

Performance Evaluation of Hematology Analyser Sysmex KX – 21 for Platelet and WBC Count

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Abstract

Objective: To evaluate the performance of Sysmex KX – 21 for the estimation of Platelet and WBC count in comparison with microscopy.

Study Design: It is prospective cohort study.

Place and Duration: It was conducted in the Pathology department, Allama Iqbal Medical College, from 7th Oct. 2009 to 6th Nov. 2009.

Materials and Methods: Out of the total 1500 samples, 1458 (97%) samples after exclusions were finally evaluated for the study. On each sample, automated blood cell count was performed using Sysmex KX – 21 and the results were compared by peripheral smear examination for Platelet count, WBC count and its differential. The samples were from Medicine, Pediatrics and Oncology wards only.

Results: Out of 1458 samples, WBC count of 1452 (99.5%) samples matched the total count on peripheral smear examination. 06 (0.5%) samples showed spurious WBC count due to the presence of nucleated

RBCs and lyse resistant RBCs (indicated by respective flags on Sysmex KX – 21). 262 (17.9%) samples missed differential count on automated analyser, due to low count or high count with immature cells and normal count with immature cells. Differential of rest of the 1196 (82.1%) samples also matched the manually done differential count. Regarding platelets, 1435 (98.4%) samples matched the platelet count on peripheral smear. 23 (1.6%) samples didn't correlate with the smear due to platelet clumps and fragmented RBCs (indicated by respective flags on Sysmex KX – 21).

Conclusion: Sysmex KX – 21 is a reliable automated analyser for total WBC and platelet count while re-evaluation by peripheral smear is only required for those samples where the automated analyser indicates with flagging.

- Non-toxic, biodegradable reagents.
- Reliable hardware and results.
- Network capability via your LIS.

Key words: Sysmex KX – 21, microscopy, WBC count, platelet count.

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Introduction

Traditionally, the blood counts were performed manually using the hemocytometers. The differential leukocyte counts were done by studying the peripheral blood smears (also referred to as the 100 – cell slide differential, eye count leukocyte differential or manual counts). For manual method, experience is needed to make technically adequate smears consistently. There is non-uniform distribution of red blood cells and

WBCs over the smear. It is subjective, time consuming, labor – intensive, and statistically unreliable (only 100 – 200 cells are counted).¹

The increasing workload experienced by many hematology laboratories coupled with the reduction in staff numbers lead to the introduction of automated hematology analysers. The automated hematology analyzer with complete blood count (CBC) results has replaced the traditional manual or individual assay methods for haematological parameters and the eye count leucocyte differential as the initial screening and detection system for haematological abnormalities in modern hospitals and clinics.² Cell counting with these instruments is rapid, objective, statistically significant (8000 or more cells are counted), and not subject to the distributional bias of the manual count. They are also more efficient and cost effective than the manual method. Some of these cell counters can process 120 – 150 samples per hour.¹

Sysmex KX – 21 is a discrete hematology analyzer designed for high – volume testing in clinical laboratories. It is an automatic multiparameter blood cell counter for in vitro diagnostic use in clinical laboratory. It employs impedance technology for counting of red and white cell and platelet count. It provides a CBC with 17 reportable parameters and 3-part WBC Differential, which includes an Absolute Neutrophil Count (ANC). The results include histograms for WBC, RBC and PLT. For the detection of hemoglobin, it uses cyanide free method that does not pollute the environment.³

Although it has adequate reproducibility, there are concerns over accuracy. It may produce cell counts which are falsely increased or decreased. Falsely low platelet count can be given by analyser due to platelet clumping. But these discrepancies are mostly indicated by ‘flags’ which are warnings generated and displayed by the machine to alert the laboratory personnel that the machine has detected some abnormality in cell population or distribution that needs attention. This study evaluated the performance evaluation of Sysmex kx – 21, comparing the results of WBC count, its differential and platelet count with and without flags on Sysmex kx – 21 with microscopy.

