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Article

A Maturity Model for the Accredited Food Laboratory in Malaysia: A Case Study

Li Hui Ling[1], Mohd Sukri Hassan[2], Che Wan Zanariah Che Wan Ngah[2] and Mehmet Ozturk[3]

[1]*Department of Chemistry Malaysia, Jalan Sultan, 46661, Petaling Jaya, Selangor, Malaysia.*
[2]*Faculty of Science and Technology, Universiti Sains Islam Malaysia, 71800, Nilai, Negeri Sembilan, Malaysia.*
[3]*Faculty of Science, Department of Chemistry, Mugla Sitki Kocman University, 48000 Kötek Mugla, Turkey.*

Correspondence should be addressed to:
Li Hui Ling; lhling@kimia.gov.my

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***Abstract*— A Maturity Model (MM) is essential for laboratories aiming to improve and compete globally. Despite being accredited for over 20 years, some laboratories lack evidence of system maturity necessary for international competitiveness. A higher maturity level indicates a robust quality management system, leading to improved efficiency, accuracy, and customer satisfaction, while also assuring stakeholders, such as customers and regulatory bodies, of the laboratory's commitment to continuous improvement. The MM is designed to assess the success of laboratory processes, management styles, and the development of quality management practices, based on the 4M model (Manpower, Method, Machine, Material). The MM was developed using Analytes Accurate Certain Score (AACS) for the ten most common tests and System Maturity Scores (SMS), which incorporate proficiency testing and audit scores over two accreditation cycles (six years). While the model identifies inefficiencies, it helps organizations pinpoint areas of improvement and devise strategies to enhance their operations. This study applied the MM to a commercial laboratory, ABC (anonymized), accredited since the early 1990s and having undergone eight assessment cycles. The laboratory was found to be at a "leading" maturity level with a score above 80%, although improvements are still needed. Key areas for improvement include: 1) **Manpower**: maintaining competent staff by adjusting management strategies, 2) **Method**: validating all in-house methods according to Analytical Laboratory Accreditation Criteria Committee (ALACC) guidelines, 3) **Machine**: applying good laboratory practices (GLP) for equipment sharing, especially for specific analytes, and 4) **Material**: ensuring metrologically traceable reference materials and proficiency testing for all analytes. These improvements will help the laboratory further enhance its global competitiveness.**

***Keywords*— maturity model, analytes accurate certain scores, proficiency testing, audit/assessment scores**

I. INTRODUCTION

Established on August 15, 1990, by the Department of Standards Malaysia (Standards Malaysia), the Skim Akreditasi Makmal Malaysia (SAMM) aims to provide reliable accreditation services to testing and calibration laboratories. SAMM ensures that test reports and calibration certifications supported by SAMM are globally recognized by the International Laboratory Accreditation Co-operation (ILAC) and the Asia Pacific Accreditation Cooperation (APAC). ISO/IEC 17025 serves as the primary international standard for testing and calibration laboratory competence. SAMM encompasses several components, including MS ISO/IEC 17025, SAMM Policy (SP), Specific Criteria (SC), Specific Technical Requirements (STR), Accreditation Policy (AP), and SAMM Circular. Over the past decade, SAMM implementation in chemical testing laboratories has shown significant progress, with the number of accredited laboratories

increasing from 493 in 2010 to 769 in 2020, marking a 35.9% increase according to Department of Standards Malaysia statistics. It is important to note that while implementing a laboratory quality management system (LQMS) does not guarantee an error-free laboratory, it contributes to establishing high-quality laboratories capable of detecting and preventing errors, particularly in food analysis. As of March 2021, Standards Malaysia had accredited 773 Malaysian laboratories, covering 73% of testing laboratories.

Accreditation serves as an independent evaluation that testing laboratories are competent in performing specific analyses according to accreditation standards, ensuring the reliability of their results and facilitating international recognition through organizations like European co-operation for Accreditation (EA) and ILAC. This competitive advantage is further strengthened by the introduction of a maturity model, which assesses the level of maturity attained by accredited laboratories. Going beyond the basic requirements of accreditation, the maturity model evaluates the overall operational effectiveness, implementation of quality management systems, and commitment to continuous improvement within the laboratory. Through this assessment, the model provides valuable insights to laboratory management, enabling them to identify areas for enhancement and refine their processes, thus improving their ability to compete on the international stage. It is important to emphasize that while this study emphasizes the need for maturity evaluation, it does not diminish the significance of accreditation. On the contrary, accreditation serves as the foundation upon which laboratories can build and continuously improve, ensuring their ongoing competence and reliability in meeting international standards. By combining the benefits of accreditation and the insights provided by the maturity model, laboratories can strive for excellence and maintain their reputation as trusted providers of reliable testing services.

II. Literature Review

The ISO 9001 standard is widely recognized as the most popular certification for Quality Management Systems (QMS). It primarily focuses on the management aspect and includes six mandatory procedures: control of documents, control of records, internal audit, corrective action, preventive action, and control of non-conforming products [1]. On the other hand, ISO/IEC 17025 specifies the requirements for the competence of testing and calibration laboratories. Its clauses cover various aspects such as personnel competency, equipment calibration and maintenance, metrological traceability, method validation, sampling, evaluation of measurement uncertainty, and ensuring result validity [2]. The process of obtaining ISO/IEC 17025 is referred to as accreditation, which signifies formal recognition of a laboratory's competence to perform specific analyses [3]. Testing laboratories can seek accreditation through Standards Malaysia, the national accreditation body that has been accepted as a signatory to ILAC and APAC, playing a crucial role on the international stage.

Accreditation brings several benefits to a laboratory, including enhancing its reputation among customers. Evaluations have shown that implementing a QMS based on ISO/IEC 17025:2005 is achievable in laboratory settings. However, the accreditation process itself is complex and time-consuming, typically taking around two years for laboratories to establish their systems [4]. Effectiveness in a testing laboratory is demonstrated when it can effectively manage flexibility, customers, production, value orientation, and the primary tasks of its personnel [5]. The application of ISO standards in testing laboratories further ensures the quality of analysis. Validation of a proposed method according to the ISO/IEC 17025 standard revealed its accuracy, precision, and sensitivity, surpassing the Association of Official Agricultural Chemists (AOAC) method [6]. ISO implementation has become prevalent across various industries, from food to medicine. Post-accreditation, laboratories have shown a higher level of quality compliance, ultimately improving the reliability of test results [7]. In the case of the National Medicines Regulatory Authority Quality Control laboratory, ISO/IEC 17025 accreditation significantly enhanced their quality system and increased the reliability of their test results.

Many companies have tried to gain a competitive advantage by providing high-quality services and implementing general quality management standards. No matter the type of laboratories, it was necessary to adopt the quality management method in their work, especially the application of ISO/IEC 17025, improving these laboratories' administrative and technical performance. Malaysia assigns a government agency responsible for halal regulation and certification matters, thus being the first country to hold a special position in the global halal market [8]. This is the main reason for establishing a halal laboratory to measure the quality of the national food supply. Food quality assurance programs are compulsory to ensure the competency of laboratories to provide accurate results in food control systems consistently. This is sensible since it is much easier to assess the level of system functionality in firms where the system has been accredited to a widely established worldwide standard [9]. There are three essential elements: i) the use of established analytical methods, ii) accreditation involving third-party auditing, and iii) involvement in proficiency testing systems in most food analysis and regulation fields to assure laboratory quality [10].

