Noor Haslina Mohd Noor [1,2], Zefarina Zulkafli[1,2], Nurul Izzah Abdul Razak[1]

[1]Department of Hematology, School of Medical Sciences, Health Campus, Universiti Sains Malaysia, 16150 Kubang Kerian, Kelantan, Malaysia.

[2]Hospital Universiti Sains Malaysia, 16150 Kubang Kerian, Kelantan, Malaysia.

Evaluation of the Performance of Automated Haematology Analyser Dymind DH73 Compared to Sysmex XN 1000 System

***Abstract*—** Many types of automated haematology analysers are available for the used in clinical laboratories. It is reasonable to assume that a newly acquired piece of diagnostic equipment would run as intended, as manufacturers perform their own validation testing to prove intended use prior to launching a product in the market. Thorough validation testing on all new haematology analysers must be performed to ensure patient safety. This study was carried out to validate Dymind DH73, the automated haematology analysers in the Hospital Universiti Sains Malaysia setting. Blood samples send for complete blood count were selected randomly (n = 40) from healthy subjects and those who have different blood disorders. Blood specimens and quality control materials were analysed on the Dymind DH73 to evaluate precision, carry over and linearity. For correlation, we used the Sysmex XN-1000 as the comparative method. The study showed very good correlation (R > 0.9) between Dymind DH73 and Sysmex, XN-1000 in the parameters such as white blood cell, red blood cell, hemoglobin, platelet, nucleated rbc, neutrophil, lymphocyte, monocyte, eosinophil, and low correlation for basophil. In conclusion, the Dymind DH73 displayed a satisfactory performance with respect to precision, linearity and carry over. The performance of the Dymind DH73 analyser was good and compared favorably with the Sysmex XN-1000.

Received 26 July 2023.
Revised 25 Apr 2024
Accepted 14 May 2024.
Published Online 05 June 2024

*Corresponding author:
Zefarina Zulkafli
E-mail: zefarina@usm.my

***Keywords*—Automated haematology analysers; correlation; Dymind DH73; haematological parameter; Sysmex XN-1000**

1 INTRODUCTION

Currently, automated complete blood count, differential, reticulocyte and nucleated red blood cell counts are customarily being accepted and used as a routine practice in the initial screening for haematological paramater abnormalities in healthcare service centre worldwide (1,2). Hence, a number of different automated haematology analysers are available in the market today (1-3).

The benefits and clinical usefulness of automated haematology analysers includes the accuracy, precision as well as shorter sample turnover time as compared to manual methods have been validated in many studies (3,4). However, false results of haematological parameters from complete blood count can occur for examples false low of platelet counts being detected due to platelet agglutination in the presence of ethylenediamine tetra-acetic acid (EDTA) (1,5).

The main and important function for haematology analysers is to minimize false-negative results. Therefore, most of the instruments using different methods, such as impedance, flow cytometry, as well as fluorescence techniques to optimized cell classification (6,7). Thus, the selection of an automated haematology analyser has direct impact on the accuracy of patient results and laboratory efficiency (3,4).

Dymind DH76 (Dymind Biotech, China) is a new automated haematology analyser designed to report 29 parameters, including a 5-part WBC differential count, with a capacity for the analysis of 80 samples (CBC/DIFF) per hour. Dymind DH73, is an automated haematology analyser with 25 reportable parameters including a 5-part WBC differential count. The test requires 20ul of venous blood. The throughput is up to 80 tests per hour (8). A foremost anticipation of all the clinical laboratory from an automated haematology analyser is to lessen the evaluation rates and produce satisfactory result. Therefore, the performance, advantages and limitations of the analysers need to be assessed properly (6-9).

The aim of this study was to evaluate the automated haematology analysers Dymind DH73 in term of precision, carry over and linearity and correlate with Sysmex XN-1000 regarding inter-instrument comparison of haematological parameter.

2 MATERIALS AND METHODS

2.1 Samples

Blood samples in 3ml EDTA bottle send for complete blood count in Haematology laboratory Hospital Universiti Sains Malaysia were selected randomly (n = 40) from healthy subjects and those who have different blood disorders. The samples were analysed for complete blood count using Dymind DH73 (China) and Sysmex, XN-1000 (Kobe, Japan) within four hours of collection following the manufacturer's operational guidelines.

