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Performance Evaluation of Cell-Dyn 1800 and Sysmex KX-21 Hematology Analyzers at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia.

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A Thesis submitted to the Department of Medical Laboratory Sciences, College of Health Science, Addis Ababa University, in partial fulfillment of Master of Science Degree in Clinical Laboratory Sciences (Hematology and Immuno-hematology track)

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This is to certify that the thesis prepared by Tibebe Adinew, entitled:

"*Performance Evaluation of Sysmex KX-21 and Cell-Dyn 1800 Hematology Analyzers at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia"* and submitted to in fulfillment of the requirements for the Degree in Master of Science Degree in Clinical Laboratory Sciences (Hematology and Immuno-hematology track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abbreviations

AAU	Addis Ababa University
ART	Antiretroviral Therapy
CBC	Complete Blood Count
CLSI	Clinical Laboratory Standard Institute
CV	Coefficient of Variation
DLC	Differential Leukocyte Count
EDTA	Ethylene Diamine Tetra Acetic Acid
EPHI	Ethiopian Public Health Institute
HCT	Hematocrit
HGB	Hemoglobin
HTV	High Target Value
ICSH	International Council for Standardization in Hematology
ISO	International Organization for Standardization
IRB	Institutional Review Board
MCH	Mean Cell Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Cell Volume
MLT	Medical Laboratory Technology
MPV	Mean Platelet Volume
PCT	Platecrit
PDW	Platelet distribution width
PI	Principal Investigator
PLT	Platelet
RBC	Red Blood Cell

RDW	Red cell Distribution Width
SD	Standard Deviation
SOP	Standard Operating Procedure
SPHMMC	St. Paul's Hospital Millennium Medical College
WBC	White Blood Cell
WHO	World Health Organization

Abstract

Background: To assure the accuracy of results and performance of hematology analyzers, each laboratory must evaluate their performance. Different models of Sysmex and Cell- Dyn analyzers are commonly used in Ethiopia including St' Paul's Hospital Millennium Medical College. However, their performance has not been evaluated in most cases. If hematology analyzers are not verified and evaluated for the specific population they serve the diagnosis of many of diseases and hematology related clinical disorders will be unreliable.

Objective: To evaluate the performance specifications of Cell-Dyn 1800 and Sysmex KX-21 that are found in St. Paul's Hospital Millennium Medical College.

Methods: A hospital based cross-sectional study with purposive sampling technique was used at St. Paul's Hospital Millennium Medical College from April 1 to April 8; 2015. A sample of normal values was used for repeatability, high target values of hemoglobin, RBC, WBC and platelets for linearity and carryover checks with subsequent background count were used. Data were collected using observation checklist and then entry, cleaning and analysis were performed by Microsoft Excel 2007 and SPSS version 20. Percentage, %CV, residual plotting, and Pearson´s correlation coefficient were used to describe the results.

Result: precision check revealed that both Sysmex KX-21 and Cell-Dyn 1800 values fall within the manufacturers' specifications. Linearity verifications of WBC, Hemoglobin, RBC and Platelet showed that both analyzers produced a very good correlation coefficient of > 0.97, which is also confirmed by residual plotting where all the values of the diluted samples surpassed the manufacturers' specifications. As to carryover both analyzers showed an excellent carryover percentage of <1% which surpassed the manufacturers' specifications.

Conclusion: Sysmex KX-21 and Cell-Dyn 1800 met the manufacturer's specifications for precision, linearity and carryover.

1. Background

1.1 Introduction

Automated Hematology analyzers bring one step change to hematological investigations. The first automated hematology analyzer was introduced in 1956 by Wallace Coulter and hence named after his name. The complete blood count (CBC) and differential leukocyte count (DLC) provide valuable information about the blood, used for diagnosis of different diseases including; anemia, leukemia and bleeding tendencies (1). Automated hematology analyzers provide several parameters with a rapid turnaround time and they incorporate flowcytometry and new system technologies (Impedance). Since these analyzers are very basic for a day to day hospital service, they must be evaluated for proper performance according to the specifications provided by the manufacturer (2).

