

## Original Research Article

**Diagnostic performance of automated Analyzers versus manual method for WBCs measurement among Population of Wad Madani, Gezira State, Sudan**Tayseer Ibrahim Elsidigge<sup>1</sup>, Albadawi Abdelbagi Talha<sup>1</sup>, Mohammed Siddig Younis<sup>2</sup><sup>1</sup>Faculty of Medical Laboratories Sciences University of Gezira, Wad Madani, Sudan<sup>2</sup>Department of Medical Laboratory Technology, College of Medical Applied Science Taibah University, Almadina Almonawwarah, Saudi Arabia.**\*Corresponding author**

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**Abstract:** The automated hematology analyzer with complete blood count (CBC) results has replaced the traditional manual or individual assay methods for hematological parameters and the eye count leukocyte differential as the initial screening and detection system for hematological abnormalities in modern hospitals and clinics. Automated method for the estimation of complete blood count is commonly used in routine practice laboratory but many other labs still work on manual procedure for the abnormal automated results as well as health care workers in laboratory can be optimized by doing test on manual microscopic procedure as validation technique for automated method. This study carried out to compare the WBCs by different automated analyzers and manual method. Study carried out in Wad Madani city capital of Gezira State, central Sudan during the period of July to August 2016. The study included 75 healthy individuals selected randomly, 31 of them were males and 44 were females, their age ranges from 20 to 50 years who came for medical examination. Three mls of venous blood were collected from participants in EDTA anticoagulant. The samples were analyzed using haemocytometer, Sysmex XP-300 and Mindray BC-6800. The results showed that repeatability of white blood cells by chamber, mindray and sysmex were (5.1707, 5.0293, 4.9560), (5.8680, 5.8573, 5.8507) and (6.0093, 5.9800, 5.9627)  $\times 10^3/\mu\text{l}$  respectively, there was no significant different between the repeated result for manual and mindray but there was significant different by sysmex P.value (0.04). And when we compared the means+ SD of white blood cells by manual, mindray and sysmex were (5.0520 $\pm$ 1.6460), (5.8587 $\pm$ 1.7355) and (5.9840 $\pm$ 1.7130)  $\times 10^3/\mu\text{l}$  respectively, there was highly significant different by all three method P.value (0.001). Our study concluded that, there was no significant difference between repeatability of WBCs by manual and Mindray, significant difference between repeatability of WBCs by Sysmex and application of automated method is easier when there is load of work which takes less time.

**Keywords:** White blood cells, automated hematology Analyzers, Manual Method

**INTRODUCTION**

The average human adult has more than 5 liters of blood in his or her body. Blood carries oxygen and nutrients to living cells and takes away their waste products. It also delivers immune cells to fight infections and contains platelets that can form a plug in a damaged blood vessel to prevent blood loss [1]. The methods used to determine the WBC values are important since the assessment of white blood cells counts play an important role in diagnosis and treatment of patients. These require results that are reliable and accurate. In addition the WBC values provided valuable information about the blood and the bone marrow,

which is the blood forming tissue [2]. The WBC is used for the following purposes: to identify persons who may have inflammatory conditions particularly an infection, acute and chronic illness, blood diseases for example white blood cell disorders such as leukemia, effects of treatment and monitoring of treatment especially to determine the effects of chemotherapy and radiation therapy on blood cells [1, 3].

Hematology analyzer is an automatic instrument programmed to give an idea about the number of the blood cells through aspiration of a blood sample flow through an electric field. This method has

proved its value when used clinically in hospitals instead of the traditional manual method that depends on the visual counts of the blood cells, which takes time and effort [4].

Automated method for the estimation of complete blood count (white blood cells, hematocrit and hemoglobin etc.) is commonly used in routine practice laboratory but many other labs still work on manual procedure for the abnormal automated results as well as health care workers in laboratory can be optimized by doing test on manual microscopic procedure as validation technique for automated method [5]. The automated hematology analyzer with complete blood count (CBC) results has replaced the traditional manual or individual assay methods for hematological parameters and the eye count leucocyte differential as the initial screening and detection system for hematological abnormalities in modern hospitals and clinics [6]. No automated cell counter can equal the performance of manual differentiation for the presence of old results for leukocyte [7]. White blood cells (WBCs), also called leukocytes or leucocytes, are the cells of the immune system that are involved in protecting the body against both infectious disease and foreign invaders [8].