The current accreditation still needs to be improved to maintain the laboratory's reputation. It is more trustworthy if it has a maturity index supporting the laboratory management system. Application of the maturity model for most management systems, such as Information technology, includes software development; productivity management which covers electric, electronic, and high-tech industries; banking management, maintenance management; manufacturing or service industry for business purposes; product specification and geometrical tolerancing as well. Process maturity can be defined as the degree to which a process is defined, managed, measured, and continuously improved. Referring to the [11], either to compare the level of maturity to other processes or to find development opportunities were the target working with the maturity model. The maturity models are a powerful factor since they assist organizations in better positioning themselves and identifying better transformation solutions in information technology management [12]. A maturity model is presented to help manufacturers determine the level of sustainable manufacturing activities such as materials, energy, and water usage. All the input from the stakeholders was gathered for sustainability improvement to achieve high–level targets based

on the maturity model [13]. Maturity models are decision-making aids because they support the understanding of the organization's current condition and encourage the implementation of measures that identify, implement, and measure improvement actions; the model might lead to a better perspective to support the system [14]. The most famous maturity model is the Capability Maturity Model (CMM) from the Software Engineering Institute, which was first developed to measure the level of maturity for software development in 1987 [15]. Table 1 shows the list of common maturity models from the CMM year 1987 until Innovation Maturity Model (IMM) year 2018.

TABLE I. THE LIST OF COMMON MATURITY MODELS FROM THE CMM YEAR 1987 UNTIL INNOVATION MATURITY MODEL (IMM) YEAR 2018.

	Model Name	**Short name**	**Year**	**Field**	**Company**	**Level**
1	Capability Maturity Model	CMM	1987	Software	Software Engineering Institute	5
2	European Foundation for Quality Management (EFQM) Excellence Model	EFQM Excellence	1989	General (private sector, public and voluntary sector)	CEOs of large European businesses (Brussels)	Scoring system
3	Trillium	Trillium	1991	Telecommunication	Bell Canada, Northern Telecom and Research Bell Northern	4
4	Balanced scorecard	BSC	1992	Business	Robert Kaplan and David Norton	Scoring system
5	Integrated Capability Maturity Model	FAA-iCMM	1997	Engineering	US Federal Aviation Administration	5
6	Microframe's Project Management Maturity Model	PM3	1997	Project management	Microframe Technologies & Project Management Technologies	5
7	Organizational Project Management Maturity Model	OPM3	1998	Project management	Knapp & Moore Pty Ltd	4
8	Project Management Maturity Model	ProjectFRAMEWORK	1999	Consulting firm	ESI International	4
9	Berkeley Project Management Maturity Model	(PM)2	2000	Project management	Kwak and lbbs	5
10	Project Management Maturity Model	PMMM	2001	Project management	Harold Kerzner	5
11	Capability Maturity Model Integration	CMM I	2002	Software	Software Engineering Institute	5
12	IBM Progress Maturity Model	-	2007	Data Governance	IBM	5
13	PRINCE2 Maturity Model	P2MM	2007	Project management	Murray and OGC	5
14	Barron Maturity Model	-	2010	Project management (Ortho Clinical Diagnostics)	Douglas S. Barron Ortho Clinical Diagnostics	5
15	Financial Management Maturity Model	-	2010	Finance Management	National Audit Office	5
16	Project Management Maturity Model	PMBOK®	2013	Project management	Project management Institute	Guide
17	Continuity of Care Maturity Model	CCMM	2014	Health care	Healthcare Information and Management Systems Society, HIMSS	8
18	Adoption Model for Analytics Maturity	AMAM	2015	Health care	Healthcare Information and Management Systems Society	8
19	Account-Based Marketing Maturity Model	ABM Maturity Model	2016	Accounts	MarTech	3
20	LARC Capability Maturity Model	LARC CMM	2016	Health facilities	The Laboratory African Regional Collaborative	5
21	The Information Systems for Health Maturity Assessment Tool	IS4H-MM	2017	Information Systems for Health	Pan American Health Organization, PAHO	5
22	C4i4 Lab's Industry 4.0 Maturity Assessment Model	I4MM	2017	Organization's digital maturity	The Centre for Industry 4.0 (C4i4) Lab	5
23	Innovation Maturity Model	IMM	2018	Innovation capabilities	TIM Foundation	5

Based on the abovementioned list, the author decided to develop the maturity model for an accredited testing laboratory with five maturity levels. Similar to the service offered by the sales & marketing firm, MM of the accredited laboratory, as shown in Figure 2, was modified based on the sales maturity model of the Sales Cadence powered by the must-react system, as shown in Figure 1.

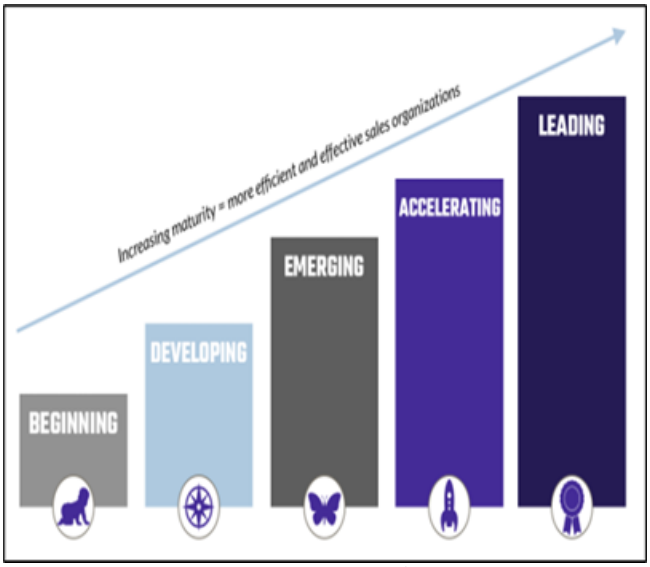

Figure 1. The Sales Maturity Model (SMM) of The Sales Cadence powered by The Must-React System

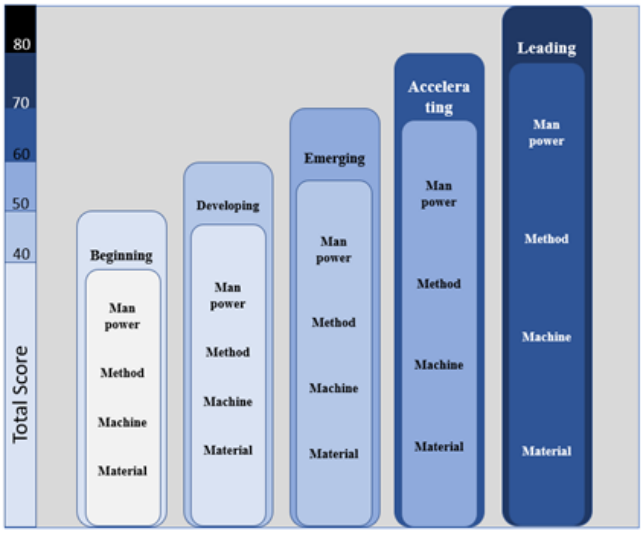

Figure 2. The modified MM based on SMM.

