ADDIS ABABA UNIVERSITY

SCHOOL OF GRADUATES STUDIES

COLLEGE OF HEALTH SCIENCES

COMPARISON OF HEMATOLOGICAL PARAMETERS DETERMINED BY SYSMEX XT-2000I AND CELL DYN 1800 IN TIKUR ANBESSA SPECIALIZED HOSPITAL IN ADDIS ABABA ETHIOPIA

A thesis submitted to school of graduate studies, Addis Ababa University, in partial fulfillment of the requirements for Degree of Master of Science in Clinical laboratory Science

BY

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COMPARISON OF HEMATOLOGICAL PARAMETERS DETERMINED BY SYSMEX XT-2000I AND CELL DYN 1800 IN TIKUR ANBESSA SPECIALIZED HOSPITAL IN ADDIS ABABA ETHIOPIA

A cross sectional study

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List of Acronyms

Baso	Basophil
CBC	Complete Blood Count
CLSI	Clinical and Laboratory Standards Institute
CML	Chronic myelocytic leukemia
CV	Coefficient of Variance
DC	Direct current
Diff	Differential white cell count
DLC	Differential Leukocyte Count
FCM	Flowcytometry
EDTA	Ethylene di amine tetra acetate
Eos	Eosinophil
FDA	Food and Drug Administration
HB	Hemoglobin
HCT	Hematocrit
ICSH	International Committee for Standardization in hematology
IRB	Institutional Review Board
Lym	Lymphocyte
MCH	Mean Cell Hemoglobin
MCHC	Mean Cell Hemoglobin Concentration
MCV	Mean Cell Volume
MPV	Mean Platelet volume
Mon	Monocyte
Neu	Neutrophil
PLT	Platelet
RBC	Red Blood Cell
RDW	Red cell Distribution Width
RET	Reticulocyte
SD	Standard Deviation
SLS	Sodium lauryl sulfate
SSC	Side scatters

1. Introduction

1.1 background

Automated analyzers bring one step change to hematological findings. The first automated analyzer was introduced in 1956 by Wallace coulter. The complete blood count (CBC) and differential leukocyte count (DLC) provide valuable information about the blood, used for diagnose of different diseases including; anemia, leukemia and bleeding tendencies (1). Automated hematology analyzers provide several parameters and they incorporate flowcytometry and new system technologies. Since these analyzers are very basic for a hospital, there must be a good comparison of results from different analyzers in the decision making process when selecting analyzer (2).

After selection of new hematology analyzer each Laboratory must compare the new method with the one currently in use to see whether their measurements are indeed comparable. (3).When comparing the new and the reference method there are statistical approaches to compare their performance. This analysis consists of paired measurements by the two methods and testing for the agreement of two analytical methods (4). Now days there are many hematological analyzers from many companies in different countries, including Ethiopia. In this study we compare sysmex XT-2000i and Cell dyne 1800 hematology analyzers in one of the largest tertiary care referral and teaching hospital of Ethiopia.

Cell-Dyn 1800 is an automated, multi parameter hematology analyzer built with an open sampling section. The Cell-Dyn 1800 is designed to automatically perform the following functions; Aspirate and dilute whole blood, Count, size, and classify cells present in a whole blood specimen, Analyze raw data collected and Output results to the display on printer. It generated flags (alerts or warnings) resulting from; Measured parameters outside pre-defined limits, Sample abnormality, Interference in the measurement process and Detection of an abnormal sub population. It performs a Complete Blood Count (CBC), Platelet Count, and a Three-Part Differential (5).

Cell-Dyn 1800 uses two independent measurement methods; they are Electrical Impedance Method for determining WBC, RBC, PLT data and Modified Met hemoglobin Method for determining HGB. During each instrument cycle, the sample is aspirated, diluted, and mixed

before each parameter is measured. The sample used is a Whole blood collected in an EDTA tube. Minimum sample volume is 0.5 mL using the Open Sample Mode. The instrument aspirates 30 μL of patient sample (5).

The automated hematology analyzer, sysmex XT-2000i, is the fully automated hematology analyzer manufactured by Sysmex Corporation, founded in Kobe, Japan in 1968 as a company specializing in hematology (6). According to a study in China, Sysmex ranks second in the global market (17%) following Mindray (40%) and Abbott ranks around (4%) in 2009 (7).

Sysmex XT-2000i is capable of performing the differentiation of 5 white blood cell types and it provides 30 parameters for anticoagulated blood samples. The anticoagulants to be used are EDTA-2K, EDTA-3K and EDTA-2Na. A hydrodynamic focusing DC detection is used for the measurement of RBC and PLT. HGB is measured using SLS-HGB, a cyanide-free method; it is the sum of all the RBC size measurements and reported in proportion to the total volume of the analysis sample (8). It uses Fluorescence flowcytometry to measure WBC, Diff, the optical PLT count, and reticulocyte count. Fluorescence and scatter measurements are combined to characterize white cell populations. Basophiles are measured separately using cell size and SSC properties. By combining conventional and new technologies, XT-2000i realized a compact, high performance and high accuracy instrument (9).

Sysmex xt-2000i hematology analyzer was evaluated to determine analytical performance and workflow efficiency with CELL-DYN Ruby, in Netherlands. Systematic biases were found for mean cell volume, reticulocyte, platelets and mean platelet volume (10). However, there are only few method comparisons performed on sysmex and CELL-DYN; thus this study aims to evaluate the agreement between the two hematological instruments because now a day's both Sysmex and CELL-DYN are used interchangeably in our country.

1.2. Statement of the problem

Several hematological analyzers are found both in public and private health facilities in Ethiopia. Some of the facilities even have more than one type of analyzer and use results from both interchangeably without documented evaluation of the newly introduced machine against the existing one. Moreover, different results are obtained from different laboratories. Tikur Anbessa Specialized Hospital, the largest teaching and referral hospital of the country has different models of hematology analyzers. The hospital being referral center for different cases including hematological malignancies uses Sysmex and celldyn1800 interchangeably. While for example patients with Chronic myelocytic leukemia receiving GLIVEC need to be monitored seriously even to discontinue treatment if patients develop severe thrombocytopenia and leucopenia. Thus, it is very important to evaluate Sysmex against the existing cell dine and manual for different hematology populations and document data for using available hematology analyzers interchangeably.

1.3 Literature Review

Although Sysmex automated hematology analyzers are relatively introduced late in the global market, several method evaluation studies have been carried out in the earlier automated analyzers. For example, Sysmex XT-2000i automated hematology analyzer was evaluated at Saint Louis children's Hospital in USA by Langford K et al. CBC result from the sysmex XT-2000i was compared to the results from sysmex XE-2100 for 114 patient samples. Manual differentials, Carryover, precession, linearity, correlation and stability studies were also performed. The sysmex XT-2000i results showed excellent correlation with the results from the sysmex XE-2100 for the following parameters; WBCs, RBCs, HGB, HCT, MCH, MCHC, RDW by standard deviation, RDW by coefficient of variation, MPV, platelets, percent neutrophil, lymphocytes, monocytes, and basophiles; and Reticulocyte percent and absolute number. XT-2000*i* demonstrated comparable analytical performance to its predecessor, the XE-2100 (11).

Another study was done by Leers et al to evaluate and determine the analytical performance and workflow efficiency of two mid-range hematology analyzers; Abbott CELL-DYN Ruby and Sysmex XT-2000i. It was performed in the Netherlands. Total sample of 418 were processed for determining equivalence of CBC measurements, and 100 for Reticulocyte comparison. Blood smears served for assessing the agreement of the differential counts. Systematic biases were found for MCV, Reticulocyte, platelets and MPV. WBC subpopulation counts were in good agreement with no major outliers. Following first-pass CBC/differential analysis, 88 (21%) of XT-2000i samples required further analyzer processing compared to 18 (4.3%) for the CELL-DYN Ruby. Smear referrals for suspected WBC/nucleated red blood cells and platelet abnormalities were indicated for 106 (25.4%) and 95 (22.7%) of the XT-2000i and CELL-DYN Ruby samples respectively (10).

In Belgium a study was conducted by Ghys et al (2008) to evaluate, Sysmex XS-1000i instrument according to CLSI and ICSH guidelines. Precision, carry-over and linearity were determined using a total of 700 patient samples, results from the Sysmex XS-1000i were compared with those from a Sysmex XE-2100, an Abbott Cell Dyn 4000 and the manual reference leukocyte differential. Using quality control material, total and within-run imprecision was less than 3% except for platelets. The system demonstrated good linearity over the entire reporting range and no carry-over (<0.5%). The Sysmex XS- 1000i showed good correlation

with XE-2100, CD-4000 and the manual reference leukocyte differential. Overall flagging sensitivity and specificity were 91% and 48%, respectively. Sysmex XS-1000i demonstrated good analytical performance and it is able to generate a complete blood count with five-part differential on low blood volumes and has considerable back-up capacity (12).

Studies have documented results of evaluation of Mindray automated analyzers against other machines. In Korea a study was done by Jo et al to evaluate Mindray BC-6800 (Mindray, China). In this study, they evaluated the performance of the BC-6800 for CBC, WBC differentials, Reticulocyte counts, erythroblast counts and analyzed the efficiency of its flag system. Specimens from 100 healthy controls and 95 patients were used. The precision were <2% for most CBC parameters and <5% for neutrophil, eosinophil, and Reticulocyte counts. The results obtained using the BC-6800 were well correlated with those of the ADVIA 2120 (Siemens, USA) and LH 750 (Beckman Coulter Corporation, USA). R were >0.9800 for CBC. In which R was >0.9500 for WBC differentials. The efficiencies of the flag system were 77.9% for Blasts, 82.1% for Immature Gran, 86.3% for Atypical Lymph, and 92.6% for NRBC present. (13).

A study was done in peking university hospital, Beijing, china in 2013 by Qiao et al, to verify the performance of automated hematology analyzers LH750, BC 5800 and XE-2100 in clinical laboratories. They use a total of 15 fresh whole blood specimens R values of WBC, RBC, Hgb, HCT and PLT of each analyzer were 0.953-0.998. However, R values of MCV of each analyzer were 0.751-0.821. Except platelet of XE-2100, the other parameters of each analyzer showed that the 95% confidence intervals of slope include the value 1, and the 95% confidence intervals of y intercepts included the value 0. Except platelet inter day precision of BC-5800, the intraday and inter day precision of the other analyzer complied with specification of each analyzer. Analytical measuring intervals of WBC and PLT of LH750 and BC- 5800 were wider than those of XE-2100. The performance verification of XE-2100, LH750 and BC 5800 shows roughly satisfactory results (14).

A study was done by Penig et al to evaluate sysmex SE-9500 in West China University, Sichuan, China in 2001. The results demonstrated minimal carryover <0.01% and excellent linearity for WBC, RBC, HGB and PLT i.e., r> 0.995. Samples were stable with regard to CBC parameters

after storage for up to 48hr at room temperature and 4^0c. Imprecision was generally acceptable for all CBC parameters (CV < 5%). Correlation between the SE-9500 and reference methods (manual method and CD42a flowcytometry for plt, 200-cell manual DC for differential) was excellent (r> 0.97) for all the major CBC parameters (WBC, RBC, HGB, and PLT). There was minimal interference for WBC, HGB, and PLT at high concentrations of billirubin (BIL=224M mol/L) or triglyceride (TG= 7.78 m mol/L) (15).

Another hospital based study was done to evaluate the performances of Mindray BC-5500 hematology analyze by Qing-jun et al in China. The performance of BC-5500 hematology analyzer was evaluated in regards to precision, carry-over rate, linearity. In addition, the correlation of results generated by the BC-5500 and the Sysmex XE-2100 hematology analyzer was compared. The within-and between-Batch precision and that of the total precision of BC-5500 were all within the designed range. The carry-over rate was lower than 0.5%. The linearity was good. The correlation between the Sysmex XE-2100 hematology analyzer was satisfactory (r=0.99) (16).

A recent study in a university hospital in china evaluated and compared the Mindray BC-3600 with BC-3200 3-part differential (BC-3200) and Sysmex XE-2100 5-part differential (XE-2100) hematology analyzer. They found that there were no background, minimal carryover (<0.5%), and excellent linearity for white blood cell, hemoglobin level, red blood cell, and platelet counts (r > 0.999). Precision was good at all levels for the routine blood cell count parameters: CV% being ≤2.0, except for platelet count (PLT) at the low level with CV% of ≤5.0% and WBC at the low level with CV% of <3.0%. Correlations between the BC-3600 and BC-3200, XE-2100 were excellent (r > 0.99) for all major CBC parameters (17).

As shown in the above literature there are many researches done on the evaluation performance of different models of Sysmex hematology analyzer demonstrating good agreements. However, little is known about the comparison between existed sysmex XT-2000i and Celldyn1800 in developing countries like Ethiopia.

1.4 Significance of the study

In our country there are no studies regarding method comparison of hematological analyzer like Sysmex XT-2000i and Cell Dyn1800. But now days most of hematology laboratories start using these analyzers interchangeably. It is known that Tikur Anbessa specialized hospital is the largest general public hospital and one of the university hospitals in the country. It offers for approximately 370,000 – 400, 000 patients per year.

And also there are many patients that have follow up in the hematology unit. So providing a quality service in this hospital assures health of peoples. This paper is done to see agreement between two hematology analyzers being used by the hospital with no prior validation study in order to recommend corrective actions if there is any difference and to recommend other studies based on the result. Thus, the study will help to ensure that change in instrument for any reason including break down and reagent shortage will not influence hematological profiles during follow up visits. The finding will also help to enhance physicians trust on hematology laboratory results. The finding can be used as a reference for other laboratories having similar analyzers, and hence facilitate inter-laboratory comparisons.

1.5 Hypothesis

It is hypothesized that there will be significant difference between hematological results between Sysmex XT-2000i and Cell Dyn1800 hematology analyzers.

2. Objective of the study

2.1. General objective

- To compare hematological parameters determined by sysmex XT-2000i and Cell-Dyn 1800 hematological analyzers in Tikur Anbessa specialized hospital, Addis Ababa

2.2. Specific objective

- To determine the agreement between hematological parameters determined by Cell Dyn1800 and Sysmex XT-2000i
- To determine the agreement between sysmex and manual differential count.

3. Materials and Methods

3.1 Study design

A hospital based cross sectional study was conducted at Tikur Anbessa Specialized hospital starting from December up to May 2014.

3.2 Study Area

This study was conducted at Tikur Anbessa Specialized hospital. This hospital was selected because two hematology analyzers (Sysmex XT-2000i and Cell dyn1800) are found; there are more cancer patients as a result variety of results can obtained, in addition approximately from two hundred fifty up to three hundred samples per day comes to hematology laboratory for different investigations.

It is located in the nation's capital Addis Ababa and Ethiopia's largest general public hospital in the country. In 1998 Tikur Anbessa Hospital, which is the largest referral hospital in the country was given to Addis Ababa University by the Ministry of Health the faculty as a main teaching hospital. The faculty is the oldest and the largest among the health training institutions in the country, staffed with the most senior specialists. The hospital provides a tertiary level referral treatment and is open 24 hours for emergency services. It is administered by Addis Ababa University, is the largest and oldest teaching hospital among all in Ethiopia, providing teaching for about 300 medical students and 350 Residents every year.