Nowadays, the overwhelming majority of laboratory results in clinical laboratories are being generated by automated analyzers. Modern automated analyzers are highly sophisticated instruments which can produce a tremendous number of laboratory results in a very short time. As a result, the laboratory routine work has diminished significantly. Today laboratory personnel's duties have been shifted from manual work to the verification of automated analyzers, maintenance of the equipment, internal and external quality control, instrument calibration and data management of the generated results (3).

However, even if these automated Hematology analyzers bring a significant change in different aspects of the laboratory activity the instruments could also produce inaccurate results. Thus, they should be evaluated against the specifications of the manufacturer claim to verify that whether the specific instrument meets the manufacturer's specifications at the working site (4).

The International Organization for Standardization (ISO) specifies the need for method verification as per ISO 15189:2011(4). A section of the ISO document 5.5.1.1., for example, states that "The laboratory shall select examination procedures which have been validated for their intended use…The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination"(4).

Moreover, the document under the section 5.5.1.2 states about verification of examination procedures as follows: "Validated examination procedures … shall be subject to independent verification by the laboratory before being introduced into routine use. The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure. The independent verification by the laboratory shall confirm, through obtaining objective evidence that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results" (4).

Clinical Laboratory Standard Institute (CLSI) also, recommends that the end-user laboratory should follow the principles and procedures of the manufacturer's validation protocol to verify that the manufacturer's stated performances are correct for the specific instrument at the working site (5).

In this study, precision (repeatability), linearity and carryover were determined as per the manufacturer's protocol.

Nowadays a number of hematological analyzers are available in the market, which are developed and produced by different companies and countries. The analyzers are validated for the specific characteristics of performance by the manufacturer. But, they should also be verified for those specific characteristics independently at working site in the laboratory by the laboratory personnel to check whether they meet those specific performance characteristics at a certain laboratory set up. This study tried to evaluate the performance characteristics of hematology analyzers, i.e, Sysmex KX-21 and Cell-Dyn 1800 based on the procedures of the developers and against the claims of the manufacturers, which are found in one of the largest referral and teaching hospital of Ethiopia, St. Paul's Hospital Millennium Medical College.

Cell-Dyn 1800: 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 (WBC), red blood cells (RBC), and platelets as they pass through an aperture. Blood cells are nonconductive and are suspended in a conductive isotonic

diluent. As each cell is drawn through the small aperture between two electrodes, a change in electrical resistance occurs generating a voltage pulse. The number of pulses during a cycle corresponds to the number of cells counted while 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 Hemoglobin flow cell to measure Hemoglobin (Hb) concentration (6).

The Cell-Dyn 1800 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. The instrument analyzes 18 parameters in one minute, namely, WBC, RBC, Hb, Hct, MCV, MCH, MCHC, RDW, PLT, MPV, PCT, and PDW (6).

Sysmex KX-21: is an automatic multi-parameter blood cell counter for *in vitro* diagnostic use in clinical laboratories. The Sysmex KX-21 processes approximately 60 samples an hour and displays on the LCD screen the particle distribution curves of WBC, RBC, and platelets, along with data of 18 parameters, as the analysis result (7).

The Sysmex KX-21 performs speedy and accurate analysis of 18 parameters in blood and detects the abnormal samples and employs three detector blocks and two kinds of reagents for blood analysis. The WBC count is measured by the WBC detector block using the DC detection method. The RBC count and platelets are taken by the RBC detector block, also using the DC detection method. The HGB detector block measures the hemoglobin concentration using the non cyanide hemoglobin method (7).

Performance Evaluation is an evaluation that is used to test automated laboratory analyzers for different characteristics against the manufacturer's specifications. In Ethiopia there are limited experiences regarding method verification; so, automated analyzers are being installed and used without doing any performance evaluation tests. CLSI recommends to carryout performance evaluation tests before using any automated hematology analyzers but this was done in our country for a few cases.

1.2 Statement of the problem

Several Hematological Analyzers are found in Ethiopia and provide a great deal of services in different hospitals for many patients. Only few experiences are found regarding the evaluation of the performance of those analyzers. Performance evaluation helps laboratories to determine whether those hematological analyzers met the required specifications which are set by the manufacturer in a certain laboratory environment and specific population they serve. It also assures and maintains the performance of the analyzers and hence quality of services delivered by the laboratory. Thus, if analyzers are not verified for the specific population and environment they serve, the results produced from those analyzers will not be reliable.

