost savings in IQC.

- Internal failure costs from the rework of QC (simply rerunning or repeating QCs) are reduced. With unnecessary rework reduced, we can realize tangible cost savings. External failures are related to nonconformance or complaints from customers caused by error rates, inaccuracy, or turnaround time. And because we have a proper approach in monitoring quality by the Six Sigma process management system, customer complaints have been reduced. And despite the increase in

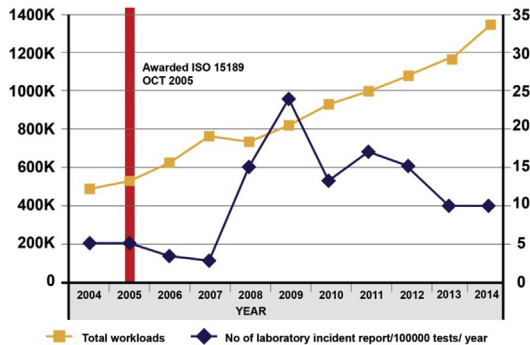


Fig. 7. Total incident report over workload per year.

workload, the laboratory error rate was reduced and has remained stable for the last several years (Fig. 7).

5. The 6 σ QMS also takes into account the competency and capability of the laboratory personnel, which is also crucial. Findings from our previous external audit by accreditation team showed that nonconformance related to staff competency decreased tremendously because staff are educated about the overall testing process from the specimen collection to the release of result. Additionally, the staff is able to handle QC-related issues and is more competent since the implementation of the 6 σ QMS. Thus, the implementation of a good QMS has given rise to a department with professional and well-trained personnel.
6. An independent verification by an external third party program such as a Sigma Verification Program enabled our laboratory to be assessed and validated, providing a strong incentive and motivation to continuously improve on Sigma metric performance and understand each assay's specific performance.
7. The implemented quality planning and goals are established as policies and procedures and are documented in the quality manual and reviewed yearly or as required.
8. The Sigma metric can be used as a predictor of risk, according to researcher Woodworth and colleagues (2014)⁵:

A risk assessment can be performed to determine if the current QC practice is adequate or requires revision. Currently, there is minimal guidance available regarding how laboratories may quantitatively estimate risk to optimize analytical QC criteria appropriate for an Individualized Quality Control Plan (IQCP). For the laboratory, risk is related to the chance of producing and reporting unreliable patient results, which are defined as results containing measurement errors that exceed a TEa specification. Evaluation of analytical performance characteristics, assay requirements, σ metrics, and statistical QC plans is one way to estimate risk during the analytical phase of testing.

A low Sigma metric results in high defect rates resulting in high number of unreliable results; thus, there is need to for close monitoring of such assays with frequent runs of control.

RISK MANAGEMENT WITH ANALYTICAL QUALITY CONTROL PLAN

Many international guidelines such as ACHS and The Joint Commission International, regulatory standards and accreditation requirements have made manufacturers implement and take responsibility for risk management of measuring systems and reagents. But today great emphasis is placed on medical laboratories to adopt risk management and develop laboratory specific QC plans.

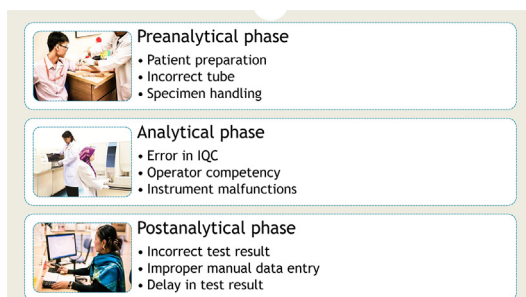


Fig. 8. Risk in the laboratory.

At SunMed, in 2014 we further adopted a risk management approach to develop a customized QC plan (QCP) based on Clinical Laboratory Improvement Amendments–approved guidelines on EP23-A Laboratory QC Based on Risk Management. This QC plan ensures addressing proactively any potential risk before wrong or unreliable results are released (**Fig. 8**).