For the precision, mean and % CV for 1 normal sample repeat 11 times for all parameters: white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), platelet (PLT), mean cell volume (MCV), neutrophil (NEU#), lymphocyte (LYM#), monocyte (MONO#), eosinophil (EO#), and (BASO#). The carryover study was performed following the CLSI H26-A2 guideline (8,9), include the assessment of high (H1, H2, H3) and low (L1, L2, L3) samples three times consecutively. The percentage of carryover was calculated by the formula (8,9):

$$\text{Carry-over Rate (\%)} = \frac{\text{First Low Value} - \text{Third Low Value}}{\text{Third High Value} - \text{Third Low Value}} \times 100\% \quad (1)$$

2.2 Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics version 19.0 (IBM Corporation, Armonk, NY, USA). Patient sample correlations were calculated using Passing-Bablok regression and a difference comparison plot from the concordance study samples that were within the reportable range on both platforms.

Pearson's correlation coefficient was employed to estimate linear relationships between the variables. Punctuate equations when they are part of a sentence, as in (1)

3 RESULTS

For the precision, all the parameters are within allowable limits of performance for DH73 as shown in table 1.

Table 1 Precision Test

		DH73 (S/N: DM11031850002)									
		WITHIN RUN PRECISION (CBC)					WITHIN RUN PRECISION (DIFF)				
No	Date	WBC	RBC	HGB	MCV	PLT	NEUT %	LYM %	MON (%)	EO %	BASO %
1 time	20.04.2021	5.73	4.43	134.0	86.2	261.0	60.9	28.0	8.6	2.4	0.1
2 time	20.04.2021	5.81	4.44	134.0	86.3	263.0	63.9	24.7	8.5	2.6	0.3
3 time	20.04.2021	5.67	4.44	133.0	86.5	270.0	61.3	27.0	8.5	2.7	0.5
4 time	20.04.2021	5.71	4.37	133.0	86.4	263.0	61.7	27.6	7.4	3.0	0.3
5 time	20.04.2021	5.71	4.43	134.0	86.5	268.0	61.6	27.6	8.0	2.4	0.4
6 time	20.04.2021	5.72	4.42	134.0	86.8	271.0	62.6	25.7	8.4	3.0	0.3
7 time	20.04.2021	5.74	4.46	135.0	86.3	260.0	62.5	26.8	8.4	2.2	0.1
8 time	20.04.2021	5.76	4.42	134.0	86.3	267.0	62.0	25.7	8.9	3.2	0.2
9 time	20.04.2021	5.65	4.42	134.0	86.8	263.0	61.5	27.5	8.0	2.9	0.1
10 time	20.04.2021	5.75	4.47	134.0	86.5	266.0	62.8	25.6	9.2	2.2	0.2
	Min	5.65	4.37	133.0	86.2	260.0	60.9	24.7	7.4	2.2	0.1
	Max	5.81	4.47	135.0	86.8	271.0	63.9	28.0	9.2	3.2	0.5
	Mean	5.73	4.43	133.9	86.5	265.2	62.1	26.6	8.4	2.7	0.25
	SD	0.05	0.03	0.6	0.2	3.8	0.9	1.1	0.5	0.4	0.14
	CV	0.79	0.61	0.42	0.24	1.42	1.42	4.2	6.0	13.4	54.2
	Precision Limit (%)	<2.0	<1.5	<1.0	<1.0	<6.0	<4.0	<3.0	<2.0	<1.5	<0.8
	PASS/FAIL	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS

The carryover for DH73 is acceptable and have passed the DH73 carry-over rate indexes. The linearity for Dymind DH73 in WBC, RBC, HGB, HCT and PLT are well acceptable, r2 = > 0.99.

The study showed very good correlation (R>0.9) between Dymind DH73 and Sysmex, XN-1000 in all key parameters such as WBC, RBC, HGB, PLT, NRBC%, NEU#, LYM#, MONO, EO, and low correlation for BASO as shown in Fig. 1.