St. Paul's Hospital Millennium Medical College is one of those referral hospitals in the country and delivers services for over 200,000 patients annually that come from different parts of the country. The hospital laboratory has two active hematology analyzers; Cell-Dyn 1800 and Sysmex KX-21 that perform complete blood count for over 200 patients daily; however, the analyzers have never been evaluated for the specifications set by the manufacturer. So, this study tried to evaluate the performance of those mentioned analyzers.

1.3 Rationale of the study

St. Paul's hospital Millennium Medical College (SPHMMC) is one of the largest general public hospital and one of the teaching hospitals in the country. It provides medical specialty services to an estimated of over 200,000 people annually as a referral hospital. CBC is the most frequently requested test for many diseases, including those many clients that have follow up in different specialty units. In addition, patients on ART are also regularly referred to the laboratory for CBC monitoring purpose as decisions, including drug regimen change, are made when patients on ART develop macrocytic anemia. Hence, providing a quality service in this hospital assures health care of many people seeking different services in the hospital.

In Ethiopia, there were few studies done regarding performance evaluation of hematological analyzers despite the fact that Cell-Dyn 1800 is widely distributed in different laboratories of the country to provide ART monitoring and other services. Besides, different models of Sysmex hematology analyzers are available in a number of public and private health facilities. For example in St Paul's Hospital there are five hematology analyzers with four brands (Sysmex KX-21-3 part diff, Cell-Dyn 1800 3 Part-Diff, Horiba ES-60 (3 Part diff), Horiba DX-120 (5 part), Mindray 6800 (5 Part diff) of which two of them are actively working.

The study is, therefore, designed to evaluate precision (repeatability), linearity and carryover of Cell-Dyn 1800 and Sysmex KX-21 analyzers according to the manufacturers' principles and procedures. The study will help to recommend corrective actions if there is any difference and to conduct other studies based on these findings. The findings can also be used as an eye opening for other laboratories having different models, and hence facilitate inter-laboratory performance evaluation.

In addition, since SPHMMC laboratory is one of those laboratories participating in WHO AFRO accreditation program, this study will have a profound input to the process.

1.4 Literature Review

ISO 15189 requires all equipment upon installation and in routine use, to be capable of achieving the performance required, and shall comply with specifications relevant to the examinations concerned; and that all methods have to be validated as extensive as are necessary to confirm that they are suitable for the intended use. Automated analyzers (autoanalysers) play an important role in the operation of a medical laboratory, especially in the disciplines of chemical pathology and hematology; and to a lesser extent, clinical microbiology and infection. Hence, laboratories are expected to carry out thorough verification of their autoanalysers as part of method validation before they are put into service (8).

A study conducted on in USA at Saint Louis children's Hospital by Langford et al. in 2003 on Sysmex XT-2000i automated hematology analyzer evaluated precession, linearity, Carryover, method comparison, correlation and stability. Linearity was up to 410 $\times 10^3/\mu L$ for WBC count and up to 6560 $\times 10^3/\mu L$ for PLT counts. The carryover was of minimal magnitude, which is less than 1% for all determinations (9).

Although on a different instrument, a study which was done by Fernandez et al in 2001 at Florida, demonstrated an excellent performance of automated differential count as compared to the manual differential count method. In their study, Fernandez et al were evaluating Coulter LH 750 Hematology Analyzer against the Gen S system analyzer by regression analysis and the mean differences between methods. A total of 383 samples were analyzed. WBC, RBC, Hgb, MCV, Plt, and RDW showed correlation of >0.98, and MPV showed a correlation coefficient of >0.96. The correlation coefficient for WBC was >0.92 while for neutrophils, lymphocytes, and eosinophils the correlation coefficient values were >0.99; for monocytes, >0.97; and for basophils, >0.81; for reticulocytes, >0.90. LH 750 hematology analyzer provides accurate and reliable results over a wide range of normal and abnormal sample types (10).