III. METHOD

A. Study Areas

Lab A was selected as the case study site due to its excellent management record. The founder of Lab A had extensive experience in laboratory management, having served as an officer in a government laboratory for over thirty years before establishing Lab A, which had been operating successfully for more than three decades. This experience likely played a significant role in the success of the laboratory as a testing facility. Additionally, the combination of ideas from the government and private sector provided a strong stimulus for the establishment of a testing laboratory, and Lab A was able to leverage resources and expertise from both sectors. The selection of Lab A as the reference lab for the study was a wise decision, given its strong management record and the founder's experience in both the government and private sectors. Even if Lab A was used as the reference laboratory for the initial study, the developed model could still be reapplied to Lab A for further testing for the next accreditation circle. In fact, reapplying the model to the same laboratory can provide additional information on the robustness and generalizability of the model. However, it is important to note that the results obtained from the initial study should not be considered conclusive for the reference laboratory itself. This is because the model was likely validated on the data from other laboratories, and it is possible that there may be differences in the performance of the model when applied to Lab A. Therefore, the results obtained from reapplying the model to Lab A should be carefully evaluated and compared with the initial results to determine the reliability of the model for this specific laboratory.

B. Calculation of MM

The methodology description will be explained through two factors: Analyte Accuracy Certain Score (AACS) and System Maturity Score (SMS), with 20% of AACS added to 80% of SMS as shown in the Equation (1). Referring to the Equity Method, [19], is used when an investor company exerts substantial influence over an investee company. Generally, owning 20% to 50% of another company's stock is deemed to be a significant influence. Accordingly, we used a minimum of 20% to represent the chemical testing influence on management system maturity, while 80% is based on the laboratory management system's overall proficiency testing performance and output from internal and external assessments. Figure 3 shows the diagram for MM development.

$$MM = 20\ \%\ AACS + 80\%\ SMS \quad (1)$$

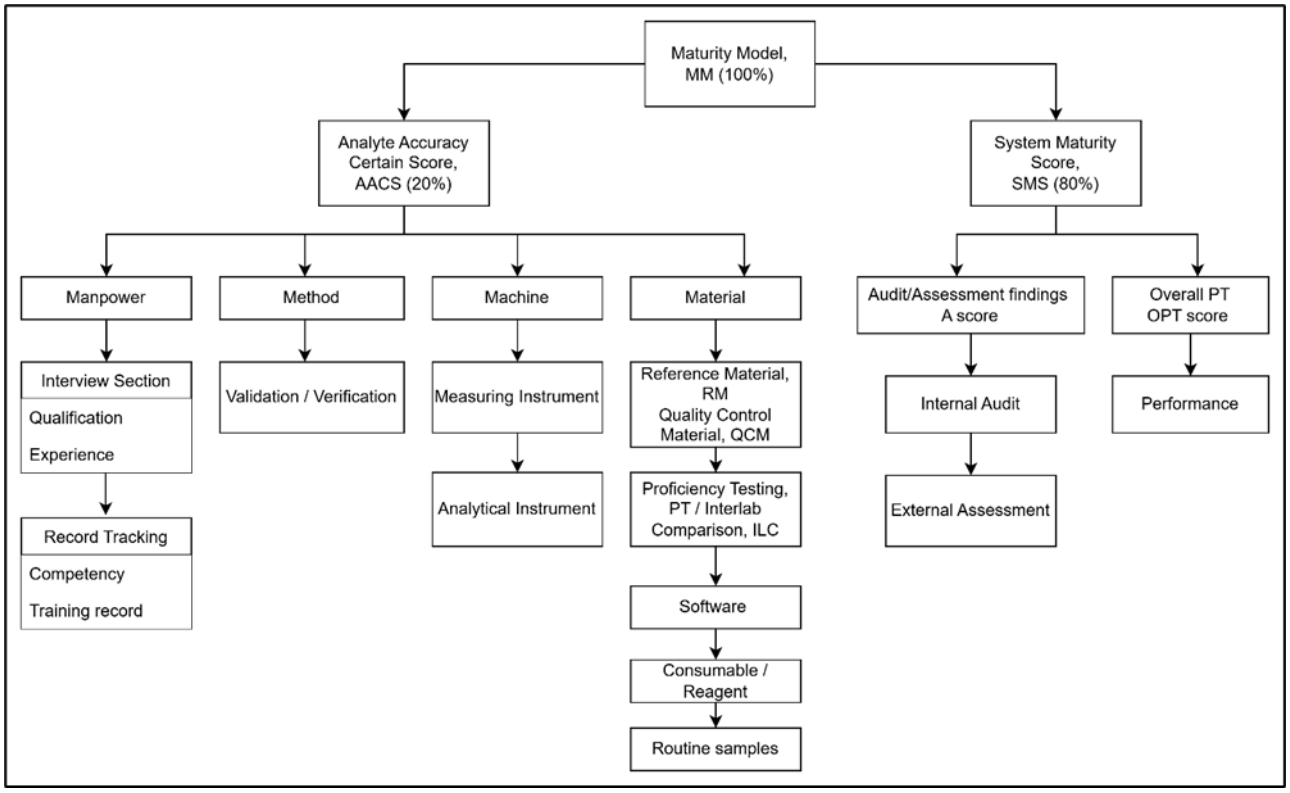

Figure 3. shows the diagram for MM development.

i. Calculation of Analyte Accuracy Certain Score, AACS

a. For this scoring, ten frequent run methods selected from the laboratory which cover proximate analysis, preservatives, and contaminants, were chosen. The process flow will be performed as shown in Figure 4. The score is based on pre-defined criteria as mentioned below. *Manpower (24%):*

The focus is on the analysts who run the testing, which is divided into two sections: the interview section and record tracking. The interview section covers the technique of sample running, which is either divided by section or run by one person. This is followed by pre-treatment sampling, sample preparation, the extraction process, sample analysis by instrument, result interpretation, and report writing. These are based on qualification, which include Sijil Peperiksaan Malaysia (SPM), Diploma, Degree, Master, and Ph.D. The experience is divided into four categories: less than 1 year, 1-5 years, 6-10 years, and more than 10 years. The years of experience directly affect the performance of the analysis. Practice helps us increase our ability to access information rapidly and automatically; thus, practice makes perfect. If the personnel perform their tasks every day, starting with the right thing, good performance can be obtained. The method was introduced in the right way for any analysis or experiments.