Black Lion hospital offers diagnosis and treatment for approximately 370,000- 400,000 patients a year. The hospital has 800 beds, with 130 specialists, 50 non-teaching doctors. The emergency department sees around 80,000 patients a year.

3.3 Study Variable

3.3.1 Dependent variable

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, PDW, MPV, PCT

3.3.2 Independent variable

Sysmex XT- 2000i, cell dyn1800

3.4 sample size

Based on CLSI or Clinical and Laboratory science institute 2011 guideline; a total of sixty samples in duplicates were taken for each analyzer.

3.5population

3.5.1 Source population

Samples that come to Tikur Anbessa specialized hospital laboratory from December to May 2014 were the source population for this study.

3.5.2 Study population

Actual study population includes blood samples that came to Tikur Anbessa specialized hospital laboratory for different investigations on specified days.

3.6 Eligibility criteria

3.6.1 Inclusion criteria

Samples that were in acceptable criteria was included in the study.

3.7 data collection and processing

3.7.1 Sample collection

Five ml blood was collected into EDTA vaccutainer tubes by phlebotomists at Tikur Anbessa hospital with the use of Standard operating procedure. It was transported to the laboratory as early as possible. Samples or study units selected conveniently from total samples.

3.7.2 Sample processing

The collected samples complete blood count analyzed on Hematology analyzers i.e., Sysmex XT-2000i and Cell Dyn 1800 by senior laboratory technologists that work in hematology department. Manual differentials were performed on each specimen by 2 experienced medical technologists. To prevent and control the bias the outlier samples run repeatedly. To maintain the quality of this method high, medium and low quality control materials run.

3.7.3 Principle of sysmex XT-2000i Hematology analyzer

The Sysmex XT-2000*i* Automated Hematology Analyzer utilizes the power of fluorescent flowcytometry and hydrodynamic focusing technologies. Using a unique diode laser bench, Sysmex fluorescent flowcytometry provides the sensitivity needed for measuring and

differentiating cell types in whole blood and body fluid samples. Fluorescent flow technology and hydrodynamic focusing enable the XT-2000*i* to consistently classify normal WBC, RBC and PLT populations form abnormal populations, thereby decreasing the number of manual interventions. XT-2000*i* technology provides clinically relevant and reportable parameters.

RBCs and platelets are counted using the direct current detection method with hydrodynamic focusing technology to minimize coincidence or recirculation. The intensity of the electronic pulse from each analyzed RBC is proportional to the cell volume. The HCT is directly determined based on the count and volume detection of each individual RBC.

The Sysmex sodium lauryl sulfate (SLS) method for hemoglobin analysis is a non-cyanide method. Hemoglobin is determined in a separate channel, minimizing interference from high leukocyte concentrations. The combination of side scatter (inner complexity of the cell), forward scatter (volume) and fluorescence of nucleic acid material determines the classification of each WBC. Fluorescent technology is also used to offer efficient and reproducible analysis of the reticulocyte count and maturation stages. The advanced technology allows an accurate count of reticulocyte and fluorescent platelets, even in extremely low concentrations and in samples with giant platelets or red cell fragments.

3.7.4 Principle of Cell-Dyn 1800 Hematology Analyzer

The Cell-Dyn 1800 Hematology Analyzer performs a Complete Blood Count (CBC), Platelet Count, and a Three-Part Differential. Whole blood is aspirated, diluted, and then divided into two samples. One sample is used to analyze the red blood cells and platelets while the second sample is used to analyze the white blood cells and hemoglobin.

Electrical impedance is used to count the white blood cells, red blood cells, and platelets as they pass through an aperture. As each cell is drawn through the aperture, a change in electrical resistance occurs generating a voltage pulse. The number of pulses during a cycle corresponds to the number of cells counted. The amplitude of each pulse is directly proportional to the cell volume. Lyse reagent is added to the diluted sample and used to count the white blood cells. After the white blood cells have been counted and sized, the remainder of the lysed dilution is transferred to the Hgb Flow Cell to measure Hemoglobin concentration.

The Cell-Dyn uses electronic sizing to determine a three part automated differential. The percentage and absolute counts are determined for lymphocytes, neutrophil, and mid-size population of monocytes, basophils, eosinophils, blasts, and other immature cells.

3.8 Quality assurance

Standard quality control protocols were performed daily. All instruments were operated according to the manufacturer's instructions. Three quality control materials i.e. high, normal and low quality control materials run before every work for each analyzer. No analysis was done if controls were out of range.

3.9 Data analysis and interpretation

Data entered and analyzed using SPSS version 20. The Pearson's correlation coefficient and the Bland Altman plot used to determine agreement between the two methods.

In the Bland Altman method the differences in hematological parameters between the test and existing method plotted against mean values. Agreement considered acceptable when the difference is lying between mean $\pm$ two standard deviation (Mean$\pm$1.96SD) for 95% and above of cases. P-Values < 0.05 considered statistically significant.

3. 10 Operational definitions

Differential count - Determination of the proportion of the various types of WBCs, it includes both normal and abnormal.

Correlation coefficient - A statistic that indicates the degree to which two measurements are related, expressed as a value from -1.0 to +1.0, with +1.0 indicating that results are in total agreement, and -1.0 indicating that results are exact opposites (i.e., 4 and -4). A 0.0 value indicates that the two measurements are unrelated.

Reference method - it is the current method of analysis, although the current method may not be the best.

The test method – it is the new method that we want to compare with the existing one.

Bias - the difference between the expectation of the test result and a true value.

Trueness- the closeness of the agreement between the average value obtained from a large series of test results and an accepted reference value. The measure of trueness is usually expressed in terms of bias.

Carry over – Carryover is the interaction of the previous sample with the current sample. High to low carryover checks to verify the high results of one sample do not affect the low results of the next sample Carryover is determined by running specimens with elevated concentrations of WBCs, RBCs, HGB, and PLTs. Each specimen is run in triplicate followed by three11 background cycles.

Acceptable criteria of samples – proper amount with right labeling and non heamoyzed sample.

Flags- Written or displayed output intended to signal or attract attention. Flags are generated by the instrument to alert the Operator to instrument malfunctions that occur during sample processing, or to data abnormalities detected during data analysis.

Random error - Variation, with no distinct pattern, between successive analysis process data. It is assumed to be a normal (Gaussian) distribution around a mean.

Systematic error - Directional or patterned variation between values obtained and the values expected.

Linearity - The measure of the degree to which a curve approximates a straight line.

Parameter - A term used in reference to the various tests performed by a hematology analyzer.

Precession - The degree of agreement in the results of a set of replicate or paired (duplicate) measurements. Precision has no absolute numerical value. It is expressed as imprecision, which is a standard deviation or coefficient of variation.

Slope - Represents a proportional systematic error. If both methods are in agreement, the slope will be 1.0. A slope of 1.0 ± 0.05 is considered acceptable agreement.

Y-intercept - A representation of constant systematic error. The interpretation depends on the substance being measured. A perfect correlation of two methods will give a Y- intercept value of 0.The lower the number, the better the correlation.

3.11 Ethical consideration

Before the research work, ethical clearance will be obtained from the Institutional Review Board (IRB) of department of Medical Laboratory Sciences, College of Health Science, Addis Abba University. Permission letter will be written to the hospital management. Leftover blood sample collected for routine examination will be utilized and no additional sample will be collected for the purpose of this study. Informed consent will be obtained from patients. Samples will be coded and confidentiality of patient data will be maintained throughout the study.

3. 12 Dissemination of result

This paper will be submitted to school of Medical laboratory technology, Addis Ababa University. So it can serve as a reference in the library. The data will primarily be communicated to Tikur Anbessa Specialized hospital for appropriate action. In addition, a copy of this material will be given to, Ministry of Health, Addis Ababa Health Bureau, and respective hospitals that uses the same hematology analyzer at the same time. This result will also be disseminated through publication in peer reviewed local and international journals and through presenting it in relevant workshops and seminars.

4. Result

Total samples involved in this study were 60 samples from patients at Tikur Anbessa Specialized Hospital. The sample was heterogeneous having low, normal and high values. From a total of 60 samples; 27 (45 %) were females and 33 (55 %) were males. Their age ranges from 2-80 (mean 37.05).

Table1. Sex distribution of the samples

sex

	Frequency	Percent
f	27	45.0
m	33	55.0
Total	60	100.0

From a total of 60 samples for WBC, cell Dyn has a mean value of 11.07 and Sysmex XT 2000i has a mean value of 11.21. They have a common mean value of 11.14 and SD value of 18.6.they have correlation r, value of 0.99 and regression on equation of y=1.01x+0.02.rfom all this results it's found that the results obtained from cell Dyne and sysmex have a good correlation for WBC . Figure one and two shows the results of WBC.

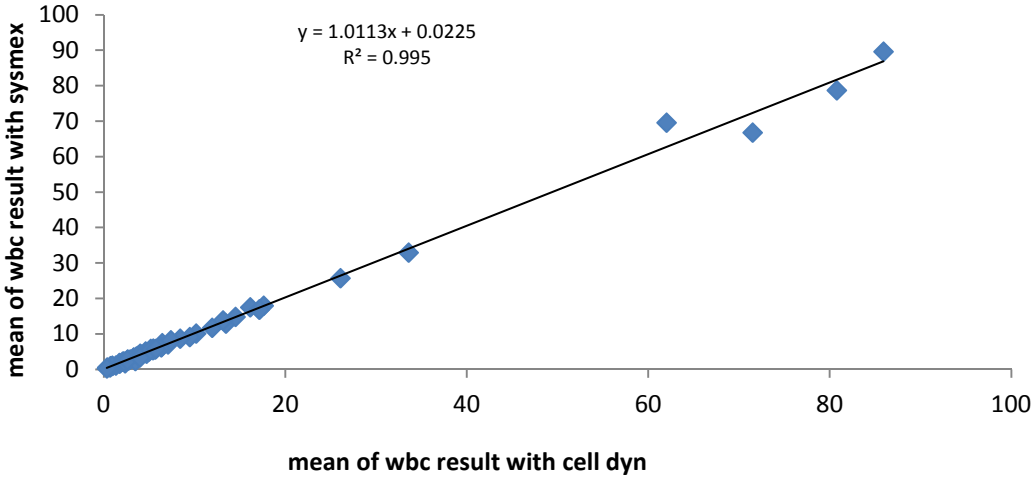


Figure 1 mean of WBC result of Sysmex Vs Cell Dyn

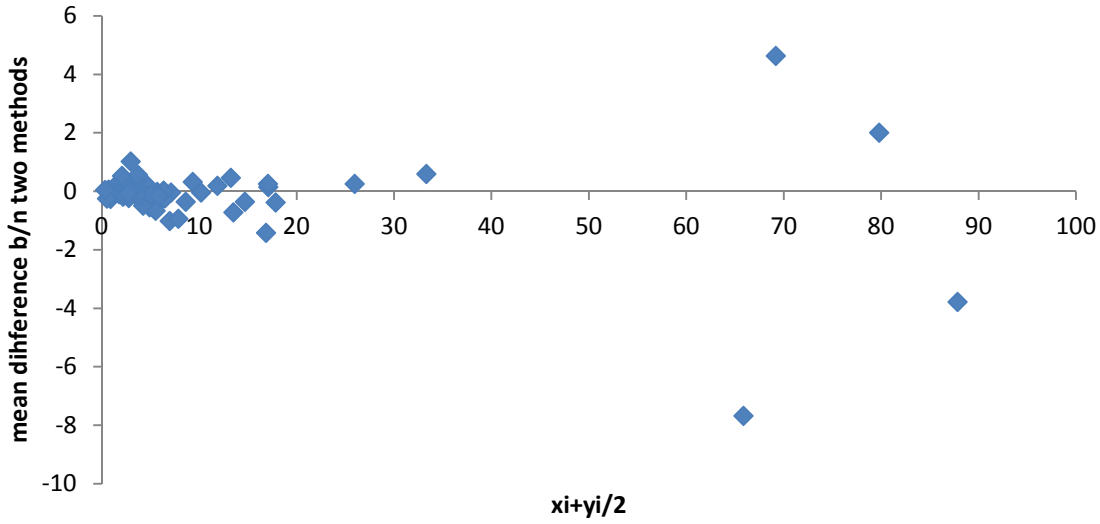


Figure2 difference plot for WBC

For RBC parameters also Cell Dyn 1800 has a mean value of 4.8 and Sysmex XT2000i has a mean value of 3.97. They have common mean value, SD and correlation value of respectively; 4.08, 1.25 and 0.92. Its regression of y=0.94x + 0.022 from this equation we get that they have a very good correlation for RBC count.

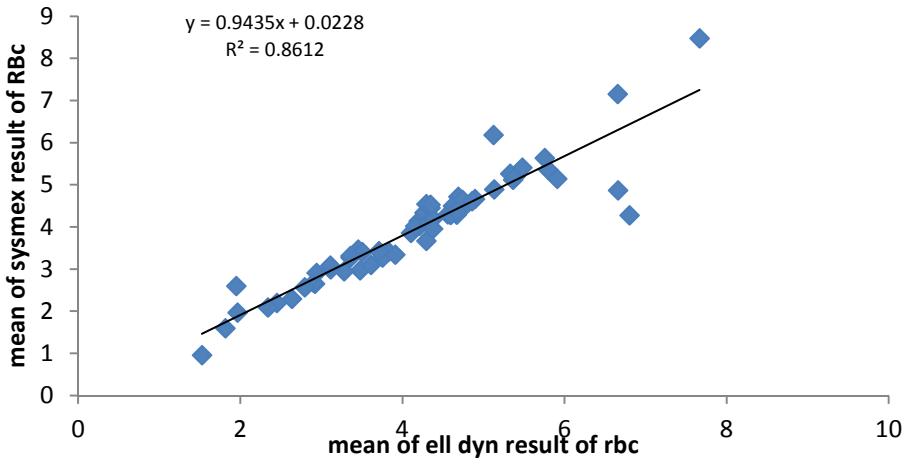


Figure 3 mean of RBC results with Sysmex Vs Cell Dyn

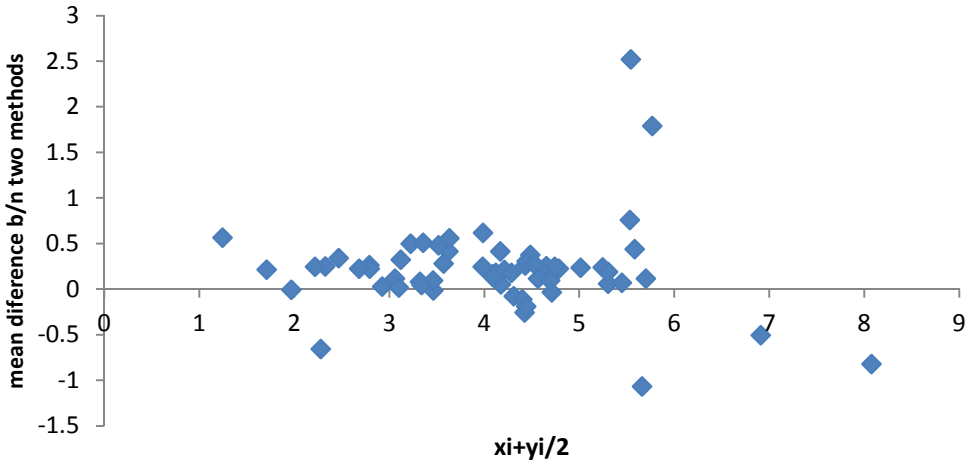


Figure 4 difference plots for RBC

For HGB the values have a good correlation having r values of 0.9557 and a regression equation y= 0.96x + 0.37.the results have mean value of 11.45 and SD of 2.99 by which 95% of the results are found within the limit of 11.45+or- 2*2.99. The mean value of the 60 sample for Cell Dyn was 11.44g/dl and for Sysmex XT2000i it has a value of 11.46g/dl.