Some of the steps taken in risk analysis and establishing the QCP include:

1. Hazard Identification through process map, followed by potential failure modes for each step in the diagram are plotted in a Fishbone cause and effect diagram (**Figs. 9 and 10**).

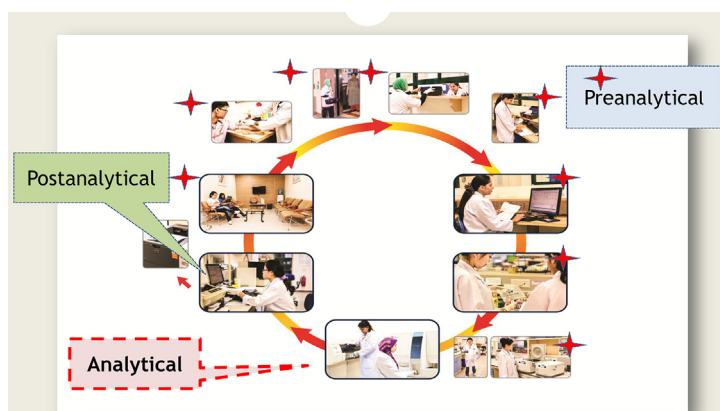


Fig. 9. Step 1a: process map. Risk in the laboratory: from blood requesting to the releasing of the report.

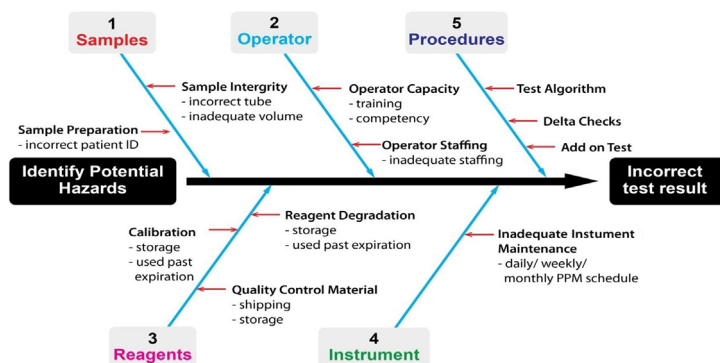


Fig. 10. Step 1 b: hazard identification.

2. Risk estimation and evaluation based on the ISO 14971 risk acceptability matrix. A Pareto chart is often plotted to show the highest failure modes with highest risk priority numbers (Figs. 11 and 12).

	Targeted failure mode	Cause of Hazard	S (Severity of Harm)	P (Probability of harm)	D (Detectability)	Hazard score	Risk acceptability
1	Samples	1. Incorrect tube	1	4	3	12	A
		2. Inadequate volume	1	4	2	12	A
		3. Incorrect patient ID	4	3	2	24	U
2	Operator	1. Lack of Training & Competency	3	4	3	36	U
		2. Incorrect and inadequate staffing	1	4	3	12	A
3	Reagent	1. Reagent and control degradation	2	4	2	16	A
		2. QC material	2	3	3	18	A
4	Instrument	1. IQC	3	5	3	45	U
		2. Instrument failure	1	3	1	3	A
		3. Inadequate instrument	3	3	1	9	A
5	Procedure	1. Test algorithm	2	4	3	24	U
		2. Delta check	2	5	1	10	A

Fig. 11. Steps 2 and 3: risk estimation and evaluation.

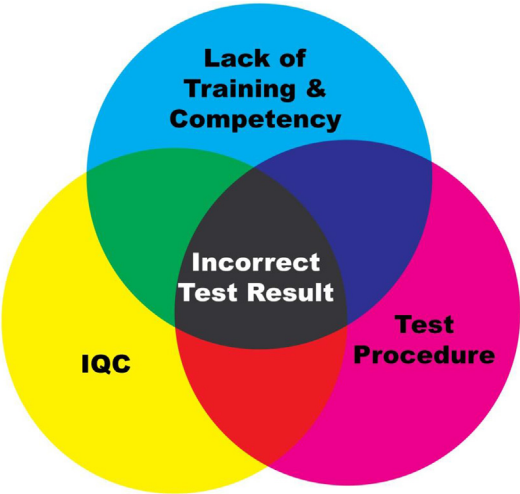


Fig. 12. Three major contributing factors to incorrect test result based on risk priority number.

