

ENHANCING THE LABORATORY QUALITY ASSURANCE USING THE MYKIMIA PROFICIENCY TESTING PROVIDER (PTP) FOOD SCHEME DATA

(Meningkatkan Jaminan Kualiti Makmal dengan Menggunakan Data Ujian Kemahiran Skim Makanan MyKIMIA PTP)

LI HUI LING & MOHD SUKRI HASSAN*

ABSTRACT

Accuracy, reliability, defensibility, and timeliness are all aspects of laboratory quality. The outcomes must be error-free in order to produce high accuracy data. Valid methods and calibrated equipment are referred to as reliability. To dispute the laboratory results, all possible errors were identified and the measurement uncertainties were estimated. The certificate of analysis or report must be issued timely. Laboratories in Malaysia was referred to the ISO/IEC 17025 for accreditation purpose. There are three essential elements defined as the backbone of the laboratory quality system. Validate analytical methods, accreditation involving third part auditing and participation in proficiency testing (PT). For this study, PT data is used as a tool to assess laboratory quality management systems' competency. Even if their performance is satisfactory according to the PT provider's evaluation criteria, participants in PT can interpret their results to detect inaccuracies and possibilities for continuous improvement. One of the PT schemes from MyKIMIA Proficiency Testing Provider (PTP) selected for the case study, the overall percentage of satisfactory for the Food Analysis Scheme (FODAS) 1-20 Benzoic acid (BA) and Sorbic acid (SA) in cordial was in the range from 82% to 88%. Statistic performance evaluation was based on a calculation of Z score for Test 1, Test 2 and Test 4. The laboratories shall recalculate the Z score based on the PTP assigned value and fit for purpose standard deviation proficiency assessment (SDPA). Zeta score can be calculated to check the plausibility of the laboratory's measurement uncertainty estimate. The outlier data received that cause the poor performance include human errors, random errors, and systematic errors. Investigation on the errors is consistently based on four main factors: manpower, method, material, and machinery (4M).

Keywords: quality assurance; proficiency testing; ISO 17025; Z score

ABSTRAK

Ketepatan, kebolehpercayaan, kebolehtahanan dan ketepatan masa adalah semua aspek kualiti makmal. Hasilnya mestilah bebas ralat untuk menghasilkan data berketalitian tinggi. Kaedah yang sah dan peralatan yang ditentukur dirujuk sebagai kebolehpercayaan. Untuk mempertikaikan keputusan makmal, semua kemungkinan ralat telah dikenal pasti dan ketidakpastian pengukuran dianggarkan. Sijil analisis atau laporan mesti dikeluarkan tepat pada masanya. Makmal di Malaysia telah dirujuk kepada ISO/IEC 17025 untuk tujuan akreditasi. Terdapat tiga elemen penting yang ditakrifkan sebagai tunjang utama sistem kualiti makmal. Mengesahkan kaedah analisis, akreditasi yang melibatkan pengauditan pihak ketiga dan penglibatan dalam ujian kecekapan (PT). Untuk kajian ini, data PT digunakan sebagai alat untuk menilai kecekapan sistem pengurusan kualiti makmal. Walaupun prestasi mereka memuaskan mengikut kriteria penilaian penyedia PT, peserta dalam PT boleh mentafsir keputusan mereka untuk mengesan ketidaktepatan dan kemungkinan penambahbaikan berterusan. Salah satu skim PT daripada MyKIMIA Proficiency Testing Provider (PTP) yang dipilih untuk kajian kes, peratusan keseluruhan yang memuaskan untuk FODAS 1-20 asid Benzoik (BA) dan asid Sorbik (SA) dalam kordial adalah dalam julat 82% hingga 88%.

Penilaian prestasi statistik adalah berdasarkan pengiraan skor Z untuk Ujian 1, Ujian 2 dan Ujian 4. Makmal hendaklah mengira semula skor Z berdasarkan nilai yang ditetapkan PTP dan sesuai untuk tujuan penilaian sisihan piawai kecekapan (SDPA). Skor Zeta boleh dikira untuk menyemak kebolehpercayaan anggaran ketidakpastian pengukuran makmal. Data terpencil yang wujud yang menyebabkan prestasi buruk termasuk ralat manusia, ralat rawak, dan ralat sistematik. Penelitian terhadap kesilapan secara konsisten biasanya berdasarkan empat faktor utama: tenaga kerja, kaedah, bahan dan jentera (4M).

Kata kunci: jaminan kualiti; ujian kecekapan; ISO 17025; skor Z

References

- Brookman B. & Mann I. (eds.). 2021. *Eurachem Guide: Selection, Use and Interpretation of Proficiency Testing (PT) Schemes*. 3rd Ed. Eurachem.
- Department of Standards Malaysia. 2020. *Annual report 2020*.
- Department of Standards Malaysia. 2013. SAMM Policy 4 (SP4) - *Policy for participation in proficiency testing activities*.
- Earnshaw A., Smith R.A. & Owen L. 2009. How proficiency testing can improve the quality of analytical data using vitamin analysis as an example. *Food Chemistry* **113**: 781-783.
- Edson D.C., Russell D. & Massey L.D. 2007. Proficiency testing: a guide to maintaining successful performance. *Laboratory Medicine* **38**(3): 184-186.
- Ellison S.L.R. & Hardcastle W.A. 2012. Causes of error in analytical chemistry: Results of a web-based survey of proficiency testing participants. *Accreditation and Quality Assurance* **17**: 453-464.
- International Organization for Standardization. 2010. *ISO/IEC 17043:2010 Conformity assessment - General requirements for proficiency testing*.
- International Organization for Standardization. 2015. *ISO 13528:2015 Statistical methods for use in proficiency testing by interlaboratory comparison*.
- International Organization for Standardization. 2017. *ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories*.
- James V.L.A. 2015. Harmonisation of performance assessment in qualitative PT/EQA. *Accreditation and Quality Assurance* **20**(4): 335–338.
- Kuselman I., Pennecchi F., Epstein M., Fajgelj A. & Ellison S.L.R. 2014. Monte Carlo simulation of expert judgments on human errors in chemical analysis - A case study of ICP-MS. *Talanta* **130**: 462-469.
- Li T., Zhao H., Zhang C., Wang W., He F., Zhong K., Yuan S. & Wang Z. 2018. Reasons for proficiency testing failures in routine chemistry analysis in China. *Laboratory Medicine* **50**(1): 103-110.
- Majors R.E. 2013. *Sample preparation fundamentals for chromatography*. Canada: Agilent Technologies, Inc.
- Peric V., Jaric D., Ketic S., Konicanin A. & Biocanin R. 2014. Quality of control of clinical-biochemical laboratories – Serbian case. *Open Access Macedonian Journal of Medical Sciences* **2**(2): 219-223.
- Portugal T.R., Udarbe M.A., Ardena J.G., Castillo L.N. & Mendez S.T. 2011. Provision of proficiency test (PT) scheme on proximate and mineral analyses: Philippine experience. *Journal of Food Composition and Analysis* **24**: 656-662.
- Stefanelli P., Generali T., Barbini D.A., Girolimetti S. & Dommarco R. 2013. Uncertainty estimation in the analysis of pesticide residues in olive oil using data from proficiency tests. *Journal of Environmental Science and Health, Part B* **48**(7): 523–529.

Enhancing the laboratory quality assurance using the MyKIMIA Proficiency Testing Provider (PTP)

Received: 31 October 2021

Accepted: 29 November 2021

*Corresponding author