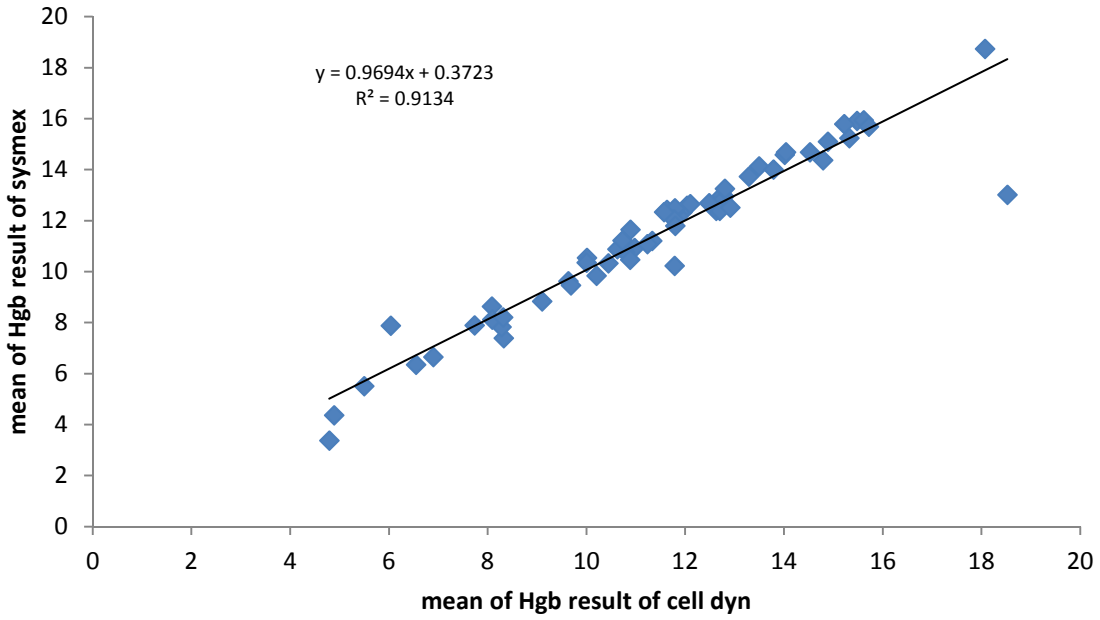


Figure 5 mean of Hgb result of Sysmex Vs Cell Dyn

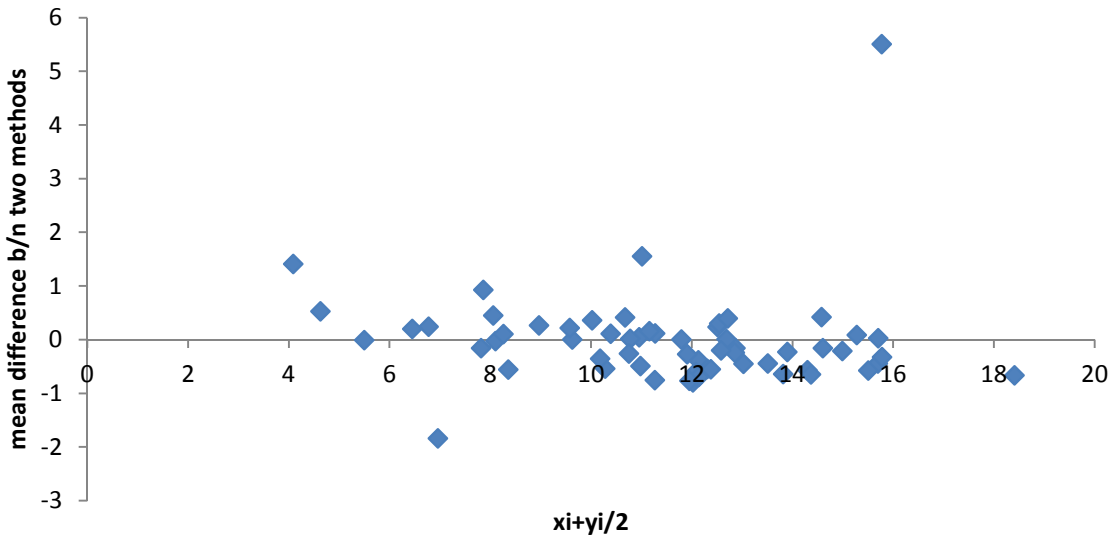


Figure 6 difference plots for Hgb

For HCT the analyzers have a correlation value of r= 0.975. This value indicates that the two have a good agreement for the sixty samples. They have a regression equation of y=0.97x-0.53. It has slope of 0.97 which tells us the proportional systematic error .and a constant systematic error of -0.53 including good correlation of the two methods. Cell Dyn have a mean value of 36.28. Sysmex has a mean value of 34.75 and SD of 8.77. The mean of the two methods is 35.51. And most results are found in the 2SD limit value.

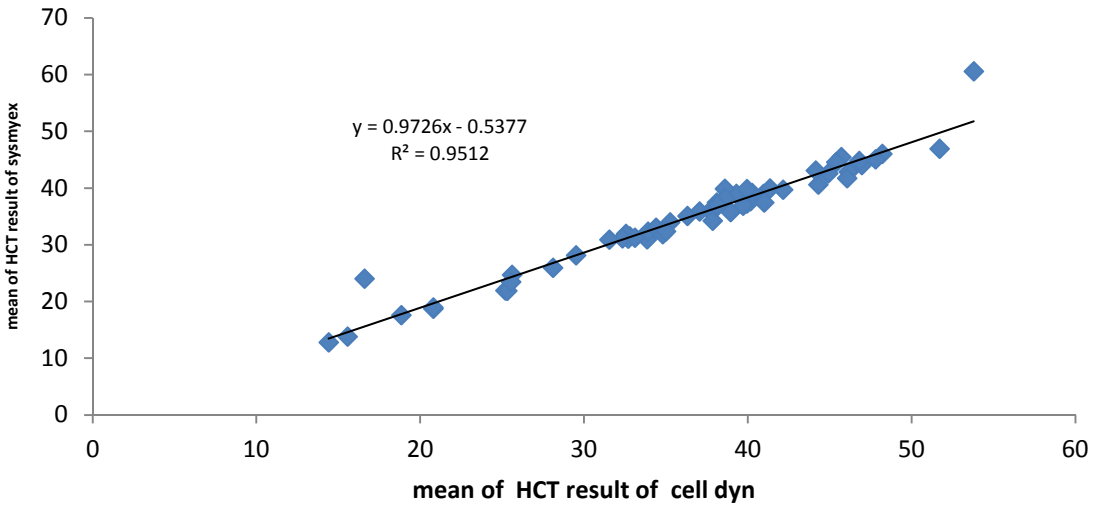


Figure 7 mean of HCT result of Sysmex Vs Cell Dyn

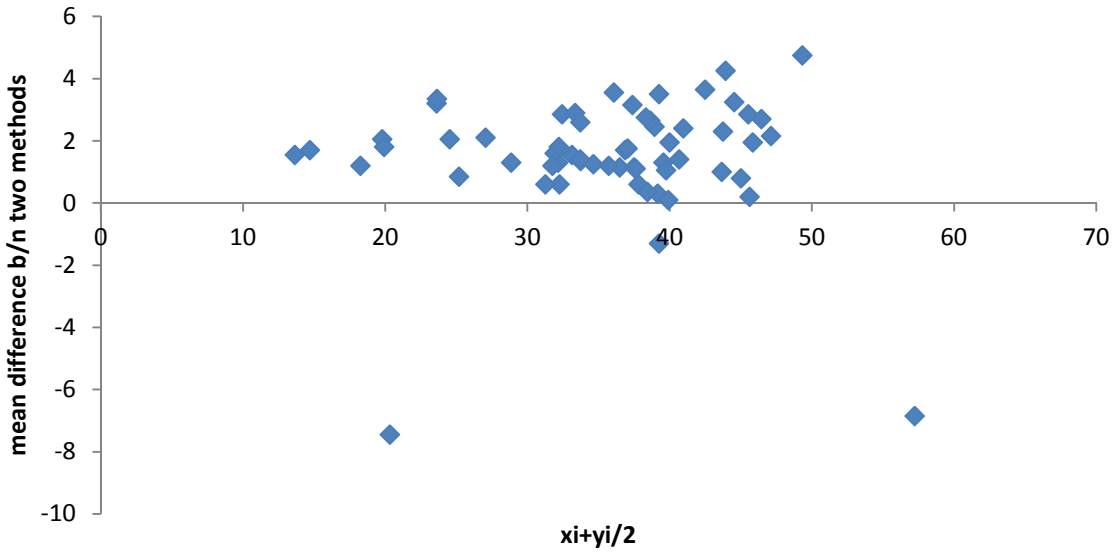


Figure 8 difference plots for HCT

The two analyzers have a correlation value r equals to 0.97 for PLT, which is a good agreement between two methods. Cell Dyn has a mean value of 243.15 and Sysmex have average value of 227.68. They have a common mean value of 239.32 and a SD of 160.1. It has a regression equation of y=0.84x+22.4. This equation shows us they have a good correlation.

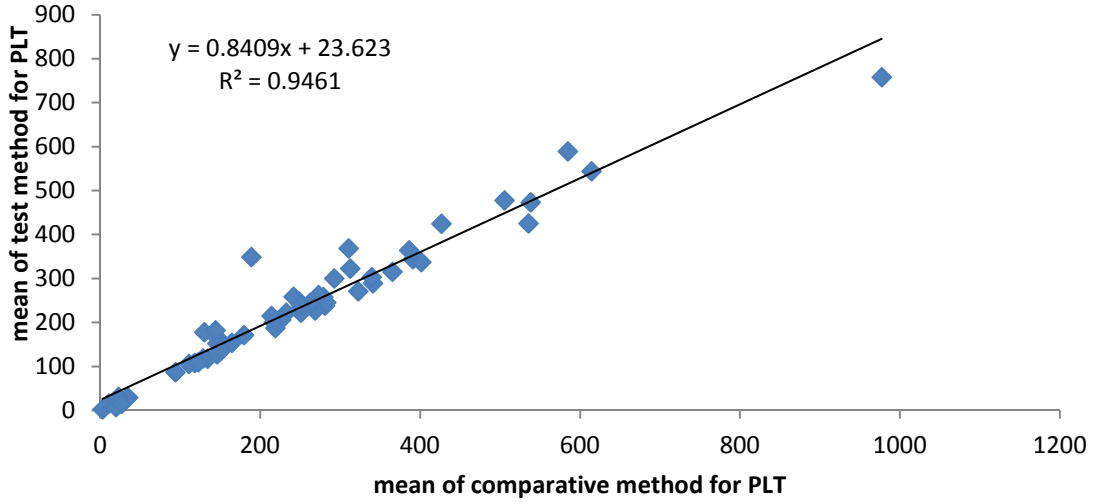


Figure 9 mean of Sysmex Vs mean of Cell Dyn for PLT

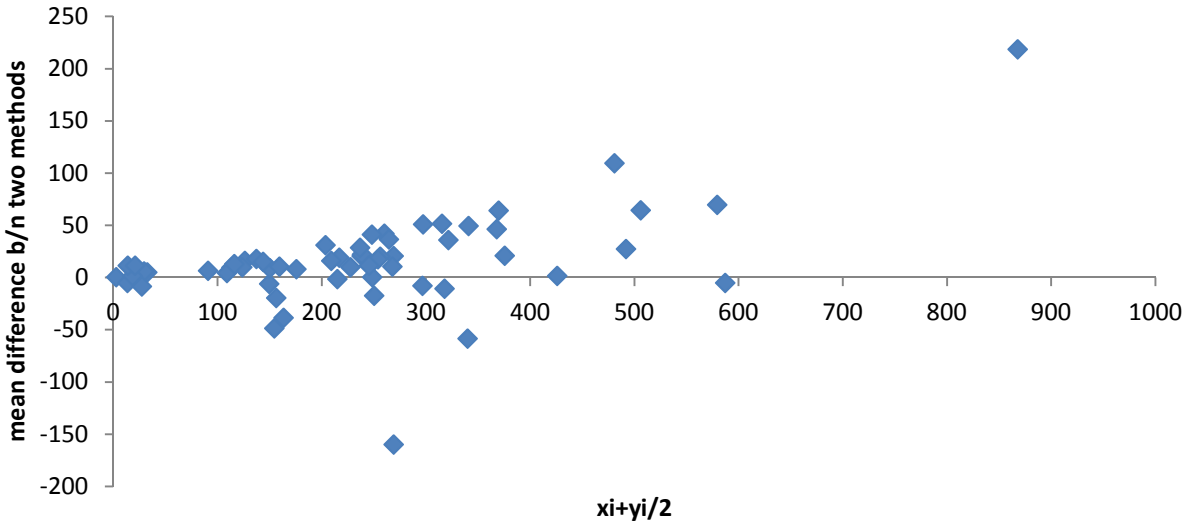


Figure 10difference plots for PLT

A Cell Dyn has a mean MCH value of 28.03 and Sysmex 28.38 and a common mean of 28.7 having SD of 3.36 and most results are found within the 95% CI of the 2SD. It has a correlation of r equals to 0.95. The regration equation of y= 1.05x-0.1. Its slope value 1.05 tells us the proportional error and it has a constant proportional error of -0.1. All the above mentioned results show that the two analyzers have a good correlation for MCH.