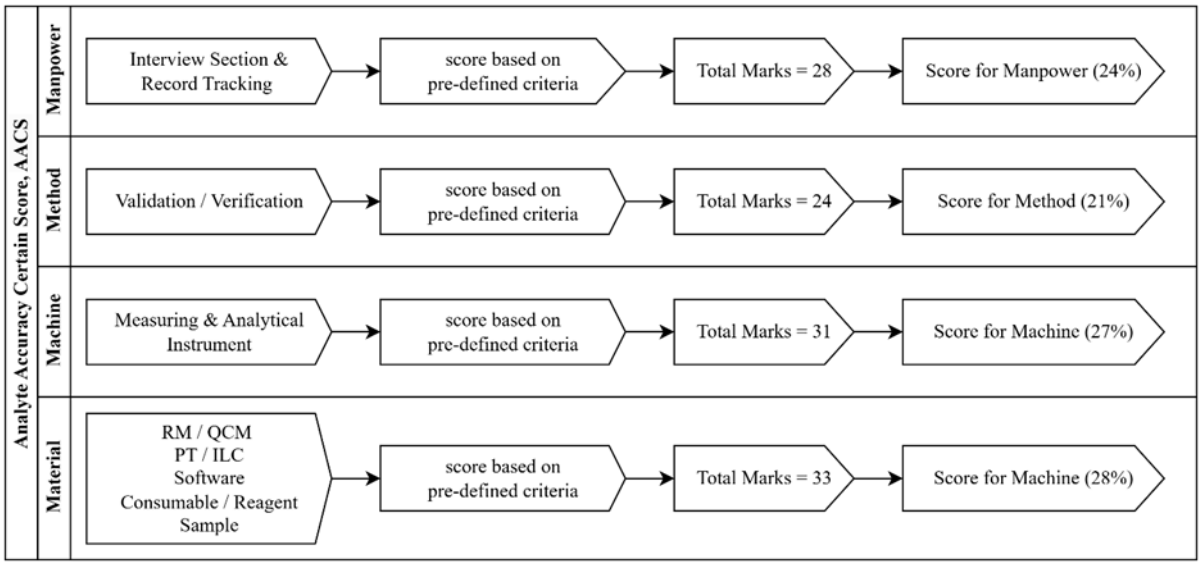

Figure 4. Development of Analyte Accuracy Certain Score, AACS

b. Manpower (24%):

The focus is on the analysts who run the testing, which is divided into two sections: the interview section and record tracking. The interview section covers the technique of sample running, which is either divided by section or run by one person. This is followed by pre-treatment sampling, sample preparation, the extraction process, sample analysis by instrument, result interpretation, and report writing. These are based on qualification, which include Sijil Peperiksaan Malaysia (SPM), Diploma, Degree, Master, and Ph.D. The experience is divided into four categories: less than 1 year, 1-5 years, 6-10 years, and more than 10 years. The years of experience directly affect the performance of the analysis. Practice helps us increase our ability to access information rapidly and automatically; thus, practice makes perfect. If the personnel perform their tasks every day, starting with the right thing, good performance can be obtained. The method was introduced in the right way for any analysis or experiments. For the record tracking section, the training module, competency method, and competency test were considered. The training module is important to understand how the laboratory trains personnel, whether it is trained by a method approach, instruments, or analysts. After training, competency is needed either before case handling or during case handling. The competency test is compulsory to ensure the validity of the results (clause 7.7.2). The period of the test can be done within 3 months, 6 months, or annually.

c. Method (21%)

The type of method used to decide the validation or verification study. The method can be categorized as follows:

• International, regional/national standards: refer to methods that have been established and published by international, regional, or national organizations responsible for standardization, such as ISO, American Society for Testing and Material (ASTM International), United States Pharmacopeia (USP), or Malaysia Standard (MS).

• Reputable technical organizations method: methods that have been developed and published by well-established and respected organizations in a particular field or industry, such as the American Chemical Society (ACS), American Public Health Association (APHA), or the Association of Official Analytical Chemists (AOAC).

• Relevant scientific texts or journals to treat as laboratory's method: can be used as a source of laboratory methods when there are no internationally recognized or accepted methods available, or when the laboratory is developing a new method for a specific application, such as the Cholesterol analysis based on the Journal of Food Composition and Analysis 21, 2008 and the Benzoic Acid analysis by HPLC based on the Journal Chromatography A 1073, 2005.

• Method based on specified by the manufacturer of the equipment refers to methods developed and recommended by the manufacturer of a particular instrument or equipment, such as the HACH method, Enzyme-Linked ImmunoSorbent Assay (ELISA), or Agilent application notes.

• Laboratory-developed or modified method refers to methods that are developed or adapted by a laboratory for a specific application or purpose. These methods may be developed in-house by the laboratory or adapted from existing methods based on the laboratory's specific requirements or constraints.

When a method's performance characteristics need to be demonstrated as suitable for a specific purpose, it is necessary to validate the method. According to Clause 7.2.2.1 of ISO/IEC 17025, validation is required for non-standard methods, laboratory-designed or developed methods, standard methods used outside of their intended scope, and modifications or amplifications of standard methods. The criteria to validate the methods must be as extensive as necessary to meet the requirement of the intended use purpose. The criteria for this study focus on selectivity, robustness, linearity/calibration model, working range, the limit of detection (LOD), limit of quantitation (LOQ), precision, trueness, and uncertainty. Whereas for method verification, is based on precision, trueness, LOD, LOQ, and uncertainty only. This is in compliance with Clause 7.2.1.5 of ISO/IEC 17025, which shows that the method can properly perform before introducing them by ensuring that they can achieve the required performance.

d. Machine (27%)

The machine is based on the instruments, which cover the measuring and analytical instruments. Measuring instruments are devices used to measure physical properties, such as weight, volume, temperature, and pressure. Examples of measuring equipment commonly used in laboratories include balances, burettes, thermometers, and pH meters. Whereas analytical instruments are specialized devices used to analyze the chemical and physical properties of substances in greater detail. Analytical instruments are typically more complex and expensive than measuring equipment. Examples of commonly used analytical instruments include spectrophotometers, chromatographs, mass spectrometers, and inductively coupled plasma machines. The accuracy and precision of both measuring and analytical instruments are critical factors in ensuring the quality and efficiency of testing. Observing the status of the instrument, whether it is used for a single particular analyte, food samples, or shared for all types of samples in the whole laboratory, is important. Calibration should be done through internal and external calibration by a certified accredited calibration laboratory, following specific acceptance criteria. To maintain the instruments, a weekly, monthly, quarterly or yearly schedule should be followed for both internal and external maintenance by specific vendors. Records of calibration and maintenance must be traceable and updated regularly.

e. Material (28%)

The term "material" in ISO 17025 includes but is not limited to, samples, reagents, standards, and reference materials. It can also refer to software and documentation that are used in testing or calibration processes. For this study, we conclude that the material refers to reference materials that cover the quality control material (QCM), consumable parts and reagents used, Proficiency Testing (PT) or inter-laboratory comparison (ILC), and sample received. The definition of the reference material is divided into 5 categories:

1. National Metrology Standard: issued by an authorized body such as National Institute of Standards and Technology (NIST), Joint Research Centre (JRC), National Measurement Institute (NMI) Australia, and the compendial standard such as British Pharmacopoeia (BP),

the European Pharmacopoeia (EP), the Japanese Pharmacopoeia (JP), and the United States Pharmacopeia (USP) which are considered to provide the highest level of accuracy and traceability.

