

**Sigma metrics as a tool for evaluating the analytical performance of hematology laboratory: A first report from Sri Lanka**Rathnayake H. N.<sup>1</sup>, Perera M. J. H.<sup>1</sup>, Weerathne T. D. U. N. R.<sup>1</sup> and Rasaratnam K.<sup>1\*</sup><sup>1</sup>*Department of Medical Laboratory Sciences, Faculty of Allied Health Sciences, University of Jaffna, Sri Lanka.  
karunaitas@univ.jfn.ac.lk*

Clinical laboratories enhance patient care efficiency by selecting appropriate tests, providing trustworthy results, and accurate interpretation. Quality management strategies, such as sigma metrics, are crucial for reducing errors and improving quality control processes. However, the applicability of sigma metrics for evaluating the analytical quality of hematological tests in Sri Lankan laboratories is limited. Thus, the present study aimed to assess the analytical process performance of a hematology laboratory in Sri Lanka using Six Sigma models. A retrospective study was conducted by extracting internal quality control (IQC) and external quality assessment (EQA) data from a tertiary care hospital in the Western province of Sri Lanka over one year, from May 2023 to April 2024. The mean, standard deviation, coefficient of variation, percent bias, and sigma values of White blood cell (WBC) count, Red blood cell (RBC) count, Hemoglobin (Hb) concentration, Hematocrit (Hct), and Platelet (PLT) count were calculated in Microsoft Excel using the total allowable error (TEa) of Clinical Laboratory Improvement Amendments-2024. The analytical performance of the tests was assessed based on the sigma level: <3 displayed poor performance, 3-6 was graded as acceptable, and >6 implied good performance. For the low-level IQC, two analytes (WBC and PLT) showed an acceptable performance of 3-6 sigma level and three analytes (RBC, Hb, and Hct) showed poor performance of <3 sigma level. For high-level IQC, PLT exhibited a good performance of >6 sigma level while WBC showed an acceptable performance. Furthermore, three analytes (RBC, Hb, and Hct) showed poor performance. For normal-level IQC, WBC, Hb, and PLT demonstrated good performance while RBC and Hct exhibited poor performance. Overall, the reliability of the results of Hct and RBC is questionable since they show <3 sigma values. The calculation of Sigma metrics clearly exhibited the test performance of hematological parameters; thus, Sigma metrics can be used as a valuable tool for evaluating the analytical process performance of hematology laboratories in Sri Lanka.

**Keywords:** *Sigma metrics, Analytical performance, Hematology, Sri Lanka*