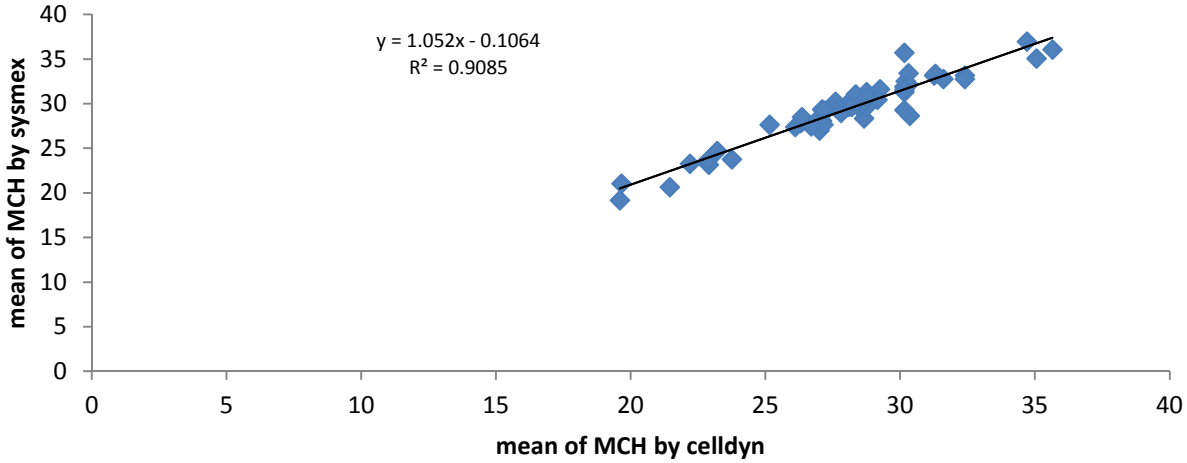


Figure 11 mean of MCH for Sysmex Vs Cell Dyn

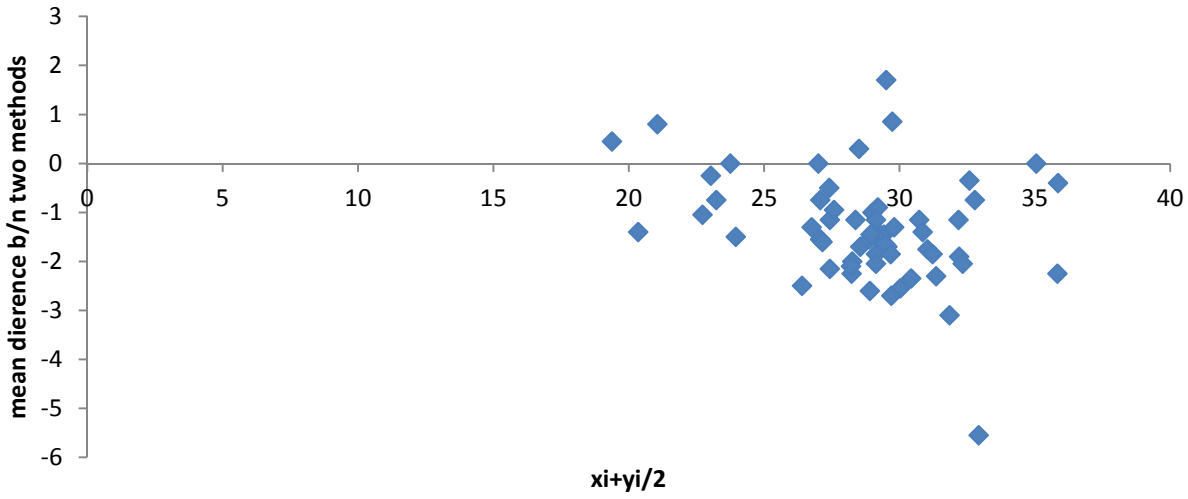


Figure 12 difference plots for MCH

For MCHC value a Cell Dyn has a mean value of 31.38 and Sysmex has a mean value of 32.54 and they have a common value of 31.96 and SD of 1.77. it has a correlation of r equals to 0.75. The regression equation of y=0.88x + 4.6. The above result shows us both analyzers have a good correlation for MCHC.

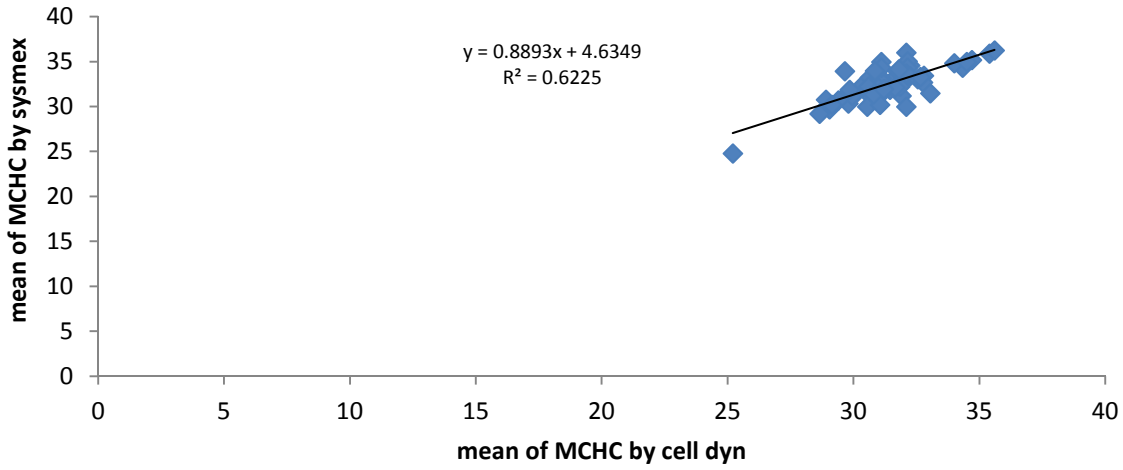


Figure 13 mean of MCHC result of Sysmex Vs Cell Dyn

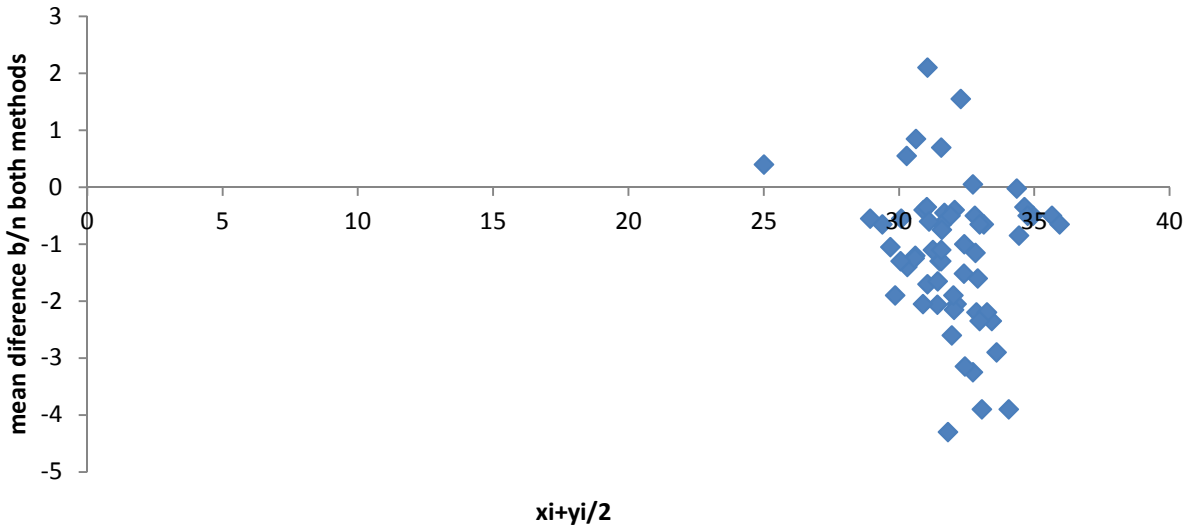


Figure 14 difference plots for MCHC

For MCV the mean value is 91.5 for Cell Dyn and 89.87 for Sysmex and they have a common mean 90.69. Their SD was 9.75, 95% of the results were found within limit of 2SD. It have a correlation of 0.96 and a regression equation of y=1x-3. All the above mentioned value tells us they have correlation.

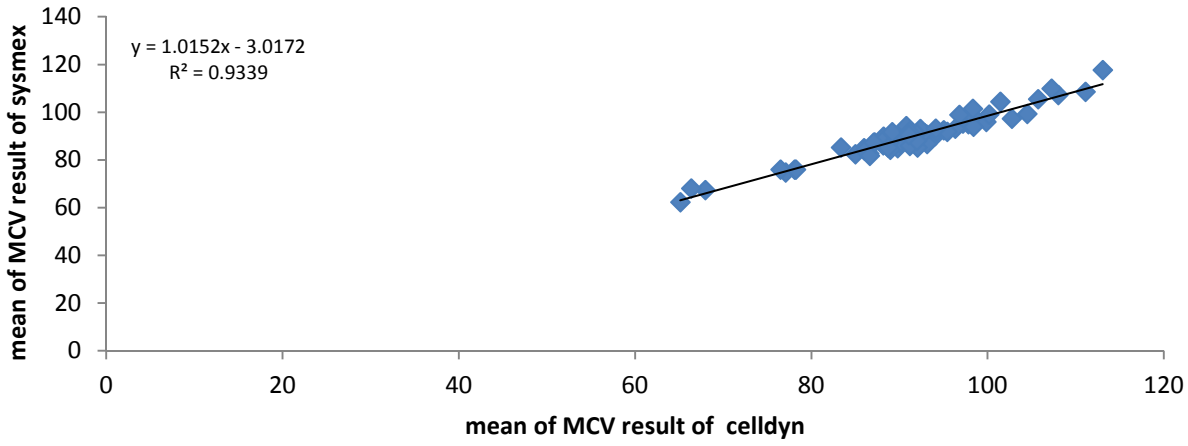


Figure 15 mean value of MCV results of Sysmex Vs Cell Dyn

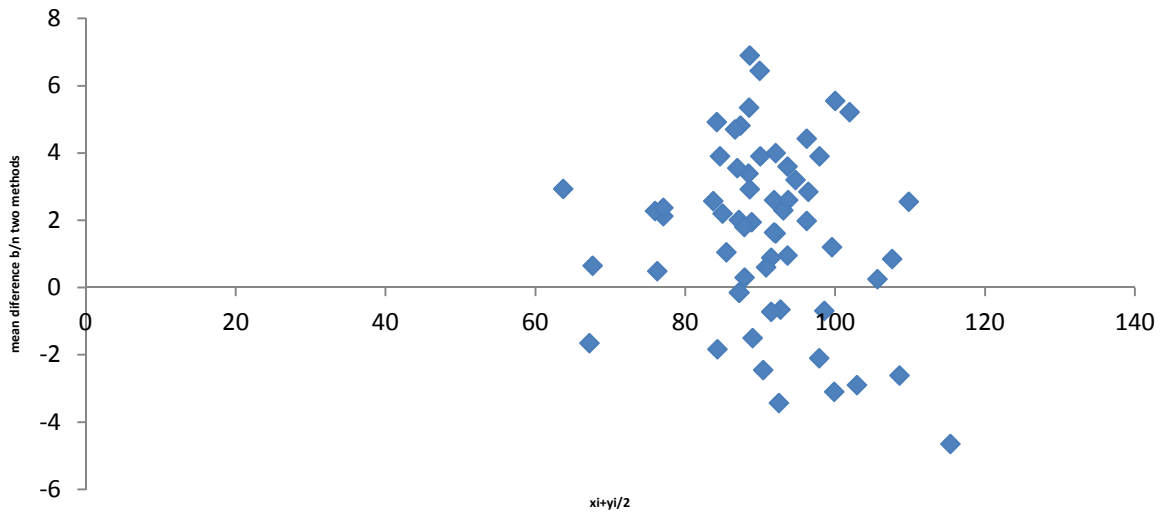


Figure 16 difference plots for MCV

Cell Dyn and Sysmex have a mean value of 17.17 and 17.18 respectively for RDW. They have a common mean value of 17.8. SD value is 4.05 and correlation value of 0.92. Its regression equation of y=0.99x+0.15. So the analyzers have a good correlation for RDW.

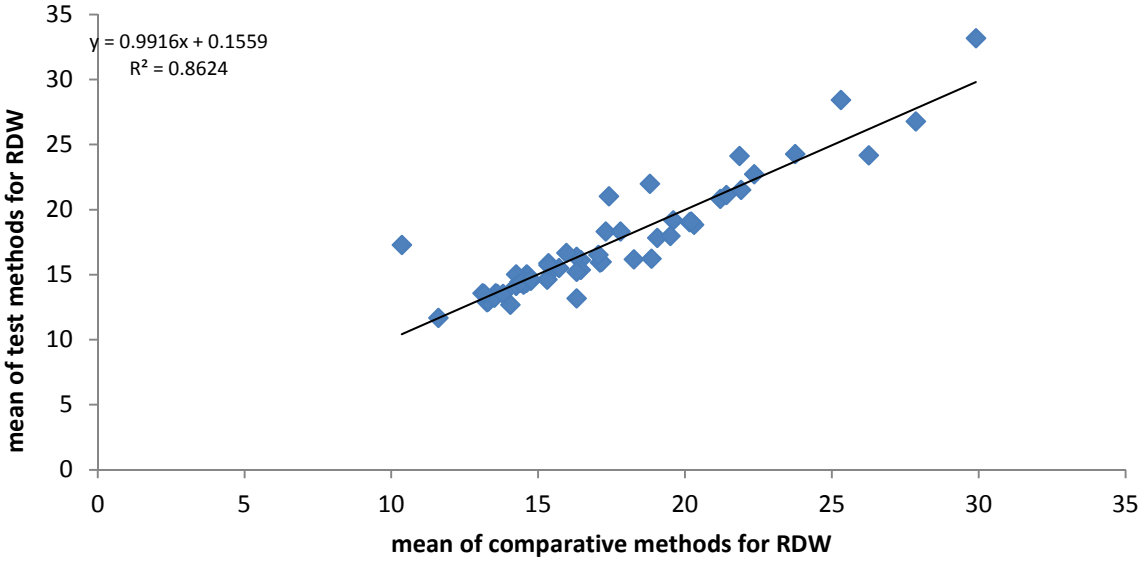


Figure 17 mean of sysmex Vs mean of Cell Dyn for RDW

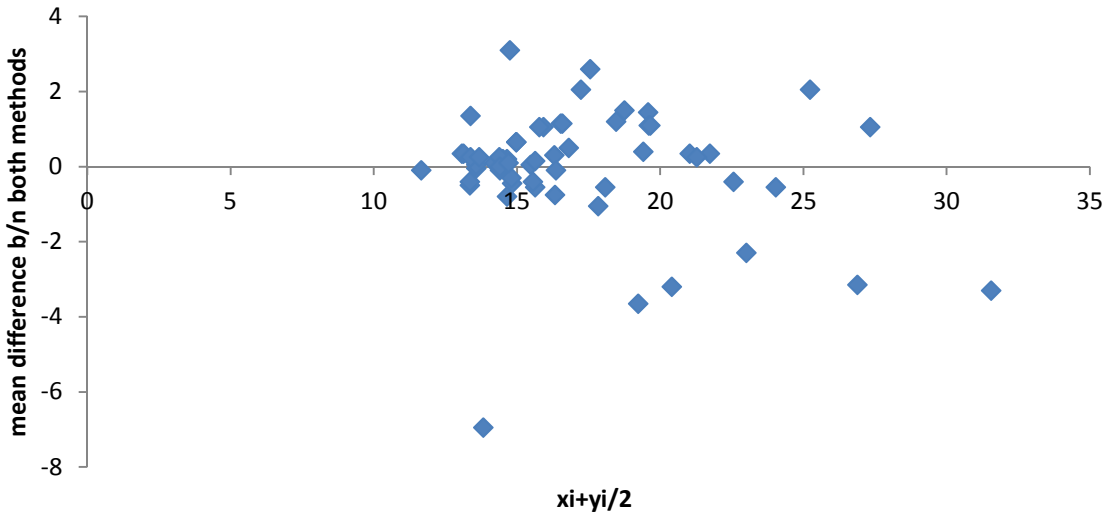


Figure 18 difference plots for RDW

For PDW Cell Dyn have a mean value of 13.44.are w Sysmex have a mean value of 12.32, they have a common mean value of 12.88. Their SD is 2.78, 95% of the values are within 2SD. They have a correlation value of r=0.8 and a regression equation of y=0.67x+3.26. It has a proportional systematic error of 3.26 and constant systematic error of 3.26. From the above results we found that they have a good correlation.