Quality assurance (QA) should include, besides internal quality control (IQC) and external quality assessment (EQA), all elements of its extended concept: these include clinical specimen handling, preservation, storage, transport, identification and data processing (including reporting of results, recording and charting, interpretation of results and feedback [9]. Internal quality control [IQC] ensures that factors determining the magnitude of uncertainty do not change during the routine use of an analytical method over long periods of time. IQC is conducted by inserting one or more control materials in to every run analysis. The control materials are treated by an analytical procedure identical to that performed on the test materials [10].

The precision and accuracy were highly dependent on the number of counted cells and at a reasonable level of effort, were subjected to fluctuations of up to 10%. [11]. External quality control [EQC] is

used to describe a method that allows for comparison of a laboratory testing to a source outside the laboratory. This comparison can be performance of a peer group of laboratories or to the performance of reference laboratory (ISO 5725-1:1994). This was an analytical cross sectional study aimed to assess diagnostic performance of manual, Sysmex and Mindray in measurement of WBCs in Wad Madani city, Gezira State- Sudan.

## MATERIALS AND METHODS

This was an analytical cross sectional study conducted on **75** Adults people selected randomly from July to August 2016 to assess diagnostic performance of manual, Sysmex and Mindray in measurement of WBCs in Wad Madani city, Gezira State- Sudan. Ethical approval was obtained from the ministry of health of Gezira state. The specimens and information were collected from individuals under privacy and confidentiality and were not used for any purposes rather than this study. Three (3) mls Venous blood were drawn from antecubital vein using aseptic technique using evacuated blood collection tube containing tri-potassium ethylene diamine tetra-acetic acid (K3EDTA) anti-co-coagulant and the tubes was labeled with an identification number. A sample of whole blood is mixed with glacial acetic acid, the diluted blood is added to the hemo cytometer chamber and WBC counting was done manually .The same sample was also measured by the automated analyzer Sysmex XP-300TM and Mindray BC-6800. The WBC values by manual method and automated method recorded. Data were analyzed by Microsoft Excel sheet, Medical Calculator computer program (MedCalc version16.8) and SPSS version16.

## RESULTS

75 subjects were enrolled in this study, 31 of them were males (47%), while 44 were females (53%), their age between (20-56) years. The study revealed there was no significant difference in repeatability of WBCs by Manual method Table 1, there was significant difference in repeatability of WBCs by Sysmex XP-300 P.value (0.044) Table 2. And no significant difference in repeatability of WBCs by Mindray Table 3s

**Table 1: Repeatability of White Blood Cell count using Manual method**

Factor	Mean	Std. Error	95% CI	P
Manual reading 1	5.1707	0.2137	4.7449 -5.5964	0.206
Manual reading 2	5.0293	0.2019	4.6271 - 5.4316	0.210
Manual reading 3	4.9560	0.1920	4.5734 -5.3386	0.210

**Table 2: Repeatability of White Blood Cell count using Sysmex XP-300**

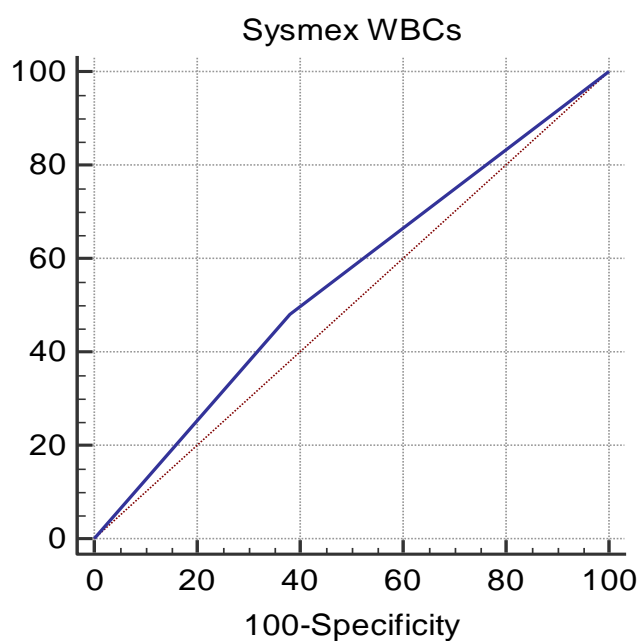
Factor	Mean	Std. Error	95% CI	P
Sysmex reading 1	6.0093	0.1993	5.6122 - 6.4065	0.044
Sysmex reading 2	5.9800	0.1974	5.5867 - 6.3733	0.044
Sysmex reading 3	5.9627	0.1976	5.5689 - 6.3564	0.044