2. Certified Reference Material (CRM): considered to have well-defined properties and provide the highest level of accuracy, uncertainty, and traceability to an SI unit of measurement. These are manufactured by an accredited Reference Material Producer with ISO 17034 and ISO 17025.
3. Reference Material (RM): fulfilling ISO requirements which are less demanding than for CRMs, manufactured by accredited Reference Material Producer with ISO 17034 or ISO 17025.
4. Analytical Standard: a pure substance of known concentration, purity, and identity that is commonly used as a reference for comparison with the analytical results obtained from the analysis of samples. The Certificate of Analysis (COA) is available, and it might obtain ISO 9001 but is not considered metrologically traceable.
5. Reagent chemical: may come with a COA but are not characterized for use as reference materials.

For the QCM category, it is performed together with the reference material. For the method using the analytical instruments, it will be marked by RM, and for methods without analytical instruments, it will be marked by QCM. The objective of QC used in the laboratory is to ensure the validity of the results by generating control charts, troubleshooting poor performance in the PT, training of the new staff, or maintaining the competency of current staff. QCM is divided into 5 categories:

1. QCM: it is the surplus test material from the batch used for the PT, used as QC samples for generating control charts. Normally, the QCM is available immediately after the PT is reported, but the stability is estimated for short – term use only.
2. Alternative instrumentation: refers to equipment that can be used in place of the primary instrumentation to measure or analyze a particular parameter. These alternative instruments may be different in terms of design, construction, or operating principle from the primary instrumentation. They have been calibrated to provide traceable results, which means that the equipment has been adjusted to provide accurate measurements, and the results can be traced back to a recognized standard of measurement.
3. Lab Fortified Blank (LFB) and Lab Fortified Matrix (LFM): LFB is an aliquot of reagent blank water that was spiked with known amounts of analytes of interest and set to monitor matrix-free performance. The purpose of an LFB is to ensure that the analysis method being used is free from contamination and interference. LFM is a sample matrix that has been spiked with known amounts of analytes of interest. The LFM is analysed in the same way as the actual samples, and the amounts of analytes that are detected in the LFM are compared to the known amount that was added intentionally. This comparison allows the analyst to determine the accuracy and precision of the method.
4. Prepared in-house QC sample with duplicate run: obtain the necessary materials as own QC and perform the precision and accuracy study; generate a QC chart based on the study data and established acceptance criteria for the QC chart and duplicate results.
5. Prepared in-house QC sample with single run: same procedure as the above QC sample but with a single run. Acceptance criteria established for the QC chart.

For the software division, it is divided into full established online laboratory systems such as Laboratory Information Management System (LIMS), self-developed system, mixed systems that include manual and Excel systems, and manual system. Consumable parts cover changes made before schedule, on schedule, and changes made if out of service. Reagents are divided by grade and storage period. Additionally, PT or ILC are based on frequency, matrices, analytes, and the performance of the schemes. Lastly, the samples received are scheduled or non-scheduled, and the total sample received per year. From the total marks of 4M (24%+21%+27%+28%), 20% will be used in the MM calculation.

ii. Calculation of System Maturity Score, SMS

System Maturity Score (SMS) is the combination of scores from audit/ assessment findings and is named A score and overall proficiency testing performance score (OPT), as in Figure 5.

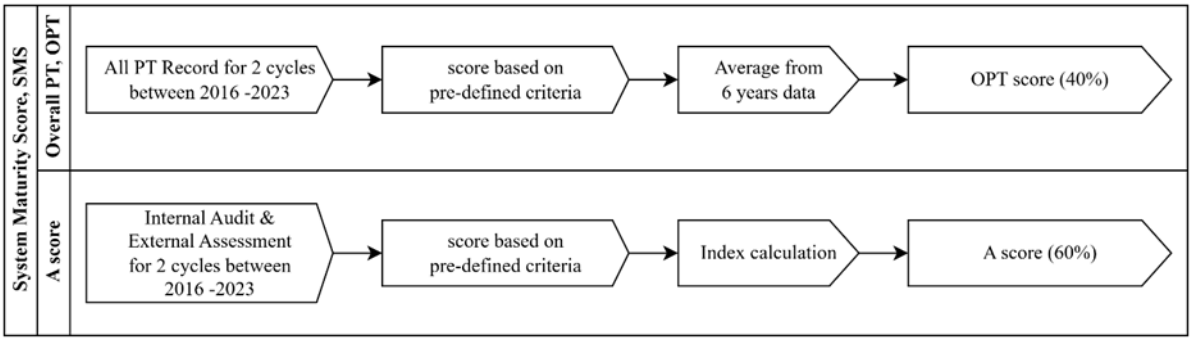

Figure 5. Development of System Maturity Score, SMS

a. A score (60%)

The audit/assessment findings score from two cycles, covering six years of internal audits and external assessments conducted by laboratories' internal auditor team and Standard Malaysia was included in the study. The laboratory must conduct internal audits at planned intervals, at least once every twelve months unless it can prove effective implementation and stability of its management system according to MS ISO/IEC 17025, which may allow a decrease in frequency. However, the maximum interval for internal audits should not exceed 18 months. As for the external assessment based on the SAMM Policy (SP) 1, 2018, the first cycle of accreditation covers two surveillance assessments and one reassessment. The present study sites mostly cover the subsequent cycle of accreditation, in which surveillance is conducted approximately 12 months from the date of the last expiry, and reassessment is conducted approximately 6 months before the expiry date. Therefore, data collection was based on the external assessment year. According to SAMM Policy 10, 2018, non-conformities are classified into Category 1 (Cat 1): very serious, Category 2 (Cat 2): quite significant, Category 3 (Cat 3): minor, and Category 4 (Observation). Based on the category of the non-conforming records (NCRs) and observations, Cat 1 scores 4 points, Cat 2 scores 3 points, Cat 3 scores 2 points, and Cat 4, which is an observation, scores 1 point. The A score index was established based on the first year of assessment (used for this study), with a total of 1 point from internal and external findings, and subsequent years were compared to the previous year's index, as shown in the Equation (2) & (3). This comparison continued until the sixth year of the assessment. However, the years of assessment may not be continuous depending on the laboratory performance. A good signal of performance is indicated by an index less than 1, while the opposite is true for an index greater than 1.

$$Index\ A, I = \frac{\sum(\text{cat no.} \times \text{point})_{Year\ 1}}{\sum(\text{cat no.} \times \text{point})_{Year\ 0}} \quad (2)$$

$$A\ score, A\% = \frac{1}{I^2} \times \frac{1}{2} \times 100 \quad (3)$$

b. OPT Score (40%)