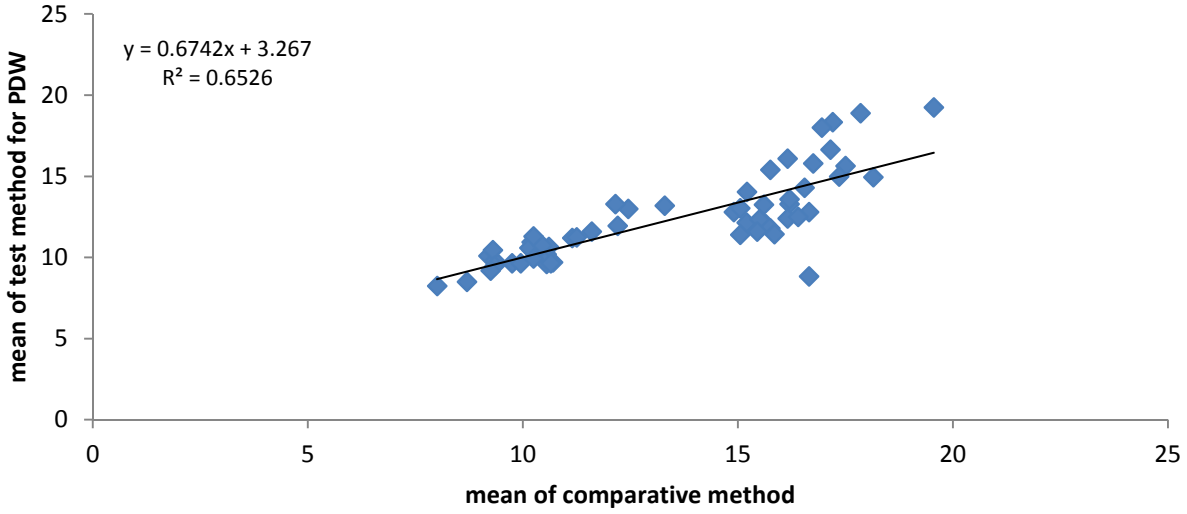
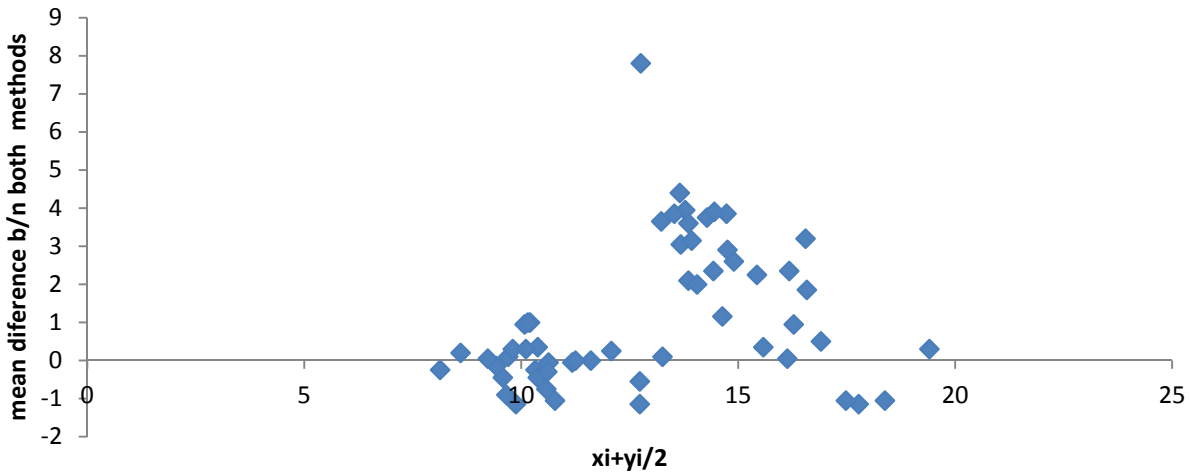


Figure 19 mean of Sysmex Vs mean of Cell Dyn for PDW



N jFigure 20 difference plots for PDW

For MPV Cell Dyn has a mean value of 9.38 and Sysmex has a mean value of 9.82.and they have a common mean value of 9.60. They have SD of 1.22. They have a correlation value of r=0.83 and regression equation of y=0.74 x+2.8.

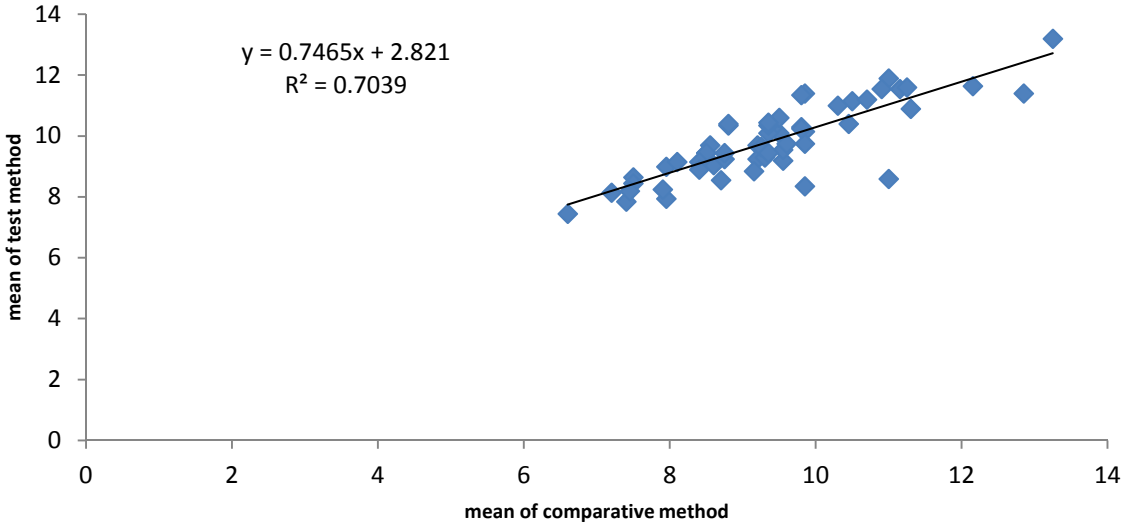


Figure 21mean of Sysmex Vs mean of Cell Dyn for MPV

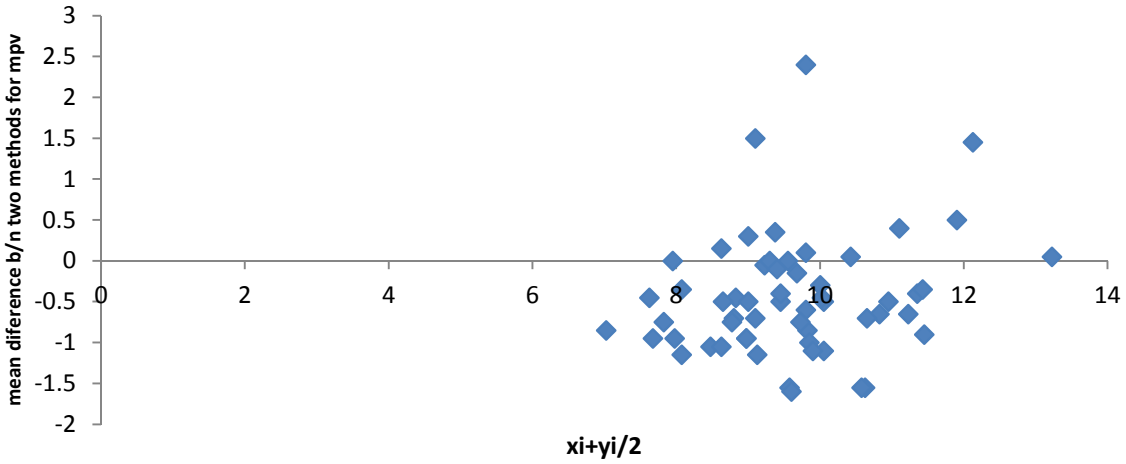


Figure 22 difference plots for MPV

For PCT Cell Dyn has a mean value of 0.21and sysmex has a mean value of 0.20. They have a common mean value of 0.21. They have SD value of 0.01. They have a correlation r value of 0.912. And regression equation of y=0.92x+0.008. From the above results we found that the two analyzers have a good correlation for PCT value.

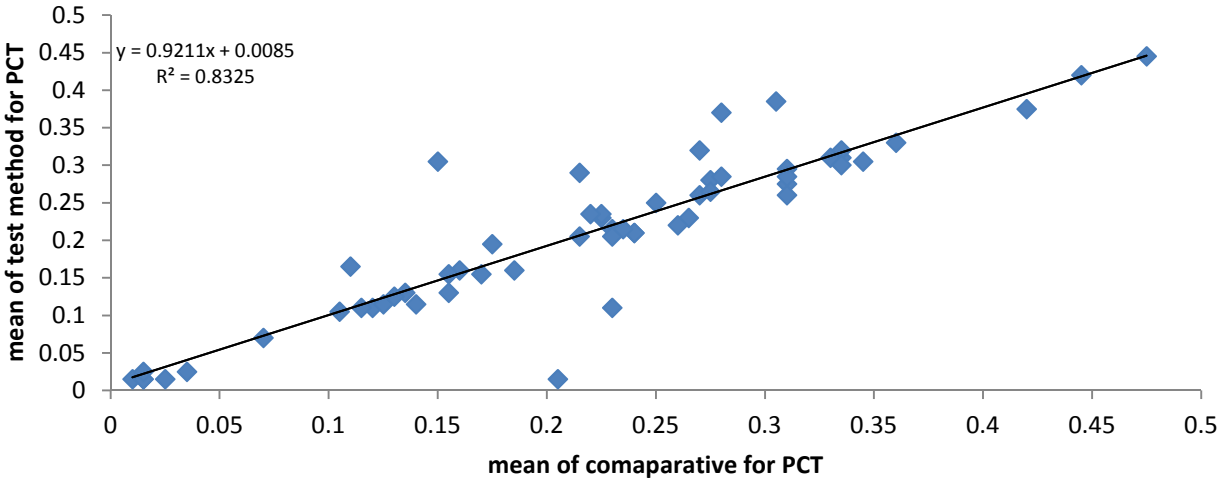


Figure 23 mean of Sysmex Vs mean of Cell Dyn for PCT

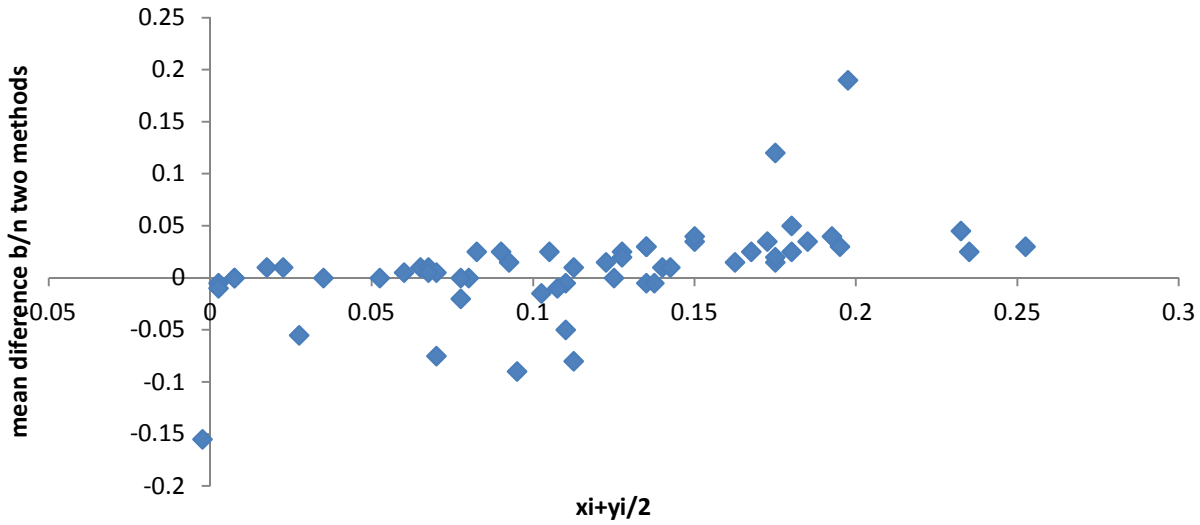


Figure 24 difference plots for PCT

Table 2 comparison of XT 2000i and Cell Dyn 1800 for CBC

Parameter	correlation	slope	Intercept
WBC, $\times 10^9$/l	0.99	1.01	0.02
RBC$\times 10^{12}$/l	0.92	0.94	0.022
HGB, g/dl	0.95	0.96	0.37
HCT	0.975	0.97	-0.53
MCV, fl	0.96	1	-3
MCH, pg	0.95	1.05	-0.1
MCHC, g/dl	0.75	0.88	4.6
RDW %	0.92	0.99	0.15
PLT$\times 10^9$/l	0.97	0,84	22.4
PDW	0.8	0.67	3.26
MPV	0.83	0.74	2.8
PCT	0.91	0.92	0.008

Also differential count between manual and Sysmex was done between the 60 samples. And it shows the correlation r=0.846 for neutrophil. r= 0.837 for lymphocyte, r= 0.957 for monocytes, r=0.692 for eosinophil and r=0.928 for basophile. When we run these sample on sysmex we found that out of 60 samples 12 were without any differential count result and 2 was with only monocyte and lymphocyte count and 3 samples have only basophile count. There graph are displayed below to see their scatter around the mean and its distribution.

