



Analytical Quality Control in Physiological Function Testing in the era of Artificial Intelligence

*Tatsuo Shimosawa, MD, PhD**

*Department of Clinical Laboratory, School of Medicine, International University of Health and Welfare, Chiba, Japan.
E-mail: Shimosawa-lab@ihwg.jp

[Lab Med Int 2025; 4(4): 103-104]

See article volume 4(4): 114-124

Physiological function tests such as electrocardiography (ECG), ultrasound, and pulmonary function assessments are critical for diagnosing cardiovascular, respiratory, and systemic conditions. Analytical quality control ensures that these tests produce accurate and reproducible results¹⁾. In the era of artificial intelligence (AI), Quality control (QC) control has two important meaning. One is AI can be used in maintaining robust QC systems is vital to prevent diagnostic errors and optimize patient care. The other is without well quality controlled data, AI can not learn from the data to draw correct and robust interpretations.

Analytical QC in ECG Testing

Electrocardiography relies on precise signal acquisition and interpretation. Analytical QC involves calibration of ECG machines, verification of signal fidelity, and artifact detection. Common analytical errors include baseline wander, electrode misplacement, and noise interference. AI algorithms now assist in detecting subtle waveform anomalies and validating automated interpretations. In the current issue of Laboratory Medicine International (LMI), Ogasawara and her colleagues reported survey of the quality management of ECG in ISO15189 accredited clinical laboratory in Japan²⁾. Their survey shows surprisingly wide fluctuations of values and certain number of laboratories do not meet the satisfactory internal or external accuracy control level.

AI Integration in Analytical QC³⁾

AI enhances QC by enabling predictive maintenance, anomaly detection, and adaptive QC protocols. For ECG,

AI can identify electrode misplacement patterns; for ultrasound, it can evaluate image quality metrics; for pulmonary function tests (PFTs), it can predict calibration drift. Challenges include data standardization, algorithm transparency, and regulatory compliance.

AI Integration in clinical decision making³⁾

It is not needed to stress that imaging, such as ECG or ultrasound are very important in our clinical evaluation. Numerical evaluation of ECG as well as the shape of each component of wave, and, ultrasound images all over the body plays a critical and pivotal role in clinical diagnosis these days. After emerging of AI, AI-powered ECG or ultrasound is becoming more mature and getting closer to routine clinical applications in recent times because of an increased need for efficient and objective acquisition and evaluation of ECG and ultrasound images. AI-assisted image acquisition made us possible to assess image quality in real time and prompt diagnosis. Because ultrasound images involve operator-, patient-, and scanner-dependent variations, the adaptation of classical machine learning methods to clinical applications becomes challenging. With their self-learning ability, deep-learning (DL) methods are able to harness exponentially growing graphics processing unit computing power to identify abstract and complex imaging features. To achieve high QCquality control in scanner and data acquisition system is essential to obtain powerful AI-assisted laboratory examination⁴⁾.

Future Directions

Future QC frameworks will integrate AI-driven analytics with traditional QC principles. Laboratories and diagnostic centers must invest in robust data governance, staff training, and collaborative research to validate AI

tools. Harmonization of QC standards across physiological testing modalities will ensure consistency and reliability globally.

Conclusion

Analytical QC in physiological function testing is indispensable for accurate diagnosis and patient safety. As AI reshapes diagnostic workflows, maintaining rigorous QC systems for ECG, ultrasound, and PFTs will be essential to realize the full potential of technological innovation.

References

- 1) ISO 15189: Medical laboratories – Requirements for quality and competence. International Organization for Standardization; 2022.
- 2) Ogasawa N, Tanabe A, Masaki K, Asashi K, Mochida T, Daimon M, Yokoyama N, Tojo N, Shirota Y, Furukawa T. Current status of quality management of standard 12-lead electrocardiography at ISO 15189 accredited medical institutes in Japan. *LMI*. 2025; 4 (4) : 114-24.
- 3) Topol EJ. High-performance medicine: AI in diagnostics. *Nat Med*. 2019; 25 (1) : 44-56.
- 4) Wiens J, Saria S, Sendak M, Ghassemi M, Liu VX, Doshi-Velez F, Jung K, Heller K, Kale D, Saeed M, Ossorio PN, Thadaney-Israni S, Goldenberg A. Do no harm: a roadmap for responsible machine learning for health care. *Nat Med*. 2019 Sep; 25 (9) : 1337-40.

This article is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License (CC BY-NC-ND 4.0).