**Table 3: Repeatability of White Blood Cell count using Mindray BC-6800**

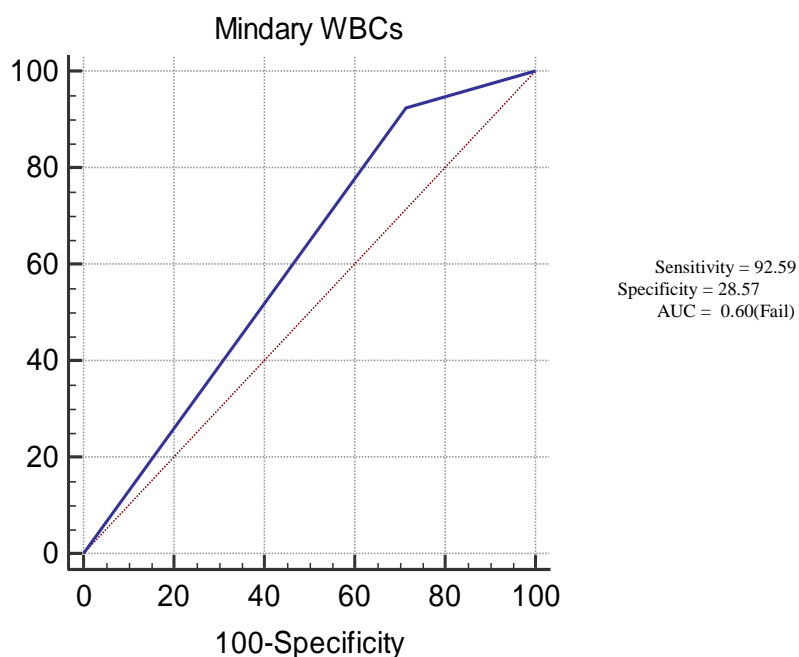
Factor	Mean	Std. Error	95% CI	P
Mindray reading 1	5.8680	0.1991	5.4713 - 6.2647	0.897
Mindray reading 2	5.8573	0.1982	5.4623 - 6.2523	0.797
Mindray reading 3	5.8507	0.2072	5.4378 - 6.2636	0.799

**Table 4 Correlation of White Blood Cell count between all methods**

Factor	Mean	Std. Error	95% CI	P
Mean_of_manual_method	5.0520	0.1901	4.6733 to 5.4307	<0.001
Mean_of_Sysmex_method	5.9840	0.1978	5.5899 to 6.3781	<0.001
Mean_of_Mindray_method	5.8587	0.2004	5.4594 to 6.2580	<0/001



**Fig 1: ROC analysis between manual method and Sysmex**



**Fig 2: ROC analysis between manual method and Mindray**

**DISCUSSION**

Automated peripheral blood, leukocyte counts are widely accepted in routine practice. However, many laboratories still reflexively perform manual CBC solely based on abnormal automated results or instruments “flags”, before any manual triage step, to established manual procedure for quality control [12].

The samples studied represented healthy subjects who were not suffering from any diseases, this study showed no significant differences in repeatability of WBCs by manual, sysmex and mindray except by sysmex P.value(0.04) (Tables 1, 2 and 3).The present study revealed that the means values of WBCs count that estimated by manual and automated method for all samples (n= 75) showed highly statistically significant difference P.value (<0.001) this correlated with the study done by Karem K *et al.*; and Ike S *et al.*; [13,14], in contrast to result reported by Babadoko *et al.*; [15], they showed no significant statistical difference between the mean total white cell estimated by automated and manual methods.

The white blood cell count in this study revealed significant positive correlation between three methods (Table 4) this indicates that the automated hematology analyzers (Sysmex XP-300) readings

correlated well with the manual methods. This is in agreement with result reported in other studies [13-16].

In this study when using Area Under the Curve (AUC), to test the sensitivity and specificity of automated versus manual method, the study indicated that Sysmex gave very low sensitivity when compared to manual (Figure 10) , this could be related to inability of Sysmex to give accurate total white blood cell count in low concentration. Like with, the specificity of Mindray is less than the recommended cut off value (70%) when compared to manual [Figure 2], this result was directly related to poorness of Mindray to differentiate between different classes of white blood cells, this finding is in contrast with report in previous studies [17,18], they reported that automated hematology instruments are more accurate in the detection of specimens with distributional or morphologic abnormalities than by the traditional eye count method.

**CONCLUSION:**

Our study shows there was no significant difference between repeatability of WBCs by manual and Mindray, significant difference between repeatability of WBCs by Sysmex XP-300 and there was significant positive correlation between manual and automated hematology analyzer Hematology

auto-analyzers can be used routinely in our laboratories to provide quick and accurate results.

#### ACKNOWLEDGMENTS:

Authors would like give my warmest thanks for all the participants and appreciate their role in this study.

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