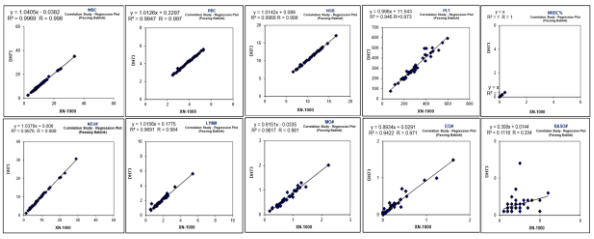

Figure 1: Correlation Between Dymind Dh73 And Sysmex, Xn-1000 In Haematological Parameters.

Table 2: Carryover Study With High And Low Patient Samples For Dymind Dh73

Carryover	WBC	RBC	HGB	PLT	HCT
	0.00	0.00	0.00	0.00	0.00

4 DISCUSSION

Automation in haematology is gaining worldwide acceptance. For haematology laboratory, all pathologists are expected the benefits of automated cell counters to give the best result in term precision, accuracy and the shorter sample turnover time compared to manual methods (1,3). Therefore, the instruments should use as per standard recommendations from the companies, as well as maintaining the regular checks and

quality control for obtaining reliable results from the instruments (1,4,6).

For advantages, automated analysers can process a large number of samples in a relatively short time, significantly increasing the throughput of a laboratory. Faster processing times lead to quicker delivery of results, enabling healthcare providers to make timely decisions for patient care. This is especially critical in emergency situations. Automation reduces the likelihood of human errors associated with manual counting and staining methods. Automated analysers can perform a wide range of haematological tests, including complete blood count (CBC) and differential white blood cell (WBC) counts, providing comprehensive information about the patient's blood profile.

Several analysers from different company and using different method are available in the market today. The XN-1000 used the laser flow cytometry for the blood cells counting. Based on the cellular characteristics, different intensities of the signals are collected, and scattergrams of respective measuring channels are populated (6,10). Meanwhile, Dymind DH73 combine impedance and flow cytometry method (11). By comparing results generated by Dymind DH73 with results obtained from an automated haematology analyser with different analytical principles, the performance of the new instrument would be reliably proven. In this study, the analyser was evaluated according to the International Council for Standardization in Haematology guideline (8).

In the study, no carryover for WBC, RBC, HGB, (hematocrit) HCT, and PLT was observed (Table 2), and all the parameters are within allowable limits of performance of DH73 precision limit (%). Carryover was defined as the amount of analyte carried by the analyser from one sample measurement into the subsequent measurement. It was mainly of importance for carryover from high to low concentrations of Hb, RBC, WBC, and platelets.

Cell types eg: basophil that present in lower numbers in peripheral blood typically exhibit lower correlation coefficients compared to more abundant parameters in the differential formula, reflecting inherent variability and measurement limitations. Understanding these variations is crucial for accurate interpretation of blood analysis results in clinical practice. The lower correlation coefficient for % basophils (0.33) in this study was likely attributed to the utilization of a more sensitive fluorescent method on the Sysmex XN 1000 system, emphasizing the impact of measurement techniques on correlation outcomes. Kaplan and colleagues recently also reported a lower correlation coefficient for basophils using a different line of cell counters, highlighting the influence of measurement methods on correlation outcomes (2, 12).

Furthermore, this study showed a very good linearity for Dymind DH73 as well as very good correlation for haematological parameters between Dymind DH73 and Sysmex, XN-1000 (Fig. 1). Hence, a thorough comparative evaluation can provide a valuable insight that may ultimately benefit the end-users, such as healthcare professionals and patients.

5 CONCLUSION

In conclusion, the Dymind DH73 displayed a satisfactory performance with respect to precision, linearity and carry over. The performance of the Dymind DH73 analyser was good and compared favorably with the Sysmex XN-1000. The study showed that the automated haematology analyser result of Dymind DH73 is as reliable as the Sysmex, XN-1000.

ACKNOWLEDGEMENT

This work was supported by the External Agencies Grant; Antah Sri Radin Sdn Bhd (304/PPSP/86150183/A153). We would like to thank all the staff at the haematology laboratory of Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan.