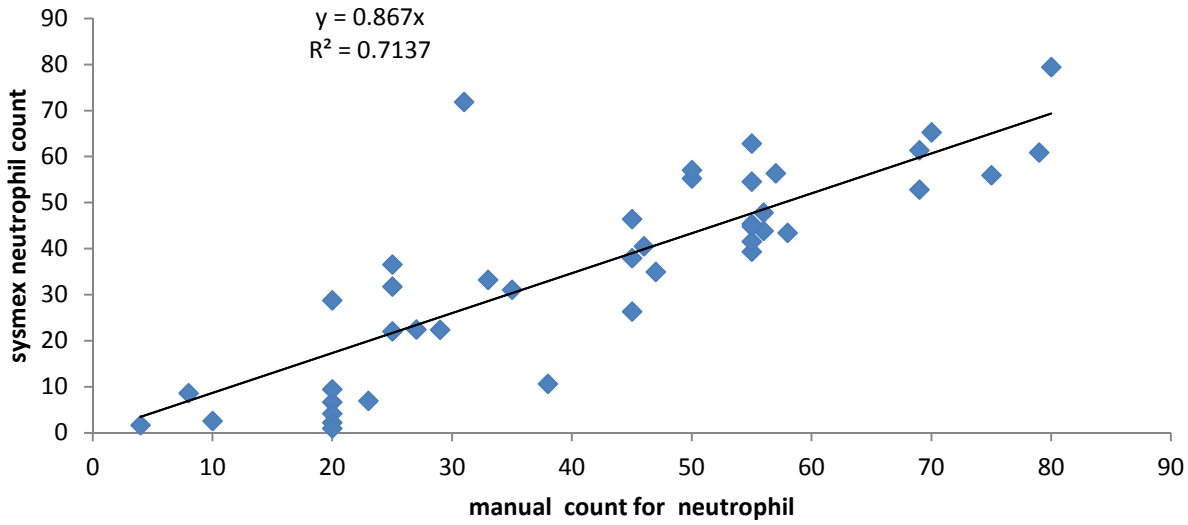


Figure 25 Sysmex count for neutrophil Vs manual count for neutrophil

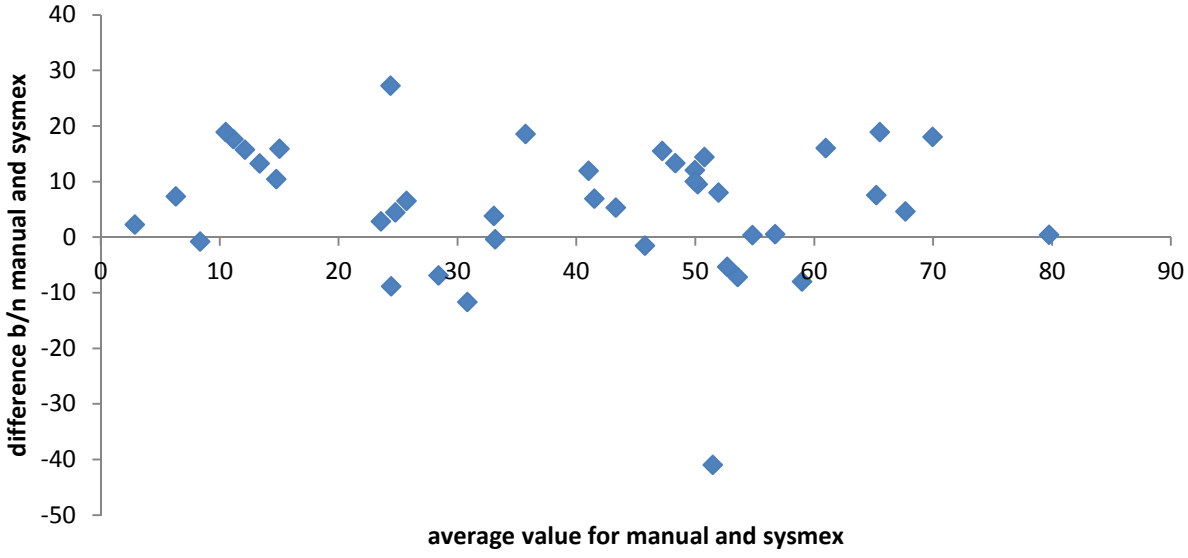


Figure 26 difference plots for neutrophil

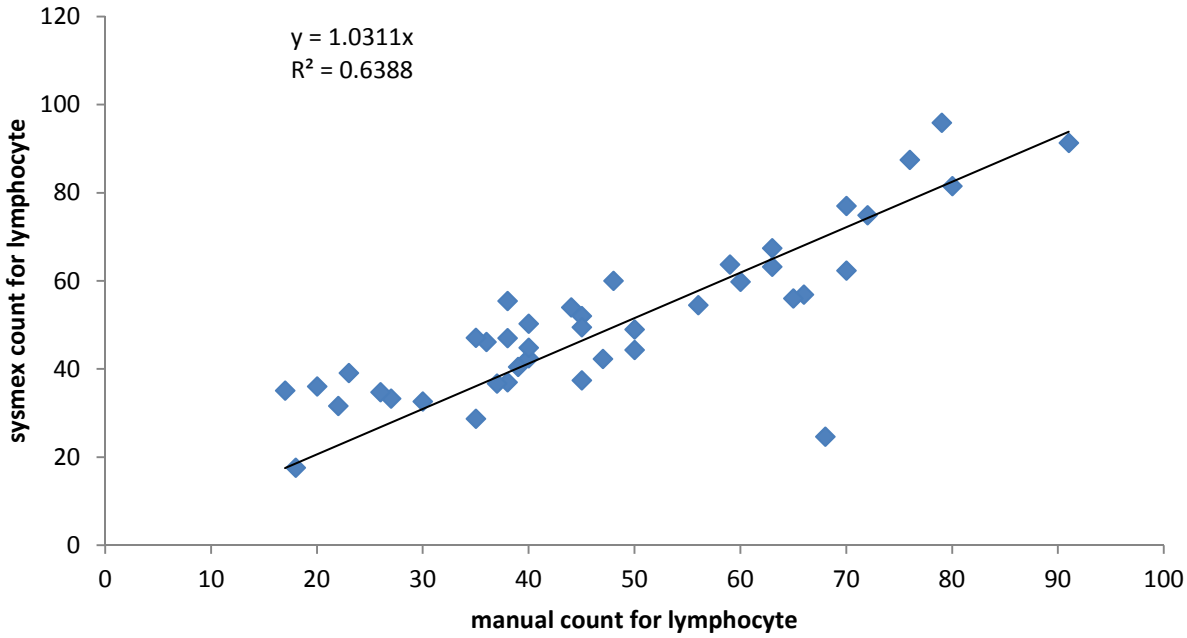


Figure 27 Sysmex lymphocyte count Vs manual count for lymphocyte

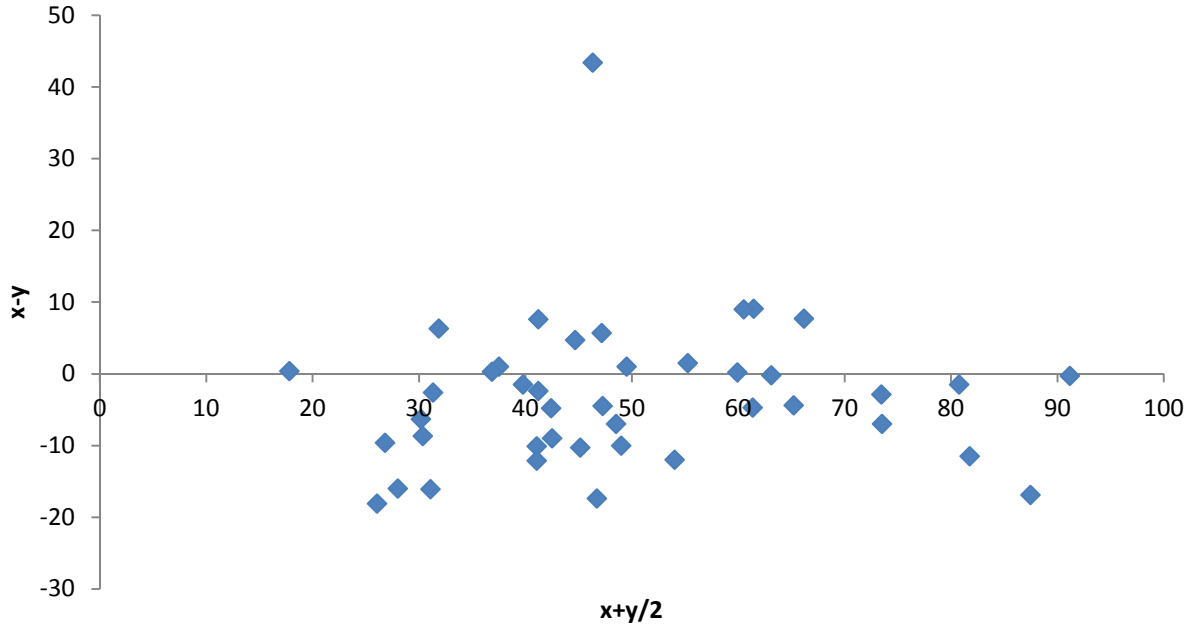


Figure 28 difference plots for lymphocytes

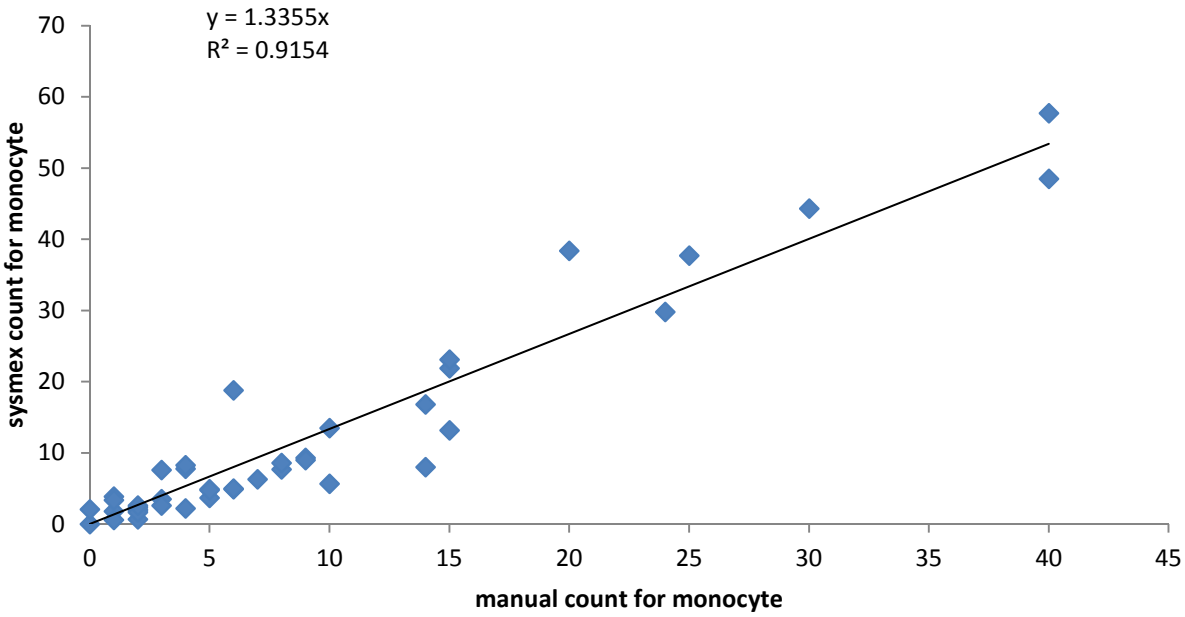


Figure 29 sysmex counts for monocyte Vs manual count for monocyte

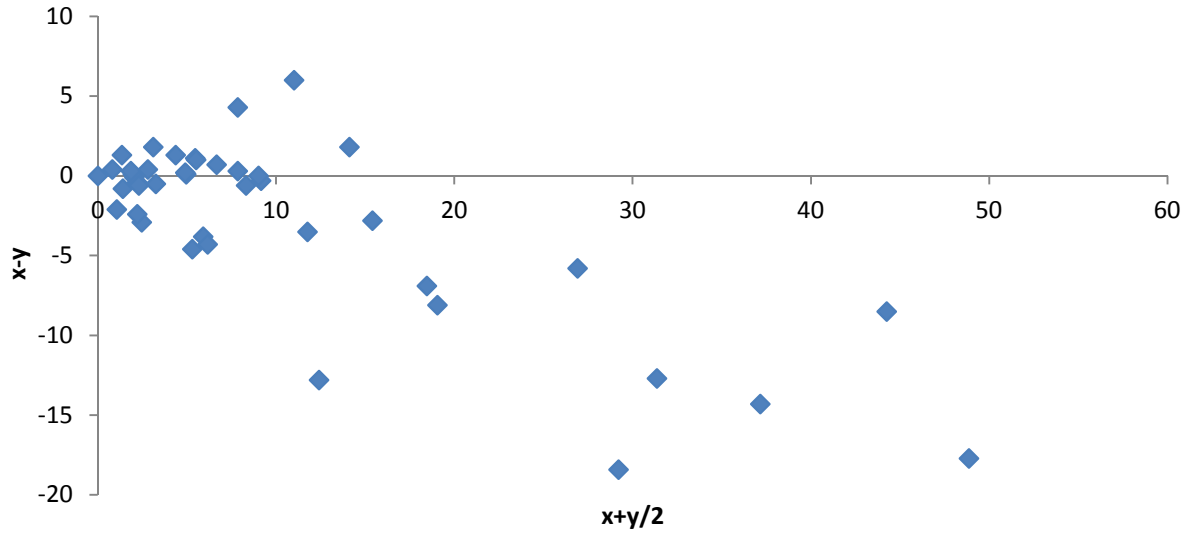


Figure 30 difference plots for monocyte

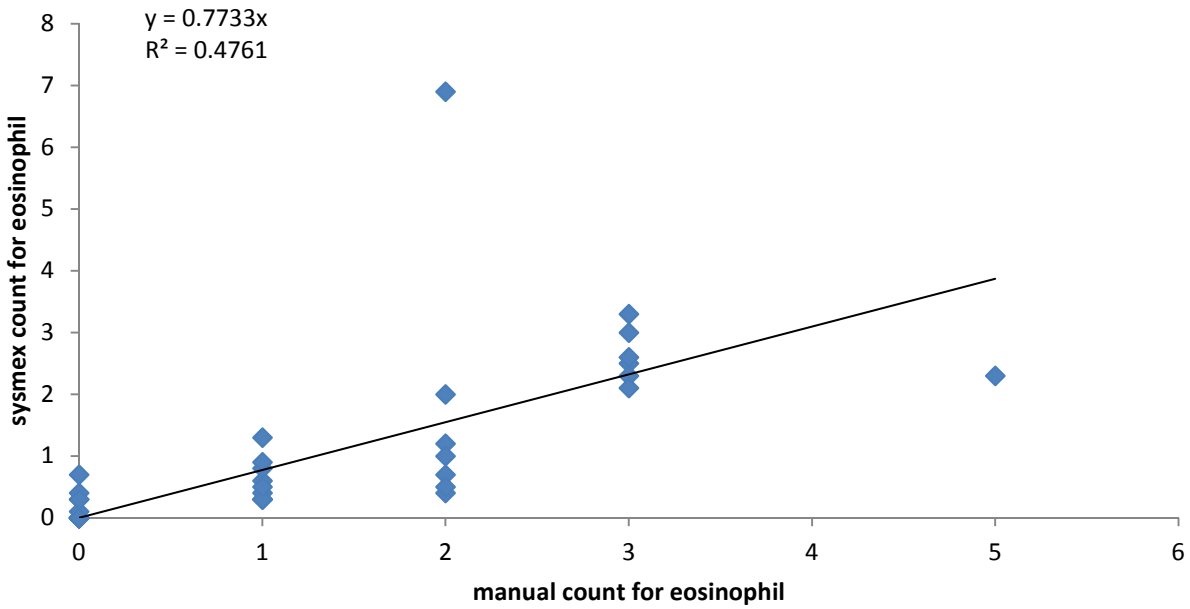


Figure 31 sysmex counts for eosinophil Vs manual count for eosinophil

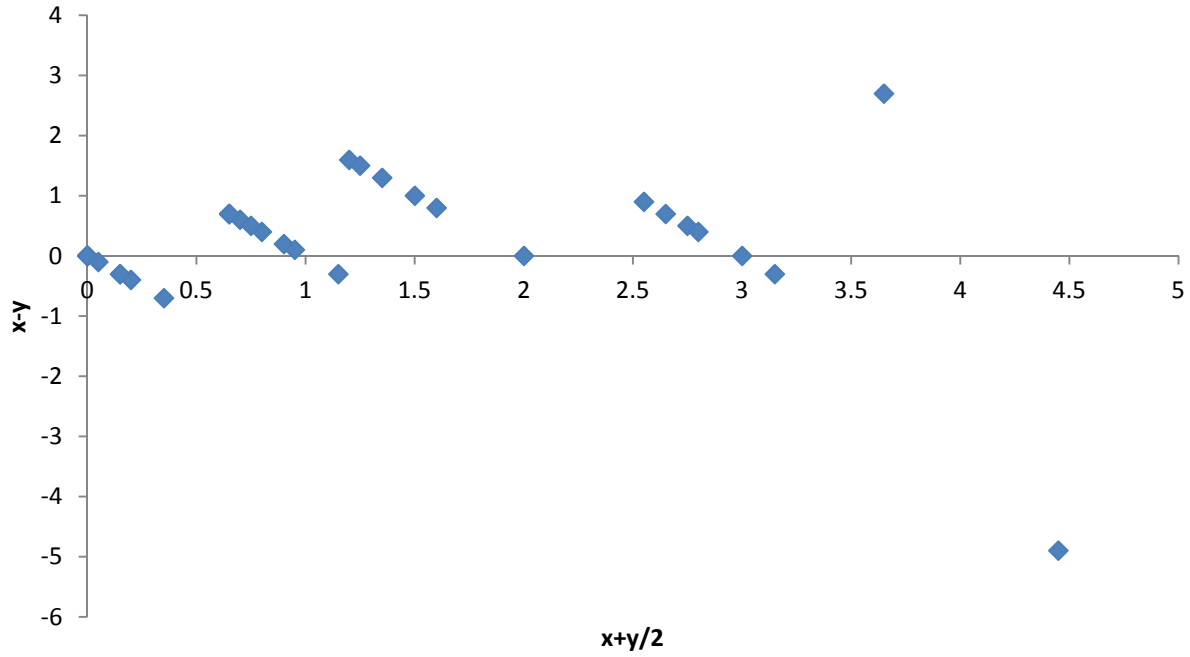


Figure 32 difference plots for eosinophil

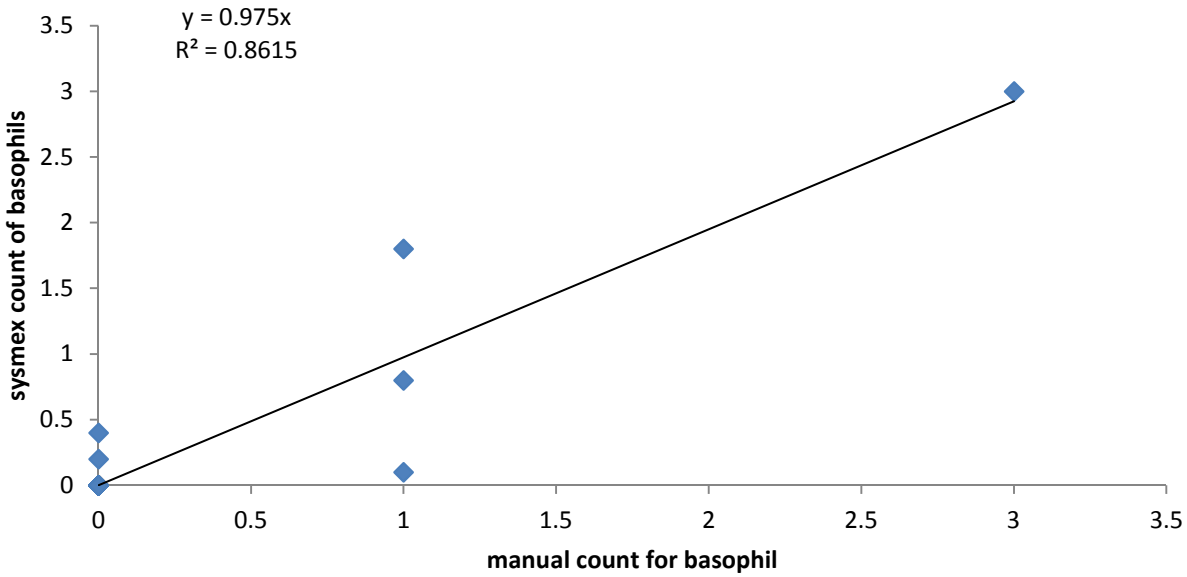


Figure 33 Sysmex basophile count Vs manual count

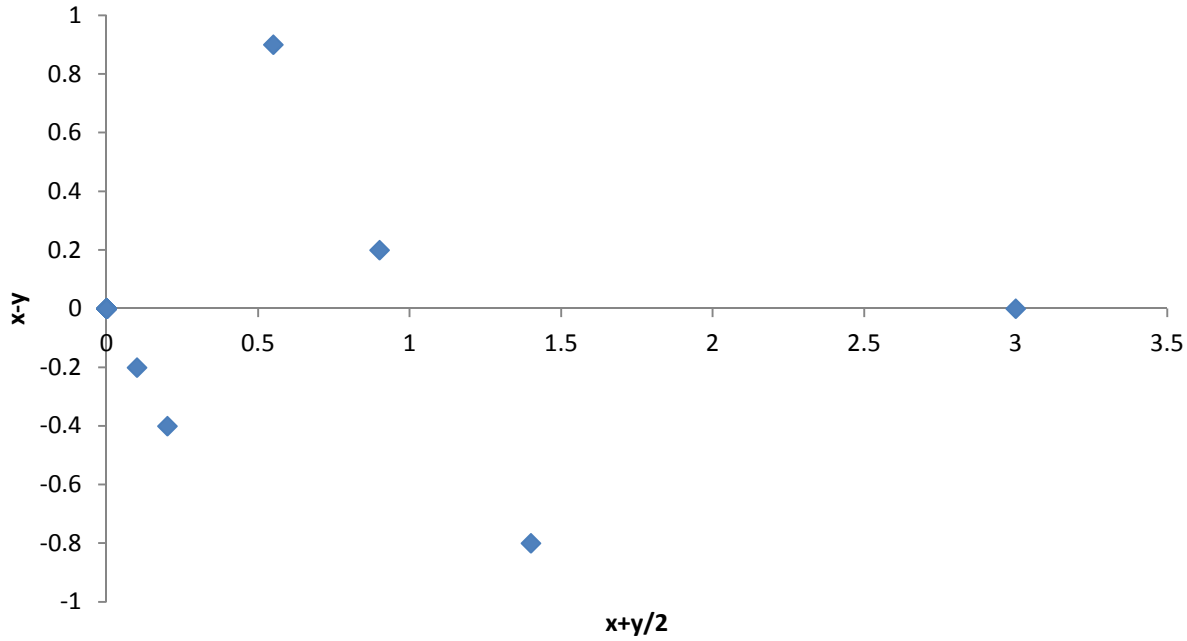


Figure 34 difference plots for basophile

Table 3 comparison of Sysmex XT2000i with the manual differential method for 5-diff

parameter	n	Correlation (r)	slope
Neutrophil , #	60	0.846	0.867
Eosinophil , #	60	0.692	0.773
Basophile , #	60	0.928	0.975
Lymphocyte , #	60	0.837	1.031
Monocyte , #	60	0.957	1.333

5. Discussion

There are limited information regarding compare CBC results between existed sysmex XT-2000i and Celldyn1800 in developing countries like Ethiopia. So this study evaluate outcome from the two machines and make us conclude whether it's acceptable to use the two analyzers interchangeably or not.

The mean value of WBC in cell Dyn 1800 was in agreement with Sysmex XT 2000i as seen in (figure 1) this result is in agreement with a study of (Leers et al, 2011), which was done at Netherland to evaluate the performance of Cell Dyn ruby and Sysmex XT 2000i.

The mean value of RBC in cell Dyn 1800 found comparable with Sysmex XT 2000i as seen in (figure 3) this result is contradictory with a study of (Leers et al, 2011).

The mean value of Hgb in cell Dyn 1800 was found similar with and Sysmex XT 2000i as shown in (figure 5) this result is consistent with a study by Ghys T et al., 2008.

The mean value of PLT in cell Dyn 1800 was in agreement with Sysmex XT 2000i as shown in (figure 9) this result is not in agreement with a study of (Ghys et al., 2008 and Penig et al.,) which report variation in the Plat value between this two machines .

The mean value of MCV in cell Dyn ruby was in agreement with Sysmex XT 2000i. This result is contradictory to study by Leers et al**,** 2011 who reported variation in mean value of MCV between cell Dyn ruby and Sysmex XT 2000i

The mean value of MPV in cell Dyn 1800 was in agreement with Sysmex XT 2000i as seen in (figure 21) this result is not in agreement with a study of (Leers et al**,** 2011) the possible variation in our result with the previous study may be the blood smear was used in pervious study of (Leers et al**,** 2011) instead of blood sample.

MCH in Cell Dyn 1800 was in agreement with Sysmex xt 2000i as seen in (figure 11) this similarly was reported in a study of (Ghys T et al., 2008).

The mean value of MCHC in Cell Dyn 1800 and Sysmex XT 2000i was found to be closer as seen in this result is in agreement with a study of (Leers et al, 2011).

The mean value of RDW in Cell Dyn 1800 was in agreement with Sysmex XT 2000i as seen in (figure 17) this result is in agreement with a study of (Leers et al**,** 2011).

In this cross sectional study values of WBC, RBC, HCT, HGB, MCV, MCH, MCHC, PLAT, and values were found to be similar in cell Dyn ruby and Sysmex XT Cell Dyn (Ghys T et al., 2008).

The mean value of neutrophil count with Sysmex and manual was in agreement as seen in figure 25. This result is in agreement with a study of Ghys T et al., 2008. It was done in Belgium at 2008 to see performance evaluation of sysmex XS 1000i automated hematology analyzer. Our study also agrees with a research done in USA to see the performance evaluation of Sysmex XT 2000i by Langford K et al., in 2003.

The mean value of Lymphocyte count with Sysmex and manual was in agreement as shown in figure 27. Our study also agrees with a study of (Ghys T et al., 2008). It was done in Belgium at 2008 to see performance evaluation of sysmex XS 1000i automated hematology analyzer. Their correlation value (r=0.98). Also our study agrees with a study of Langford K et al., in 2003 where their correlation value (r= 0.96).

The mean value of Monocyte count with Sysmex and manual was in agreement as shown in figure 29. Our study also agrees with a study of (Ghys T et al., 2008). It was done in Belgium at 2008 to see performance evaluation of sysmex XS 1000i automated hematology analyzer. Their correlation value (r=0.88). Also our study agrees with a study of Langford K et al., in 2003 where their correlation value (r= 0.9).

The mean value of Eosinophil count with Sysmex and manual was not in a good agreement as shown in figure 31. Our study disagrees with a study of (Ghys T et al., 2008). It was done in Belgium at 2008 to see performance evaluation of sysmex XS 1000i automated hematology analyzer. Their correlation value (r=0.97). Also our study disagrees with a study of Langford K et al., in 2003 where their correlation value (r= 0.94).

The mean value of basophile count with Sysmex and manual was in a good agreement as shown in figure 33. Our study disagrees with a study of (Ghys T et al., 2008). It was done in Belgium at 2008 to see performance evaluation of sysmex XS 1000i automated hematology analyzer. Their