Another study done by Veillon et al in 2000, at Louisiana State University Health Sciences Center, compared three hematology analyzers; Coulter GenS, Abbott Cell-Dyn 4000 and Bayer Advia 120. The correlation coefficient which is obtained by the study lies on the acceptable range (11).

A similar study conducted in Brazil by Maciel et al. in 2014 to evaluate the analytical performance of Sysmex XE-2100D, based on the recommendations of the document H26-A2 of the CLSI. The study includes intra-run imprecision, inter-run imprecision, linearity, carryover, auto sampler evaluation, clinical sensitivity of the atypical lymphocytes flag, as well as the comparison between automated and manual leukocyte differential count, based on an adaptation of the document H20-A2 of CLSI and using a total sample of 400. The result showed that repeatability, reproducibility, linearity and carryover were satisfactory according to the manufacturer's specifications. The correlation coefficients between the automated and manual differential counts of neutrophils, lymphocytes, monocytes, eosinophils and basophils were 0.991, 0.99, 0.872, 0.974 and 0.557, respectively. So the study concluded that the Sysmex XE-2100D showed excellent analytical performance, and is useful to provide reliable hematology data (12).

As relatively lately introduced in the market, the performance of Mindray BC-6800 (Mindray, China) was evaluated in 2013 by Jo et al in Korea. CBC, WBC differentials, Reticulocyte counts, erythroblast counts and the efficiency of its flag system were among the parameters evaluated. Specimens from 100 healthy controls and 95 patients were used. The precision was <2% for most CBC parameters and <5% for neutrophil, eosinophil, and Reticulocyte counts. BC-6800 showed good precision and correlation with pre-existing hematology analyzers (13).

A study was done in Peking University Hospital, Beijing, China in 2013 by Rui Q, et al. to verify the performance of Beckman Coulter LH750, Mindray BC 5800 and Sysmex XE-2100 in clinical laboratories. They use a total of 15 fresh whole blood specimens. Except platelet inter day precision of BC-5800 analyzers, the rest 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).

Similarly, Peng et al. evaluated Sysmex SE-9500 in West China University, Sichuan, China in 2001. The results demonstrated minimal carryover of <0.01% and excellent linearity for WBC, RBC, HGB and PLT. Samples were stable with regard to CBC parameters after storage for up to

48 hr at room temperature and 4^0C. Imprecision was generally acceptable for all CBC parameters (CV < 5%) (15).

A hospital based study was conducted to evaluate the performance of Mindray BC-5500 hematology analyzer by Qing-jun Alin et al. in 2009 at north China. The analyzer was evaluated in regards to precision, carry-over and linearity. The within-and between-Batch precision and that of the total precision of BC-5500 were all within the designed range. The carryover rate was lower than 0.5%. The linearity was good (16).

Another version Mindray BC-3600 hematology analyzer was evaluated by Shu et al. in a university hospital of China in 2013. They found that there were no background error and minimal carryover (<0.5%) was noted. There was excellent linearity for white blood cell, hemoglobin level, red blood cell, and platelet counts. 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% (17).

The performance of Cell-Dyn 1800 hematology analyzer was evaluated by Ryhanen, et al. in Finland using commercial controls of different levels for precision. Whereas, high patient samples were used for carryover determination under routine conditions. The result showed that the precision of Cell-Dyn 1800 was very good in that the highest CV was 2.8 for low level control of platelet and the smallest CV was 0.3 for low level MCV and its carryover was 0.00% for WBC and 0.37% for platelet. The authors concluded that the Cell-Dyn 1800 fulfilled the specifications set by the manufacturer (18).

Ghys et al. in Belgium evaluated the performance of Sysmex XS-1000i instrument in 2008 according to CLSI and ICSH guidelines. Precision, carry-over and linearity were determined using a total of 700 patient samples and results from the Sysmex XS-1000i were compared with those from Sysmex XE-2100, Abbott Cell Dyn 4000 and also with manual reference leukocyte differential. In all performance determinations and comparisons, the Sysmex XS-1000i demonstrated good analytical performance, is able to generate a complete blood count with five-part differential on low blood volumes and has considerable back-up capacity (19).