In evaluating the competency of laboratories to conduct tests for which accreditation is granted, Proficiency Testing (PT) serves as a crucial component of the assessment process. The guidelines outlined in this document are based on the provisions of ILAC P9 – the ILAC Policy for participation in proficiency testing activities. The PT activities include PT, Interlaboratory Comparison (ILC), External Quality Assessment (EQA), and Measurement Audit (MA) programs. Referring to the SAMM Policy (SP) 4, 2013, during each accreditation cycle, an accredited laboratory must take part in at least one relevant PT activity for each field covered by its accreditation. Additionally, the laboratory must demonstrate satisfactory performance in all PT activities in which it has participated. Other than complying with the SP 4, involvement in PT is another alternative action to monitor the competence of personnel, which refers to clause 6.2.5 f) ISO 17025. The method to obtain the mark of OPT is based on the overall PT involvement in the current year. The Z score (Z) is the common statistical evaluation used. The categories are divided into five, as follows: i. $Z < 1$ = 4 points, ii. $2>Z \geqslant 1$ = 3 points, iii. $3> Z \geqslant 2$ = 2 points, iv. $Z \geqslant 3$ = 1 point, v. Result not submitted = 0 points. Total marks are depending on the number of PT schemes in which the laboratories are involved. Full marks for a scheme are 4 points, and the points obtained are based on the performance of the laboratories. The percentage for the yearly performance will be calculated, and the average obtained from the six years of performance. From the total marks, 40% will be calculated to include in the SMS calculation.

$$Z = (xi - Xpt)/\sigma \quad (4)$$

Where: xi is the participant's result, Xpt = the assigned value, and σ = standard deviation for proficiency assessment. If the z score is equal and less than 2 implies a satisfactory result if it equals and is more than 3 implies unsatisfactory performance and generates an action signal. Between 2 and 3 indicate questionable performance and generate a warning signal. The assigned value was calculated based on the robust mean using procedures in Annex C Algorithm A, ISO 13528 [3]. From the total marks of A score (60%) and OPT score (40%), 80% will be used in the MM calculation. Thus, the MM calculated as shown in Equation (1).

IV. RESULTS AND DISCUSSION

A. Result for Analyte Accuracy Certain score, AACS

Referring to ten analytes, which include Benzoic acid (BA), Sorbic acid (SA), Ascorbic acid, sugar profile, heavy metals, Fat for liquid sample, protein, moisture, ash, and formaldehyde, the percentages obtained for all are shown in Table 2, which displays the AACS for each analyte. The highest AACS is achieved by the fat in the liquid sample, which is 77.59%, and is considered a criterion to define an expert lab for the fat analyte based on AACS, provided that the MM of this laboratory achieves a leading level. The average AACS obtained is 66%, and most of the analytes maintain a range of 60-69%. Based on the summary of Table 3, manpower obtained 60% which was influenced by the criteria of personnel experience, where the year of experience ranges from 1-5 years. The turnaround of staff in the laboratory affects the quality of the system, and the main problem faced by the management is the competency of the staff. After training the staff well, they may hope for better opportunities and opt for another high-paid company. The issue of staff turnover and the attraction of higher-paying companies is a significant problem faced by both the private and government sectors, particularly in areas where competition for talent is high, such as the location of this laboratory in the petroleum exploration industry. The lure of larger companies with more luxurious salaries can be a challenge to retain staff, and the laboratory may be seen as a training platform for such companies. This situation can be frustrating for the laboratory management who invest in training staff, only to see them leave for other opportunities. It is crucial for the laboratory to offer competitive salaries and benefits to keep staff motivated and committed to their work. The only manpower result that achieved more than 80% for the analyte of fat was obtained from the technical staff who had over ten years of experience in handling this analysis. This staff was very loyal to her job and could perform the analysis very well. Referring to [20], staying with the same employer for a

long period of time can have both positive and negative impacts on the person's career. It is generally considered that staying with the same employer for 7 – 10 years can be a critical point in the decision-making process about whether to continue as a lifer with that company. If this staff has already passes through the 10- year period, she might consider being a "lifer" and demonstrate loyalty and dedication to the company.

The method used in this laboratory obtained the same marks for all analytes, which is 66.67%. This is because the method used for this laboratory is based on in-house method, validation was done, and only focus on the linearity, working range, limit of detection and quantitation, precision study, trueness study, and uncertainty. The laboratory needs to do the selectivity and robustness testing, which are suggested by the Eurachem Guide, 2014. Food samples are complex matrices that may contain a wide range of chemical components, which can potentially interfere with the detection and quantification of the analytes of interest. For an example of the BA analysis, a test for interference from other components in the food matrix can be done by spiking the sample with known interferents and checking if they affect the accuracy of the BA analysis. Robustness testing refers to the ability of a method to remain unaffected by small and intentional variations in its parameters. This characteristic of a method is an indication of its reliability during normal usage. A rugged method can withstand small deviations or variations in factors such as temperature, humidity, pH, and other experimental conditions, and still provide consistent and reliable results. By testing the robustness of a method, it is possible to identify the critical factors that may affect the accuracy and precision of the results. This information can be used to establish more robust procedures and to reduce the variability in the results.

From a machinery perspective, achieving an above-average performance of over 74% requires well-maintained measuring equipment and analytical instruments. Regular calibration and maintenance ensure that the equipment is functioning properly and providing accurate results. It is also important to allocate the budget to specific equipment based on analytes, as different sections may require specific measuring equipment such as balance and ovens. Additionally, applying good laboratory practice is crucial for ensuring accurate and reliable results. Standard Malaysia is one of the Compliance Monitoring Authority (CMA) for monitoring compliance with the Organisation for Economic Co-operation and Development Principles of Good Laboratory Practise (OECD GLP). However, applying for the GLP is voluntary. Moreover, applying best practices for laboratory techniques such as handling chemicals requires being precautious, never returning excess reagents to the reagent bottle, placing any excess reagent into the appropriate waste container, and properly storing and labeling samples and reagents.

The materials used in the laboratory cover a wide range, including reference materials, QC samples, software, consumable parts, reagents, PT/ILC, and samples received. The lab mostly uses analytical standards, with the sugar profile analysis using RM and the heavy metal analysis using CRM for their calibration standards. For testing without using analytical instruments, such as for fat, protein, and ash, the QC practice uses the LFB & LFM method. Only moisture analysis uses its own sample with duplicate results as the QC procedure. The lab uses a mixed system that combines manual and Microsoft Excel for their sample registration, result input, and certificate of analysis generation. The lab can be continuously improved by moving forward to the Laboratory Informative Management System (LIMS). Consumable parts and reagents strictly follow the schedule and specifications and do not exceed a 1- year storage period. The marks of the Material for ascorbic acid, sugar profile, and formaldehyde decreased due to the laboratory not participating in any PT/ILC. NCR shall be issued if SP4 is followed and no PT/ILC was participated in by this laboratory. The total number of samples received per year depends on certain analytes, with some, such as ascorbic acid, sugar profile, and formaldehyde having low demand. This is the reason why the top management never spends over the budget on these analytes that do not involve any PT. There is no surplus for these three analytes. The AACS for the three analytes mentioned, namely ascorbic acid, sugar profile, and formaldehyde are currently 59.48%, 60.34%, and 59.48% respectively. These scores indicate that there is still room for improvement in the laboratory's performance to achieve expert-level status in these areas. As of now, Lab A cannot be considered an expert laboratory for these three analytes. It is worth noting that even AACS falling in the range of 66% to 70% is not considered to be indicative of expert-level performance. Although these scores may indicate a relatively strong level of analytical accuracy, they still do not meet the strict standards required by expert-level laboratories. Therefore, it is important for Lab A to continue striving towards improvement and achieving higher AACS in order to establish themselves as an expert laboratory in the future.