correlation value (r=0.57). Also our study disagrees with a study of Langford K et al., in 2003 where their correlation value (r= 0.76).

6. Strength and Limitation of study

6.1Strength

- Samples run in duplicates

6.2 Limitation

- Lack of access to regents and controls, it's the reason for changing previous topic and results delay in sample collection.
- Budget , its reason for running small sample number
- One of the instruments was with five differentials and the other was with three differentials so it was difficult to compare differential between two analyzers.
- There is only limited number of method comparison studies, so we use few studies repeatedly.

7. Conclusion and Recommendation

It is concluded form this study that the CBC values performed by cell Dyn 1800 and Sysmex XT 2000i is in agreement and using both machines interchangeably wouldn't varies the values significantly. But for some of tests like MCHC results vary so each analyzer must be evaluated and further research must be done. So the hospital can use both analyzers interchangeably by working manual count for concentrated samples. Although this result is same with our hypothesis

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Annexes

Annex I: picture, Procedure and reagent of sysmex XT-2000i Hematology Analyzer

Sysmex XT-2000i Automated Hematology Analyzer

Procedure

Analysis mode

Manual mode: after mixing the sample manually the cups of the sample tube are manually removed and each sample is aspirated via the whole blood aspiration probe.

Capillary mode: analysis performed after the sample diluted manually 1:5 dilutions. This mode is used for analyzing multiple amount of blood collected from earlobe or fingertip. The sample is aspirated via the whole blood aspiration probe, and the obtained is automatically multiplied by 5 for reporting, which is thus comparable to the manual mode.

Sampler mode: the sampler automatically mixes aspirates, and analyzes samples without removing their caps. Up to 50 samples can be loaded at a time and analyzed automatically.

Manual closed mode: the sampler is used to aspirate the sample, without opening the cup of the sample tube. This mode is basically the same as manual mode; however, mixing and continuous analysis cannot be performed automatically and have to be carried out manually.

Sampler (Auto) Mode

Standard precautions should be followed when handling specimens and performing all laboratory testing.

1. 1mL of sample required.
2. Place specimens in a rack with barcodes facing the front of the rack. Ensure that labels are securely adhered to tube with no loose edges.
3. Load up to 5 racks at one time (50 samples). A new rack may be added to the right rack pool at any time.
4. On the computer, click on the "Sampler" icon or press [F3] on the keyboard. The "Sample Number" dialog box displays.
5. Click [SAMPLER START] and [OK].
6. The specimen will be automatically mixed the sample 10 times, aspirates, and analyzes the sample according to the tests ordered for specified barcode. Results will print if specimen meets criteria that require further action by the technologist (ie. smear reviews, manual differentials, repeat of critical results).

Note: If Barcodes are not used, the sample number will increment by 1 as each sample is analyzed. The discrete test to be performed must be selected in the Sampler dialog box.

Manual Mode

1. 85 uL of sample required (short drawor pediatric capillary collection).
2. Click the "Manual" icon or press [F2] on the keyboard.
3. Enter the specimen number using the keyboard or the handheld barcode wand.

4. Discrete tests for manual mode are defaulted to C/D/R (CBC/Diff/Retic) unless changed by the operator.
5. Click [OK].
6. Mix the patient sample. Uncap the tube.
7. Place sample under the aspiration pipette so that the tip of the pipette is at the bottom of the sample tube.

After sample aspiration a part of the whole blood sample is diluted in 1:50 with lysing reagent stromatolyse 4DL and then stromatolyer 4ds dye is added.

After a pre defined response time the stained sample is introduced into the detector, where forward light scatter and side fluorescent emission are measured. From this four leucocyte populations are computed: neut count (neu #), lymph count (lymp#), mono count (mono#) and eos count (eos#) as well as neutr percentage (neu %), lymp %, mono%, eos%.

Reagent of sysmex XT-2000i

1,CELLPACK – diluents for use in hematology analyzers.

It is ready to use diluents for impedance and photoelectrical analysis of whole blood.

Ingredients: sodium chloride, boric acid, sodium tetra borate, EDTA-2K

2, STROMATOLYSER – FB

Is a ready to use lysing reagent to analyze to leucocytes and the basophilic granulocytes of a whole blood sample by resistance measurement and photometric measurement.

Ingredients: non ionic surfactant, organic quaternary ammonium salt

3, STROMATOLYSER -4DL

It is a ready to use diluents for analyzing blood by resistance and photometric measurement.

Ingredients: non ionic surfactant, organic quaternary ammonium salt.

4, STROMATOLYSER-4DS

It stains the leucocytes in diluted and lyses blood samples. Ii serves for the determination of 4 part differential count (lym, mono, eos, neu+ baso) with selected sysmex hematology analyzers.

Ingredients: Polymethine dye, methanol, ethylene glycol.