Material and Methods

This study was conducted in the Pathology Department of Allama Iqbal Medical College, Lahore from 7th October, 2009 to 6th November, 2009. It is a

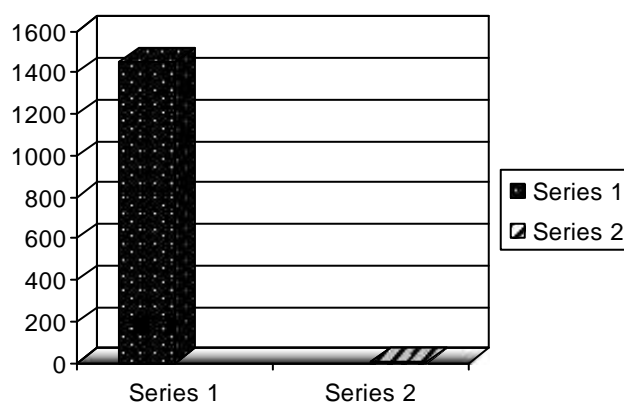
prospective cohort study. Routine samples from medicine, oncology and pediatric wards were received in EDTA vacuotainers and analyzed within 4 hours of receiving. Low volume, high volume and clotted samples were excluded from the study. CBC was performed using Sysmex KX – 21, that was maintained and calibrated as recommended by the manufacturer. Quality Control was maintained by running controls daily and maintaining Levey – Jenings Chart. Air dried blood smears were made, stained by Giemsa stain and examined under Microscope. Manual WBC Count was done by calculating estimation factor and then multiplying this estimation factor with average manual WBC Count per field. Manual Platelet Count was done by counting number of Platelets in 10 successive high power fields, calculating their average and multiplying it by 10.⁹ The data is presented as frequency tables, charts and graphs.

Results

A total of 1500 samples of CBC were received during this duration. Out of these, 1458 (97%) samples were processed and 42 (3%) were rejected. Among rejected samples, 20 (47%) were low volume, 10 (23%) were high volume and 12 (28%) samples were clotted.

The comparison of the WBC count of the samples processed by the two methods revealed that 1452 samples showed the same results while 06 samples showed discrepant results. This is shown by the figure 1.

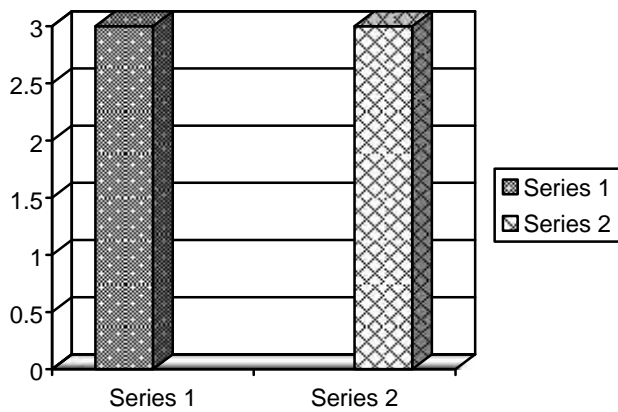
The peripheral smear of the samples showing discrepant results for WBC count revealed lyze resistant



Series 1: No. of samples with same results n = 1452 (99.5%)
Series 2: No. of samples with same results n = 06 (0.5%)

Figure 1: WBC Count Estimation.

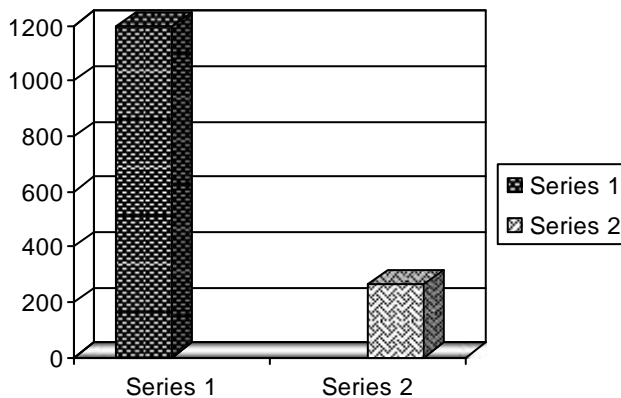
RBCs and nucleated RBCs in 03 samples each as shown in figure 2.



Series 1: Lyze - 1 Resistant RBC's, n = 03 (50%)
Series 2: Nucleated RBC's, n = 03 (50%)

Figure 2: Reason for Discrepant Results.

When the differential count estimation was done, it was found that the sysmex gave the differential of about 1196 samples while it missed the differential of about 262 samples. It is shown in figure 3.