CONFLICT OF INTEREST

No conflict of interest.

REFERENCES

[1] S.O. Ike, T. Nubila, E.O Ukaejiofo, I.N. Nubila, E.N. Shu, I. Ezema (2010, April). Comparison of haematological parameters determined by the Sysmex KX – 2IN automated haematology analyzer and the manual counts. *BMC Clinical Pathology* [Online]. 10(1). Available: https://pubmed.ncbi.nlm.nih.gov/20416068/

[2] M. Velizarova, T. Yacheva, M. Genova, D. Svinorov (2021, September). Evaluation of automated hematology analyzer DYMIND DH76 compared to SYSMEX XN 1000 system. *J Med Biochem* [Online] 40(4):367-377. Available: https://pubmed.ncbi.nlm.nih.gov/34616226/

[3] D. Dave, A.N. Pandya (2014, March). Comparative Study of Four Hematology Analyzers. *J Evol Med*

Dent Sci [Online] 3(12):3107-3113. Available: http://dx.doi.org/10.14260/jemds/2014/2251

[4] R.K. Bhola, C. Fudaly, S. Rastogi (2024, April). A Comparative Evaluation of Performance of Sysmex XN 3000 and Horiba Yumizen H2500 Automated Complete Blood Count Analysers. *Indian J Hematol Blood Transfus* [Online] 40(2):303-314. Available: https://pubmed.ncbi.nl,.nih.gov/38708164/

[5] P. Pusparini, A. Alvina (2022, September). Performance Comparison of Dymind DH-76 and Sysmex Xn-1000 Automated Hematology Analyzers. *Indones J Clin Pathol Med Lab* [Online] 257-262. Available: https://doi.org/10.24293/ijcpml.v28i3.1907.

[6] M. Bruegel, D. Nagel, M. Funk, P Fuhrmann, J. Zander, D. Teupser (2015, January). Comparison of five automated hematology analyzers in a university hospital setting: Abbott Cell-Dyn Sapphire, Beckman Coulter DxH 800, Siemens Advia 2120i, Sysmex XE-5000, and Sysmex XN-2000. *Clin Chem Lab Med* [Online] 53(7):1057-71. Available: https://doi.org/10.1515/cclm-2014-0945

[7] E. Schapkaitz, S. Raburabu (2018, March). Performance evaluation of the new measurement channels on the automated Sysmex XN-9000 hematology analyzer. *Clin Biochem* [Online] 53:132-138. Available: https://doi.org/10.1016/j.clinbiochem.2018.01.014

[8] C. Briggs, N. Culp, B. Davis, G. d'Onofrio, G. Zini, S.J. Machin (2014, March) ICSH guidelines for the evaluation of blood cell analysers including those used for differential leucocyte and reticulocyte counting. *Int J Hematol* [Online] 36(6):613-27. Available: https://doi.org/10.1111/ijlh.12201

[9] *Products & Solutions,* Dymind Biotechnology Co., Ltd. Shenzhen, China. [Online]. Available: https://www.dymind.com/en-US/products_and_solutions

[10] S. Incir, K.E. Palaoglu. (2020, November). Evaluation of the performance of Sysmex XN-3100 automated hematology analyzer regarding the Sysmex XE-2100 and microscopic examination. *Turk J Biochem*. [Online]. pp. 29-37. Available: https://doi.org/10.1515/tjb-2020-0004

[11] *XN-1000 / 2000 XN-Series Automated Haematology Analysers Shaping Haematology,* Sysmex Corporation, Kobe, Japan. [Online]. Available: https://www.sysmex-ap.com/wp-content/uploads/2020/08/XN-1000_2000-Brochure.pdf

[12] S.S. Kaplan, K. Johnson, N. Wolfe, W. Brown, M. Keeny, L. Gray-Statchuk, et al. (2004, July) Performance characteristics of the Coulter LH 500 hematology analyzer. *Lab Hematol*. [Online] 10(2):76-87. Available: https://pubmed.ncbi.nlm.nih.gov/15224763/