5, SULFOLYSER

It is ready to use diluents, for analyzing blood by photoelectrical analysis. It is a cyanide free reagent used for the determination of hgb. lyses the erythrocyte and acts upon globin of hemoglobin to form a stable hemochrome. SULFOLYSER is intended for use on all sysmex automated hematology analyzers excluding model of CC and M series

Ingredients: sodium lauryl phosphate

6. RET SEARCH (II) (diluents)

RET SEARCH (II) (dye solution)

RET SEARCH (II) is intended to diluents the sample while simultinously staining the reticulocyte to assay the reticulocyte concentration in blood with sysmex hematology analyzer.

RET SEARCH (II) is a pre packaged reagent kit consisting of RET SEARCH (II) diluents buffer and RET SEARCH (II) dye. Both reagents are only used by the XT 2000i.

Methodology: RET SEARCH (II) is a ready to use diluents with a matching dye for analysis of whole blood by resistance measurement and photometric measurement.

Ingredients: RET SEARCH (II) (diluents): tricine buffer,

RET SEARCH (II) (dye solution): polymethine dye , methanol, ethylene glycol.

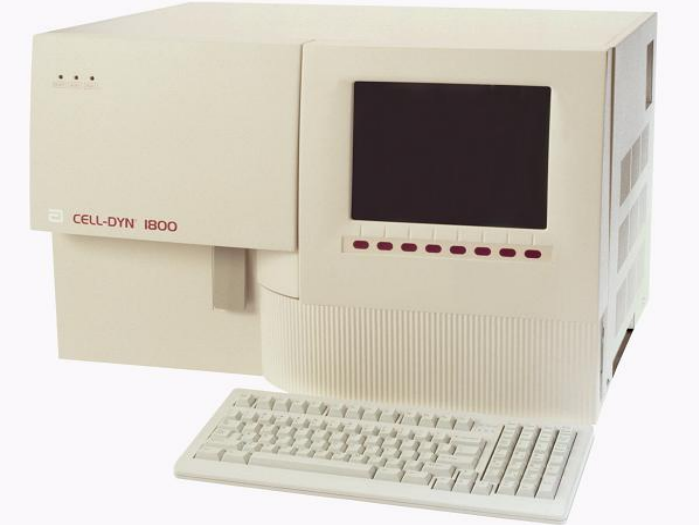
7, CELLCLEAN

Is a strong alkaline detergent to remove lysing reagents, cellular residuals and blood proteins remaining in the hydraulics osf sysmex analyzer.

Is a detergent to clean the instrument, to remove residual and blood proteins from the hydraulic systems, transducer, sample rotor valve, whole blood aspiration tube and hgb flow cell.

Ingredients: sodium hypochlorite

Annex II: Picture, procedure and reagents of Cell-Dyn 1800 Hematology Analyzer



Picture Cell Dyn 1800 hematology analyzer

Procedure for cell Dyn 1800 hematology analyzer

1. Whole blood collected in an EDTA tube with a Minimum sample volume is 0.5 ml using the Open Sample Mode. The instrument aspirates 30 µl of patient sample.
2. Run three levels of QC at the beginning of each day of patient testing. Do not perform patient testing until QC tests are performed and within acceptable limits. Rerun at least one of the three levels of QC again after eight hours of patient testing to assure the instrument is still functioning properly.
3. Press MAIN to return to the MAIN MENU. At the MAIN MENU, enter in the operator ID and press RUN, next press SPECIMEN TYPE. If the instrument has been idle for fifteen minutes or more, press normal background. Press the Touch Plate to run an Open Mode Background test. Verify that the Open Mode Background count results are acceptable.

4. Press MAIN to return to the MAIN MENU screen. Enter in the Operator ID and press RUN. Press SPECIMEN TYPE then press PATIENT SPECIMEN. Verify that RUN Ready is displayed in the Status Box. Scan patient specimen number and patient name using the keyboard. Expected ranges for blood counts differ based on gender and age.
5. The Cell Dyn is programmed to display the correct reference range. The operator, however, must first manually type in the correct gender prior to running the patient sample. Once RUN Ready is displayed in the Status Box, use the ↓key to scroll to the Limit prompt. Enter either "1" for Male or "2" for Female. Mix the patient sample well and remove the cap. Place the sample probe in the tube so that the end is immersed in the sample but not resting on the bottom of the tube.
6. Press the Touch Plate to start the run. The Status Box on the RUN menu indicates the stage of the run. When Remove Specimen is displayed in the Status Box and the probe has moved up through the wash block remove the sample tube and replace the tube cap.
7. A beep will indicate that the probe cleaning cycle has begun. After the probe cleaning cycle is complete, the probe will move down into position for the next sample and the results will be displayed on the screen.
8. If needed, press PRINT REPORT for a hardcopy of the report. After sampling is complete, press MAIN to return to the MAIN MENU. Change the Operator ID to "000"for the next user.

Reagents for Cell Dyn 1800

1. Cell-Dyn Diluents:

a. Stable at room temperature until the expiration date on the container.

b. Protect from direct sunlight, extreme heat, and freezing during storage.

c. Do not use if reagent has been frozen.

2. Cell-Dyn Lytic Agent:

a. Stable at room temperature until the expiration date on the container.

b. Protect from direct sunlight, extreme heat, and freezing during storage.

c. Do not use if reagent has been frozen.

3. Cell-Dyn Detergent:

a. Stable at room temperature until the expiration date on the container.

b. Protect from direct sunlight, extreme heat, and freezing during storage.

c. Do not use if reagent has been frozen.

4. Enzymatic Cleaner:

a. Stable at 2-8°C until the expiration date on the container.

b. Do not use if reagent has been frozen.

5. Cell-Dyn Whole Blood QC:

a. Unopened QC vials are stable at 2-8°C until the expiration date on the vial. Opened QC vials are Stable at 2-8°C for 7 days after opening. Do not use expired QC.

b. Allow QC to sit at room temperature for fifteen minutes before testing.

c. Mix QC vial by rolling the vial between palms for 20 seconds.

d. Invert the vial and roll it back and forth for another 20 seconds.

e. Gently invert the vial 10 times.

f. Do not shake.

g. Continue to mix in this manner until cells are completely suspended (3-5 times).

h. Gently invert the pre-mixed vial 5 times immediately before testing.

i. Return vial to refrigerator when testing is complete.

6. Whole Blood Calibrator:

a. Unopened calibrator vials are stable at 2-8°C until the expiration date on the vial. Opened

calibrator vials are stable at 2-8°C for 7 days after opening. Do not use expired calibrators.

b. Allow the calibrator to sit at room temperature for fifteen minutes before testing.

c. Mix the calibrator vial by rolling the vial between the palms for 20 seconds.

d. Invert the vial and roll it back and forth for another 20 seconds.

e. Gently invert the vial 10 times.

f. Do not shake.

g. Continue to mix in this manner until cells are completely suspended (3-5 times).

h. Gently invert the pre-mixed vial 5 times immediately before testing.

i. Return vial to refrigerator when calibration is complete.

Annex III: English Versions of Participant Information sheet and consent form

Participant Information sheet

Addis Ababa University, College of Health Sciences,

Department of Medical Laboratory Sciences

You are invited to participate in a study to be conducted by MSc student Lulit Hailu at Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Science. Please read the following statements and ask any unclear points before you agree to participate.

Introduction

The topic of this study is Comparison of hematological parameters determined by sysmex XT-2000i and Mindray BC- 5380 in a tertiary care teaching hospital in Addis Ababa, Ethiopia. Participation in this study is exclusively voluntarily. If you are not interested to participate, there will be no consequences. If you decide to participate, you have to sign on the consent form.

What is expected from me as participant of the study?

As a participant of this study, there is no additional blood sample taking from you. The left over sample will be used for this study.

Potential benefits to participant and/or to the society

Based on the results obtained from the result, corrections will be taken in interpreting results of different analyzers. Hence, you are indirectly benefiting other patients and the society.

Compensation for participation

You will not receive any payment for your participation in this research study.

Confidentiality

On the request paper your name or your identities will not be mentioned. Samples and information given by the participants will serve only for this research not for any other purpose.

Person to contact

Please direct any questions you may encounter during this study to the principal investigator.

Lulit Hailu

Department of Medical Laboratory Sciences, College of Health Sciences

Addis Ababa University

Cell phone: +251- 09 13 71 00 92

Email: lulithailu98@gmail.com or wrsh2000@yahoo.com

Consent form

This page contains an agreement signature to participate in the study entitled "Comparison of hematological parameters determined by sysmex XT-2000i and Mindray BC- 5380 in a tertiary care teaching hospital in Addis Ababa, Ethiopia."So please read the following points and sign your signature at the end in the space provided.

1. I understand the objective of the study in "Comparison of hematological parameters determined by sysmex XT-2000i and Mindray BC- 5380 in a tertiary care teaching hospital in Addis Ababa, Ethiopia."
2. I know that the left over sample (blood) that I gave is going to be used for this study only.
3. I understand that, all the information and the results are confidential.
4. I understand that I will not get any money for my participation.
5. All the information is explained by phlebotomist and Principal investigator.

Therefore, with full understanding of the situations I agree to give blood for laboratory analysis.

Signature of the participant: _____

Address of the participant: _____

Date: _____

Annex IV: Amharic version of Participant Information sheet and consent form

በአዲስአበባዩኒቨርሲቲ፤ የጤናሳይንስኮሌጅ

የህክምናላቦራቶሪ ት/ክፍል

በአዲስ አበባ ዩኒቨርሲቲ ፤የጤና ሳይንስ ኮሌጅ የህክምና ላቦራቶሪ ትምህርት ክፍል በሁለተኛዲግሪ ተማሪ የመመረቂያ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል፡፡ እባክዎ በዚህ ጥናት ላይ ከመሳተፍዎ በፊት ከዚህ ቀጥሎየሚገኘዉን ምንባብ በጥሞና ያንብቡ/ይመልሱ ፤ ግልፅ ያልሆነ ነገር ካጋጠመዎት ይጠይቁ፡፡

መግቢያ

የጥናቱ ርዕስ “በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል በሚገኙት በሚንድሪይ Bc-5380 እና ሲስሚክስ XT- 2000i ሄማቶሎጂ መመርመሪያዎች የሚሰጡትን ውጤት ማወዳደር “ እርስዎ በዚህ ጥናት ላይ የሚኖሮት ተሳትፎ ሙሉ ለሙሉ በበጎፈቃደኝነት ላይ የተመሠረተ ነዉ፡፡ በዚህ ጥናት ዉስጥ ላለመሳተፍ ከወሰኑ በዚህ የህክምና ቦታ ዉስጥ የሚሰጥዎት አገልግሎት አይቅዋረጥም፡፡ በጥናቱ ለመሳተፍ የሚስማሙ ከሆነ የስምምነት ቅጹ ላይ በጹሑፍ ወይም በጣት ፊርማዎትን ማስቀመጥ ይጠበቅቦታል፡፡

የጥናቱ ተሳታፊ በመሆኔ የሚጠበቅብኝ ምንድንነዉ?

የ ጥናቱ ተሳታፊ በመሆንዎ ምንም ዓይነት ተጨማሪ የደም ናሙናእንዲሰጡ አይጠየቁም። እርስዎ ለምርመራ በሚሰጡት ደም ጥናቱ የሚካሂድ ይሆናል እንጂ አዲስ ናሙና እንዲሰጡ አይጠየቁም፡፡

በዚህ ጥናት መሳተፍ የሚያስገኛቸው ጥቅሞች

በጥናቱ ውጤት መሰረት የላብራቶሪ ውጤቶቹን ለመረዳት ማስተካከያ ይደረግበታል፡፡ ስለዚህም በማሽኖች መቀያየር ምክንያት የሚመጣውን ውጤት መለያየት ያስቀራል ፡፡ በጥናቱ በመሳተፍዎ በተዘዋዋሪ መንገድ ለሌሎች ህሙማን ብሎም ለ ህብረተሰቡ ይጠቅማሉ ማለት ነው።

በዚህጥናትበመሳተፍየሚከፈልክፈያ

በዚህጥናትስለተሳተፉምንምዓይነትክፍያአይከፈልዎትም

የተሳታፊዎችሚስጢርስለመጠበቅ

በመጠየቂያው ወረቀት ላይ የተሳታፊዎች ስም ወይም ማንነት አይገለጽም። በተሳታፊዎች የሚሰጥ ናሙና ለዚህ ጥናት ጥቅም ብቻ የሚያገለግል ይሆናል።

ጥያቄ ካሎዎት

ይህን ጥናት በተመለከተ ወይም ከዚህ ጋራ በተዛመደ መልኩ ስለሚያጋጥሙ ድንገተኛ ችግሮች ወይም ጥያቄ ካሎት በሚከተለዉ አድራሻ ይጠቀሙ፡፡

ሉሊት ኃይሉ

የሕክምና ላብራቶሪ ሳይንስ ት/ክፍል፤ የጤና ሳይንስ ኮሌጅ፤ አዲስ አበባ ዩኒቨርሲቲ

ሞባይል: +251- 09 13 71 00 92

ኢ-ሚይል: lulithailu98@gmail.com ወይም wrsh2000@yahoo.com

የስምምነት መጠየቅያ ቅጽ

የጥናቱ ተሳታፊ መለያ ቁጥር: _____

የዚህ ጥናት ርእስ "በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል በሚገኙት በሚንድሪይ Bc-5380 እና ሲስሚክስ XT- 2000i ሄማቶሎጂ መመርመሪያዎች የሚሰጡትን ውጤት ማወዳደር "ጥናቱ የሚካሄደው በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ይሆናል። እባክዎትን ከዚህ በታች የተዘረዘሩ ነጥቦች በጥሞና ያንቡቡ እና በመጨረሻ በተሰጠው ክፍት ቦታ ይፈርሙ።

1. በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል በሚገኙት በሚንድሪይ Bc-5380 እና ሲስሚክስ XT- 2000i ሄማቶሎጂ መመርመሪያዎች የሚሰጡትን ውጤት ለማወዳደር የሚካየሄደውን ጥናት ዓላማ ተረድቻለሁ።
2. የ ምሰጠው ናሙና ለዚህ ጥናት ብቻ እንደሚዉል አውቂያለሁ።
3. ለጥናቱ የምሰጠው ናሙና እንዲሁም ውጤቱ በሚስጥር እንደሚያዝ ተረድቻለሁ።
4. በ ጥናቱ በመሳተፌ የሚከፈለኝ ክፍያ እንደሌለ ላውቂያለሁ።
5. ሁሉም የሚያስፈልገው ነገር በተመራመረሪው ይብራራልኛል።

ስለዚህ ከላይ የተጠቀሱትን ነጥቦች በመረዳት ናሙና(ደም) ለመስጠት ተስማምቻለሁ።

የተሳታፊ ፌርማ:_____

ቀን:_____

Annex V: Declaration

I, the undersigned, declare that this MSc proposal is my original work, has not been presented for a degree in Addis Ababa University or any other universities. I also declare that all sources of materials used for the proposal have been duly acknowledged.

Name of the candidate: Lulit Hailu (BSc)

Signature_____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____

This proposal has been submitted with my approval as university advisor.

Name of advisor: Dr. Aster Tsegaye (MSc, PhD)

Signature _____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____

This proposal has been submitted with my approval as university advisor.

Name of advisor: Jemal Alemu (MSc)

Signature _____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____