TABLE II. AACS FOR ALL ANALYTES

No.	Analytes	AACS, %
1	Benzoic Acid	67.24
2	Sorbic Acid	66.38
3	Ascorbic Acid	59.48
4	Sugar profile	60.34
5	Heavy Metal	67.24
6	Fat (Liquid)	77.59
7	Protein	70.69
8	Moisture	68.97
9	Ash	69.83
10	Formaldehyde	59.48
Total score		667.24
Average		66.72
20% for MM		13.34

TABLE III. SUMMARY PERCENTAGE, % BASED ON 4M.

Analytes	Manpower	Method	Machine	Material
1	60.71	66.67	77.42	63.64
2	60.71	66.67	77.42	60.61
3	60.71	66.67	77.42	36.36
4	60.71	66.67	77.42	39.39
5	60.71	66.67	74.19	66.67
6	89.29	66.67	77.42	75.76
7	60.71	66.67	83.87	69.7
8	60.71	66.67	77.42	69.7
9	60.71	66.67	77.42	72.73
10	60.71	66.67	77.42	36.36

B. Result for System Maturity Score, SMS

i. Audit/assessment score, A score

The score was obtained from internal audit and external assessment. The difficult part for this section was the transition period that occurred in the year 2019. The ISO/IEC 17025: 2017 version was welcomed as the new standard for the general requirements for the competence of testing and calibration laboratories. It had been 12 years since the prior version was published and a majority of the referenced documents in the 2005 version of the standard had become obsolete and needed a change. Initially, the transition period was until 30th November 2020, meaning that all the assessments cum transitions must comply before the date. But based on the ILAC ballot result decision, an extension for 6 months until 1st June 2021 was announced through the ILAC website. At the end of the transition period, the accreditation of a laboratory to ISO/IEC 17025: 2005 will not be recognized under the ILAC arrangement. Referring to Table 5 & Table 6, the clauses were based on Clause 4 for the management part of V2005 and Clause 5 for the technical part of V2005; whereas V2017 was divided into four sessions which cover: Clauses 4 & 5, Clause 6, Clause 7, and Clause 8; others cover all the SP, SC, STC, AP and others. Thus, before the transition, assessments only went through Clause 4 and Clause 5 of ISO/IEC 17025. After the transition, assessments cover all clauses from Clause 4 to Clause 8. In 2017, the laboratory obtained a total score of 142, with 90 points from the internal audit and 52 points from the external assessment. The laboratory showed improvement in 2018 with a total score of 102. However, in 2020, non-conformance increased to 23 NCR from 12 NCR due to unfamiliarity with new clauses, such as risk assessment and impartiality, brought on by the transition from version 2005 to version 2017. Some of the NCRs raised: i. Risks that affect the laboratory activities has not been adequately identified such as contamination, unauthorised procedures, handling of test items, and using incompetent personnel; ii. the person who is responsible for the management system is a member of the audit team, this arrangement created impartiality where there should be objectivity in the laboratory activities. Despite the increase in NCR, the internal audit score decreased, and the total points obtained were 99. In 2021, during the reassessment, the laboratory received a total score of 42, indicating improvement. The trend shows a decreasing number of NCR and increasing quality, as shown in Figure 6.

Figure 6. Comparison of the Total Scores for Internal audit and External assessment

TABLE IV. CALCULATION OF THE A SCORE

	Ext	Int	Total	Index A
2017 Surveillance	52	90	142	1
2018 Reassessment	31	71	102	0.72
2020 Surveillance + Transition	39	60	99	0.97
2021 Reassessment	24	18	42	0.42
Total				3.11
Average of the Index A score				0.78
A score				82.55
60% for SMS				49.53

The A score index is a metric used to evaluate the performance of the laboratory in maintaining quality and complying with relevant clauses. The calculation is based on the total scores of the laboratory's internal audit and external assessments in a given year, compared to the baseline year of 2017. In 2017, the laboratory received a score of 142, which was used as the benchmark score, resulting in an index of 1. In 2018, the total score decreased to 102, resulting in an A score index of 0.72. This was a decrease from the previous year, it indicated that the laboratory was making improvements. However, in 2020, the A score index increased to 0.97, which suggested that there was room for improvement in maintaining quality and complying with the relevant clauses. This increase in the index was probably due to the transition from version 2005 to version 2017, which included new clauses related to risk, management, and impartiality. The laboratory received 23 non-conformances in 2020, which was an increase from the previous assessment's 12 non-conformances. Fortunately, in 2021, the A score index improved significantly to 0.42, indicating that the laboratory's quality and compliance efforts were paying off. The decrease in the index was a positive sign that the laboratory was making progress towards meeting the required standard and avoiding non-conformances. In summary, an A score index less than 1 is a good sign of improvement, while an index greater than 1 indicates that the laboratory needs to work harder to maintain quality and comply with all the requirements. A score obtained from the calculation based on formula (3) involves the average of the index A score, and the result is 82.55. Table 4 shows the result of the A score, 60% of the A score was included in the SMS calculation, that is 49.53%.

TABLE IV. EXTERNAL ASSESSMENT FINDINGS AND SCORES FOR TWO CIRCLES ASSESSMENT

		Clause	Cat	Point	2017 Surv	Score	2018 Reass	Score	2020 Surv + Trans	Score	2021 Reass	Score	Total	Total scores per clause
External Assessment	NCR / OBS	V2005:4/ V2017:4&5	1	4	0	0	0	0	0	0	0	0	0	0
			2	3	0	0	0	0	0	0	0	0	0	
			3	2	0	0	0	0	0	0	0	0	0	
			4	1	0	0	0	0	0	0	0	0	0	
		V2017: 8	1	4	-	-	-	-	0	0	0	0	0	7
			2	3	-	-	-	-	0	0	0	0	0	
			3	2	-	-	-	-	2	4	0	0	4	
			4	1	-	-	-	-	1	1	2	2	3	
		V2017: 6	1	4	-	-	-	-	0	0	0	0	0	17
			2	3	-	-	-	-	1	3	1	3	6	
			3	2	-	-	-	-	2	4	0	0	4	
			4	1	-	-	-	-	4	4	3	3	7	
		V2005: 5 V2017: 7	1	4	0	0		0	0	0	0	0	0	107
			2	3	9	27	7	21	3	9	1	3	60	
			3	2	7	14	2	4	4	8	3	6	32	
			4	1	2	2	0	0	6	6	7	7	15	
		others	1	4	0	0	0	0	0	0	0	0	0	15
			2	3	1	3	1	3	0	0	0	0	6	
			3	2	2	4	1	2	0	0	0	0	6	
			4	1	2	2	1	1	0	0	0	0	3	
		Total			23	52	12	31	23	39	17	24	146	