3. Risk controls are implemented to ensure the whole testing process is addressed. This process is integrated with the careful design of SQC procedures (Table 2).

Hazard	Cause of Hazard	Control Plan	Measurand
1. Operator	Lack of training & competency	1. Gap analysis 2. Individual internal & external training plan 3. Training policy	1. CME hours 2. Competency scoring 3. Incident report 4. External audit compliance 5. Internal customers' satisfaction
2. Instrument	IQC (chemistry)	1. AQC Strategy	1. Sigma metric 2. External quality assessment performance
3. Procedure	Test algorithm (HIV)	1. Revised test algorithm 2. Reflex test for positive case	Incorrect reported HIV test result

Abbreviations: AQC, analytical quality control; CME, continuing medical education; HIV, human immunodeficiency virus.

The above risk management concept led to tremendous benefits in terms of personnel, procedures and policies, compliances to accreditation, satisfaction of consumers, and improvement in SQC design. These established steps provide a safety net that enables us to detect errors as early as possible and prevent harm to patients. The implemented QCP enables our laboratory to mitigate, sustain, and assist in preventing possible hazards or risks that may occur before incorrect results are reported to health care providers. SunMed QCP planning is an ongoing process that requires constant planning and review.

UNCERTAINTY OF MEASUREMENTS

In SunMed, besides the implementation of quality tools and techniques such as Six Sigma and risk management, we also measure uncertainty of measurement (MU) as one of our quality tools. MU is a mandated requirement of ISO 15189.

MU as defined by MS ISO 15189: 2014 in Section 5.5.1.4:

The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phases used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.

To determine the true value of a measured quantity is an important asset for good laboratory practice in every area of measurement. Determining the random and systematic errors along the processing of samples provides us information on total error and creates a doubt (uncertainty) about the true value of the measured quantity. The so called uncertainty of measurement (MU) has become an important issue in

Box 1**Why measurement of uncertainty is important**

- ISO 15189:2012; page 6 Clause 8.3
- When using an empirical method, care is required in defining the measurand to ensure that all uncertainty components are identified and accounted for including the use of different analysers in the laboratory.
- Laboratories are responsible to ensure test outputs are fit for clinical purposes by:
 - Defining what an analytical method measures
 - Meeting a defined analytical goal
 - Indicating the confidence that can be placed in a test result
 - Contributing to defining, monitoring, and indicating where a test procedure may be improved

clinical practice, and its importance has been increasingly realized by clinical laboratories.⁶

MU parameters involve variable sources that potentially contribute to dispersion of the values that could be finally attributed to the measurand. All possible variable sources that can contribute to MU must be taken into account, and several possible sources of uncertainty are listed below⁷:

- The measuring instruments can suffer from errors including bias, changes caused by aging or other kinds of drift, poor readability, and noise from electrical instruments
- The measurement process—preanalytical, analytical, and postanalytical
- Imported uncertainty—calibrator, control
- Operator skill and changes
- The environment

Thus, in every result, the value will contain the actual result given by the instruments and uncertainty measurement from variable sources gained along the processes.

At SunMed, MU is calculated at the analytical process, and bias is ignored and not assessed. Even though MU from preanalytical and postanalytical phases cannot be determined, MU still plays an important role in defining a good quality result. The importance of MU is simplified in **Box 1**.