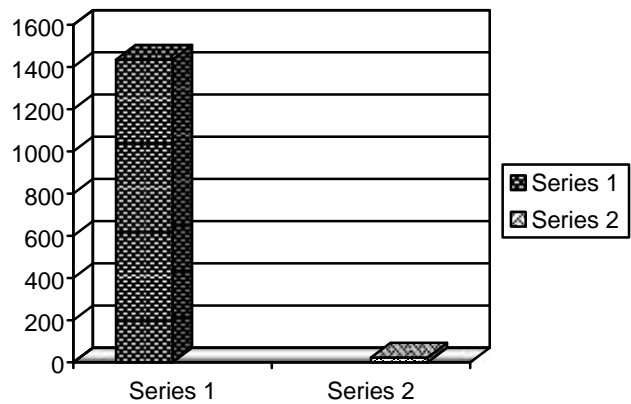
Series 1: Differential given by Sysmex n = 1196 (82.1%)
Series 2: Differential not given by Sysmex n = 262 (17.9%)

Figure 3: Differential by Sysmex KX - 21.

Correlation of the differential count given by sysmex kx - 21 and peripheral smears showed the following results (Table 1).

The sysmex missed the differential of about 262 samples due to following reasons (Table 2).

The comparison of the platelet count of the samples processed by the two methods revealed that 1435 samples showed the same results while 23 samples showed discrepant results as shown in figure 4.



Series 1: No. of Samples with Same Results
n = 1435 (98.4%)
Series 2: No. of Samples with Disc repant Results
n = 23 (1.6%)

Figure 4: Platelet Count Estimation.

Out of these 23, 17 samples showed platelet clumping while 06 samples showed fragmented RBCs on peripheral smear (Table 3).

Discussion

In WBC count estimation, 99.5% samples correlated well with manual WBC Count. Ike et al described that the two methods of WBC counting correlated positively.² 0.5% of the samples showed discrepant results due to lyze resistant RBCs and nucleated RBCs indicated by respective flags on Sysmex. Hanse et al described that the correlation between the automated flagged

Table 1: Correlation of differential Count between Sysmex and Smear.

Total No. of Differential Given by Sysmex	No. of Smears correlating with Sysmex	No. of Smears not correlating with Sysmex
1196	1186 (99.1%)	10 (0.9%)

Table 2: Causes of Missing differential Counts.

Total Samples	Low WBC Count	Low WBC Count with Abnormal cells	Normal WBC Count with Abnormal cells	High WBC Count with Abnormal cells	Old Samples
262	122 (46.5%)	09 (3.4%)	38 (14.5%)	68 (25.9%)	25 (9.5%)

Table 3: Causes of Discrepancy in Platelet Count.

Total Samples	Platelet Clumping	Fragmented RBCs
23	17 (73.9%)	06 (26.1%)

and manual results was excellent.⁴

Differential count given by Sysmex KX – 21 also showed very good correlation (99.1%) with the manually done differential. 0.9% of the samples showed discrepancy related to mixed cell population. Povall et al showed a strong correlation of DM₉₆ and manual methods with the Sysmex data for the neutrophil, lymphocyte and eosinophil count. However, monocytes are correlated less well.⁵

17.9% samples missed differential due to markedly low WBC Count and also due to the presence of abnormal cells, again indicated by the flagging system. According to Ike et al, the automated analyser misses differential because of the inability of the instrument to identify immature cells.² Martin S. described that these analyzers have been developed to perform automated differential counts but they are still inferior to manual techniques as far as reliability and ability to discover abnormal cells is concerned.⁷ These analysers are able to provide much more information about WBCs, both quantitative and qualitative. The latter is represented by flags that indicate technical problems e.g malfunction, analytic interference and above all, presence of cells like blasts, atypical lymphocytes, immature granulocytes and nucleated RBCs.⁵

Platelet count of 98.4% samples correlated with the peripheral smear. 1.6% samples showed discrepant results due to platelet clumps and fragmented RBCs (Indicated by respective flags). Molok et al described that manually done platelet count showed no statistical difference in mean from the automated platelet count except for those samples that showed flags on Sysmex.⁸ According to Ike et al, the platelet count by the two methods, i.e, manual and automated correlated positively.² Cohan et al described that pseudothrombocytopenia should be considered in the assessment of low platelet count. Microscopic examination of blood

smear may avoid erroneous diagnosis of thrombocytopenia.⁹ Nishiyama M et al described fragmented red cells as the major cause of spuriously high platelet count.¹⁰

Conclusion

The results of the present study confirm that counting performance by Sysmex KX – 21 is robust and clinically useful. Sysmex KX – 21 is a reliable automated analyzer for total WBC Count, its differential and Platelet count. But for the automation to be effective, the controls should be run daily and the results of the control should be precise and accurate. KX – 21 also saves time and requires less labour as verification by peripheral smear is required only for those samples that are indicated by flagging.

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