TABLE VI. INTERNAL AUDIT FINDINGS AND SCORES BASED ON THE YEAR OF ASSESSMENT

		Clause	Cat	Point	2017	Score	2018	Score	2020	Score	2021	Score	Total	Total scores per clause
Internal Audit	NCR / OBS	V2005:4/ V2017:4&5	1	4	0	0	0	0	0	0	0	0	0	45
			2	3	3	9	2	6	0	0	0	0	20	
			3	2	4	8	1	2	1	2	1	2	19	
			4	1	3	3	0	0	0	0	0	0	6	
		V2017: 8	1	4	-	-	-	-	0	0	0	0	0	0
			2	3	-	-	-	-	0	0	0	0	0	
			3	2	-	-	-	-	0	0	0	0	0	
			4	1	-	-	-	-	0	0	0	0	0	
		V2017: 6	1	4	-	-	-	-	0	0	0	0	0	51
			2	3	-	-	-	-	7	21	2	6	30	
			3	2	-	-	-	-	6	12	2	4	20	
			4	1	-	-	-	-	0	0	1	1	1	
		V2005: 5 V2017: 7	1	4	0	0	0	0	0	0	0	0	0	225
			2	3	13	39	17	51	5	15	1	3	141	
			3	2	15	30	6	12	3	6	0	0	72	
			4	1	1	1	0	0	4	4	2	2	12	
		Total			39	90	26	71	26	60	9	18	321	

ii. Overall Proficiency Testing score, OPT score.

The score was evaluated based on the results obtained from participating in the PT scheme for two circles. Table 7 provides a summary of the laboratory's results from year 2016 to 2021. The laboratory achieved its highest percentage of 92.31% in the year 2020, with a total of 39 analytes involved in the PT schemes. The laboratory focus was on the local accredited PT provider, the scheme such as FODAS, ENVITEST, KATEST, and WAPAS was chosen. However, the lowest percentage was obtained in 2021, with only 82.08% and four outlier results, refer to Table 8. In 2019, the laboratory achieved a relatively high performance of 90.79% with only one outlier result. From 2016 to 2018, the percentage obtained were 87.50%, 87.00%, and 86.03%, respectively. To evaluate laboratory improvement, it is important to assess the trends in the laboratory's PT results over time. By comparing the percentage obtained each year, we can determine whether the laboratory's performance is improving, declining, or remaining stable. However, it is important to take note that the total number of analytes involved in each PT scheme must also be taken into consideration to ensure a comprehensive assessment. It is necessary for the laboratory to cover all the accredited methods within a circle to ensure that they are proficient and comply with the SAMM policy. If the laboratory uses the PT for competency purposes, then regular involvement in PT schemes is necessary to maintain the competency of laboratory personnel.

TABLE VII. SUMMARY OF THE OPT SCORE FROM THE YEAR 2016 TO 2021.

Year	Total Analytes	%
2021	60	82.08
2020	39	92.31
2019	38	90.79
2018	34	86.03
2017	50	87.00
2016	50	87.50
Average		87.62
40% for SMS		35.05

The OPT average was calculated to be 87.62%. To determine the SMS, 40% of the OPT score was used, which resulted in a score of 35.05%.

iii. Combination of AACS and SMS

Based on the information provided, the laboratory's AACS score is 13.34%. The SMS score is calculated by combining the A score (49.53%) and OPT score (35.05%), resulting in a total score of 84.58%. The contribution of SMS to the overall score is 80%, which means that the SMS is 67.66%. Finally, the MM score is calculated by combining the AACS score (13.34%) and the SMS (67.66%), resulting in a total score of 81%. It appears that Lab A fall in the "Leading" level for the Maturity Model.

V. CONCLUSION

The primary aim of this research is to assess the maturity level of the laboratory and identify areas for further improvement, utilizing the 4M framework (Manpower, Method, Machine, and Material) as outlined in the SAMM document. The findings of this study indicate that the laboratory exhibits significant potential for global expansion, having achieved a leading level of maturity. However, there are opportunities for continuous improvement that can further strengthen the laboratory's maturity level. The following recommendations are proposed to enhance the laboratory's maturity level:

Manpower: To maintain a competent workforce, it is recommended that the laboratory management consider implementing a revised strategy. This strategy could include measures such as providing regular training and professional development opportunities for staff, fostering a culture of continuous learning, and promoting employee engagement and motivation.

Method: All in-house testing methods should undergo validation procedures in accordance with the guidelines set forth by the Analytical Laboratory Accreditation Criteria Committee (ALACC). Method validation ensures the robustness, reliability, and compliance of the laboratory's analytical procedures with international standards, thus enhancing the accuracy and consistency of the test results.

Machine: To optimize equipment utilization and efficiency, it is advised to implement Good Laboratory Practices (GLP) for equipment sharing. This involves establishing protocols and guidelines for equipment usage, maintenance, and calibration. By implementing GLP, the laboratory can ensure that equipment specific to certain analytes is appropriately shared among different testing activities, minimizing downtime and maximizing resource utilization.

Material: To ensure traceability and accuracy in testing, it is recommended that the laboratory adopt metrological traceable reference materials (RMs). These RMs should be utilized in the calibration and validation of testing methods, enabling the laboratory to demonstrate the accuracy and reliability of its measurements. Additionally, active participation in proficiency testing (PT) programs across all analytes can provide valuable external validation and enhance the laboratory's overall confidence in its testing capabilities.

By implementing these recommendations, the laboratory can further strengthen its maturity level, improving operational efficiency, accuracy of results, and overall quality management. These measures will contribute to the laboratory's ability to compete globally, meet international standards, and continue to provide reliable testing services to its clients.

VI. FUTURE RESEARCH AND LIMITATIONS

This study is based on questionnaires referring to records and interviews with top management to technical staff from the private laboratory. Referring to the company's policy, only six years of records were maintained. Thus, only two cycles of the records were collected and analysed. Further research will include the expert laboratory based on AACS. The analyte with the higher AACS score will be the expert lab for that particular analyte. The contribution of the expert lab in the MS ISO/IEC 17043 will upgrade the reputation of our department's PT provider.

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DATA AVAILABILITY

Department of Chemistry Malaysia Proficiency Testing Provider, MyKIMIA PTP PT scheme data from the year 2012 to 2021.

DECLARATIONS

Conflict of Interest: Li Hui Ling declares that she has no conflict of interest. Mohd Sukri Hassan declares that he has no conflict of interest. Che Wan Zanariah declares that she has no conflict of interest. Mehmet declares that she has no conflict of interest.

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