In the beginning stage of adopting this tool, we were unfamiliar, and we stumbled in the calculation process of MU. Despite having 2 consecutive observations from the auditors during external assessment by an accreditation team, we were still uncertain about the procedure and the importance; nevertheless, we ensured the calculated value was always there for assessment purposes. Only procedures for which we are able to include all the sources of variables will give the total true estimate of MU, which we at SunMed were unable to do. However, in 2012, calculation of MU became mandatory by MS ISO15189 and with the guidance of Guideline Uncertainty Measurement article,⁸ we started to calculate the MU following the top-down approach. We also updated it in our Quality Control Manual and is now calculated on yearly basis.

Some of the benefits gained after many years of calculating measurements of uncertainty include:

1. Adherence and compliance to the mandated requirement of the accreditation standard MS ISO15189:2014
2. For improvement of the sample testing process, the numerical value given also indicates the magnitude of doubt about that certain result. This doubt or standard

deviation will include systematic and random error. The total error from biological variation provides quantitative estimates of the level of confidence that a laboratory has in its analytical precision of test results. The value of uncertainty helps improve quality of services of clinical chemistry either to the diagnosis or monitoring effects of the treatment of patients.

3. MU is an essential parameter of the reliability of measurement results. MU provides quantitative evidence that measurement results meet clinical requirements for reliability.^{9,10} We are in the progress of setting rules in middleware for auto verification. If there is any repeat run needed, the acceptance on repeat rerun will rely on the MU value of the analytes.
4. MU is useful in alleviating concern from clinicians. MU will determine the variation between two results are acceptable or not, therefore the value of MU shall be available for Clinicians if requested to clear their doubt on variation of test results.

Limitation of MU through SunMed experience.

1. Variable sources: There are many sources and contributing factors to MU. We are unable to determine all variable sources. Not only by precision and calibrator but other factors will also contribute variances, for example, sample matrix, instrument noise, operator, or preparation of QC.
2. Standardization: Multiple analyzers will have slightly different MU. The laboratory needs to be certain which patient samples are running on which analyzers. No standardization on calculating MU is possible if we have more than 1 instrument.
3. Standardization of calibrators: Major sources of calibrator error include differences in analysis methods used by different laboratory instruments, lot-to-lot variance in calibration materials, and lack of traceability between secondary reference material and primary standards. Some of the commercial suppliers provide the uncertainty estimates of assigned value, but there are still some manufacturers who do not provide information.⁶ Of course, the former is preferable by clinical laboratory practitioners.
4. MU values for calibrators are from vendors: If information on restandardization of calibrator values or levels is not disseminated in a timely manner to the end user, delays for data collection or MU review will occur.
5. Limited MU range: If we use intermediate-term precision from controls as our approach to estimate MU, then our estimates depend on the QC range. Beyond this range we can only assume the percentage of the MU.
6. Awareness: Initially, MU needs to be reported with patient results on a routine basis. But practically there is a need for ongoing education and training to create awareness, both for laboratories and requesting doctors to understand its benefit and limitation of MU concepts. With more stable and modern instruments, the margin of doubt is smaller, but less technical training is being provided on MU, making it more challenging for increasing clinician awareness.

MU with its benefits and limitation is still crucial for the clinical laboratory, especially to know test performance, even if currently the value is not reported with the patient's results. As Albert Einstein famously said, "Every number has its value but not all value has numbers."

SUMMARY

Quality is a priority if we wish to gain and sustain the confidence of our customers, both clinicians and patients, and satisfy their evolving needs. In order to provide our continuous commitment toward enhancing the overall quality of test results in line with our vision as leading medical center in ASEAN region and our mission to achieve

world standard in quality services, safe facilities and increase consumers either patients or doctors satisfaction, thus the use of appropriate tools and techniques is crucial as well as essential. We feel that the tools adopted such as TEa and MU help the laboratory in ensuring reliability of test results, each from a different perspective. However, tools for establishing the statistical QC alone are not sufficient to ensure the quality of service that we provide to our customers. A good QMS with an excellent analytical QC plans is essential to provide the bigger picture, which will not only give confidence in our analytical performance but span to provide assurance across the total testing process, workflow, and staff competency. It's not an easy task to achieve good quality, but with a proper QMS in place, it is definitely within our grasp.

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