As shown in the above literature there are many researches done on the evaluation performance of different models of hematology analyzer and demonstrating good carry over, linearity and precession. However, in our context there are few published reports about evaluating the performance of Hematology analyzers in Ethiopia.

2.0 Objective of the study

2.1. General objective

- To evaluate the performance of Cell-Dyn 1800 and Sysmex KX-21 at St Paul's Hospital Millennium Medical College

2.2. Specific objectives

- To evaluate precession (repeatability or intra-run) of Cell-Dyn 1800 and Sysmex KX-21
- To assess linearity of Cell-Dyn 1800 and Sysmex KX-21
- To evaluate carryover of Cell-Dyn 1800 and Sysmex KX-21

3. Hypothesis

There is no difference between the manufacturer's claim and this verification result for those specified hematology analyzers.

4.0. Materials and Methods

4.1 Study Area

The study was conducted at the second biggest referral hospital, St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia. The hospital is a tertiary level teaching and referral hospital with catchment sub-city coverage of Gullele, Addis Ketema and Kolfe Keraneo. There are 334 beds for inpatients and rendering referral health services for over 200,000 patients annually. The hospital provides inpatient, outpatient and emergency services.

4.2 Study design

A hospital based cross sectional study was conducted at St. Paul's Hospital Millennium Medical College.

4.3 Study Period

The study was conducted from April 2015 to May 2015.

4.4 Samples

4.4.1 Source samples

Blood samples from all Patients who gave blood sample for hematology laboratory investigation at St Paul's Hospital Millennium Medical College from April 1 to April 8, 2015 were the source samples for this study.

4.4.2 Study samples

Left over samples were selected purposely from all patients that gave blood sample for hematology laboratory investigation at St. Paul's Hospital Millennium Medical College within

the specified days. Those which fulfilled the required sample quality criteria and also suitable for the intended purpose of the study were included as study samples.

4.5. Sample size calculation and Sampling procedures

4.5.1 Sample size

The Clinical and Laboratory Standard Institute (CLSI) guideline recommends using the manufacturer's principles and procedures for method verification experiment. Thus, as per the analyzers' manual and procedures for repeatability one sample with all parameters lay in the normal range and no flag was used. For linearity verification, high target value samples of platelet, RBC, Hemoglobin and leukocyte that can cover the whole range of the analytical measuring interval were used. Both high and low value (background count) samples for Hemoglobin, RBC, WBC and Platelet parameters were used for carryover verification and those high target value samples specified above were selected purposively from those leftover samples that fulfilled the required sample quality criteria and manipulated to obtain the best matrix.

4.5.2 Sample processing

The collected samples were analyzed on Cell-Dyn 1800 and Sysmex KX-21 Hematology analyzers by the principal investigator.

4.6 Inclusion and exclusion criteria

4.6.1 Inclusion criteria

Blood samples that were within the acceptable criteria of the laboratory SOP (with proper specimen collection, with proper amount of blood to anticoagulant ratio, non hemolyzed sample, non clotted sample) were included in the study.

4.6.2 Exclusion criteria

Blood samples that did not fulfill the required criteria of the laboratory SOP i.e. those that did not fulfill the inclusion criteria were excluded from the study.

4.7. Study Variable

4.7.1 Dependent variable

Precession (repeatability), linearity, and carryover

4.7.2 Independent variable

Hematological parameters at various categories (low, normal, and above normal)

4.8 Data collection and processing

4.8.1 Sample collection

Fresh whole Blood with over 3 milliliter volume were collected into EDTA anticoagulant containing tubes by phlebotomists at St. Paul's Hospital Millennium Medical College reception following SOPs, and transported to the hematology section of the laboratory immediately.

No additional samples were collected for this study as left over samples of patients was utilized.

4.8.2 Data Collection Procedure

Four medical laboratory technologists together with the principal investigator were involved in data collection. One of the medical technologists together with principal investigator acted as supervisor. The data collectors and supervisor were trained for two days with the objective of uniformity of the data collection and with basic skill of collecting the data. Before the actual data collection, a pre-test was conducted and corrective measures were taken. The precession (repeatability), linearity, and carryover related data were collected.

4.8.3 Principle of Cell-Dyn 1800 Hematology Analyzer

Cell_Dyn 1800 hematology analyzer follows a method of counting and volumetric sizing based on the detection and measurement of changes in electrical resistance produced by a particle suspended in a conductive liquid as it is drawn through a small aperture. It employs the non conductive nature of blood cells (6).

Cell-Dyn 1800

4.8.4 Principle of Sysmex KX-21 Hematology analyzer.

Sysmex KX-21 employs two basic technologies to achieve precise measurements at the micro-liter level. These are sheath flow DC detection in which a constant electric current is passed through a solution; this method measures the changes in electrical resistance that occur when blood cells pass through detection aperture. The second one is flowcytometry which is the measurement of cellular properties as they are moving in a fluid stream (flow), past a stationary set of detectors.

Sysmex KX-21

4.8.5 Quality Assurance

- Samples were checked whether they are in the acceptable criteria like; hemolysis, clotting, volume and collection time.
- Manufacturer procedures and SOP were strictly followed.
- Prior to analysis samples were checked for time of collection.

- Prior to analysis, samples were homogenized and inverted 10-15 times.
- Three levels hematology cell controls (Normal, Low and High) for the respective machines were run.

4.8.6 Data Analysis and Interpretation

Data were entered and analyzed using both Excel 2007 (Microsoft Corporation, USA) and SPSS version 20 (SPSS INC, Chicago, IL, USA). Standard deviation, coefficient of variation, Proportions, percentages, figures and tables were used for the description of the data as appropriate. The Excel 2007 was specially used for calculation of residual plotting and coefficient of variation.

4.8.7 Ethical Consideration

Before the research work, ethical clearance and approval was obtained from St. Paul's Hospital Millennium Medical College Institutional Review Board (IRB) and from Research ethical committee of Addis Ababa University; Department of Medical Laboratory Sciences to use leftover blood samples collected for routine examination. Samples were coded and also confidentiality of patient data was maintained throughout the study.

4.8.8 Dissemination of Result

The final paper primarily will be communicated to St. Paul's Hospital Millennium Medical College laboratory and the respective supply agencies about the results and observed gaps in order to take 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 analyzers. The result will also be disseminated through publication in peer reviewed, local and international journals and through presenting it in relevant workshops and seminars.

4.9. Operational Definition

- **Precession:** is closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions (ISO/IEC Guide 99) and usually expressed numerically by measures of

imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

- **Linearity:** is assuming no constant bias, the ability (within a given range) to provide results that are directly proportional to the concentration of the measured (analyte) in the test sample and performed by diluting fresh whole blood specimen which is suitable for the measurement (WHO BS/95.1793)
- **Carryover**: is a condition that happens when a sample with high target value of analyte has an effect on the subsequent analysis of sample with low target value of analyte and expressed in percentages.

5. Result

Total samples used in this study were twenty; among these two samples were used for precision (within sample), ten samples were used for linearity study, and eight samples were used for carryover study. For precision study samples were selected based on the recommendation of the manufacturer which is a sample where all its parameters lay in the normal range, and for linearity and carryover verifications, samples were manipulated in order to get the best matrix which is needed for the studies. All the samples used for the study were not aged later than four hours of collection.

5.1 Precision (Repeatability) verification:

The objective of this test was to determine the analyzer capacity to reproduce the results for a certain parameter in a given sample. Analysis was carried out in normal conditions, by the same operator, within a short period of time, same location and with the same reagents. In order to fulfill the manufacturer's recommendation, samples to the analytical ranges of normal values and no flags were used. The prepared samples were analyzed 20 consecutive times in the open mode of Cell-Dyn 1800 and Sysmex KX-21. The mean, the standard deviation (SD) and the coefficient of variation (CV) were calculated for each parameter. It is worth highlighting that before samples were analyzed, controls were run and checked for their passing. Prior to the analysis, samples were homogenized and inverted 20 times. Table 1 summarizes the calculated coefficient of variation values of Cell-Dyn 1800 for the five directly measured parameters. As shown in the table, the precision (repeatability) values of the directly measured parameters lie within the verification specification of the manufacturer.

Table 1: Imprecision (within sample variation) of Cell-Dyn 1800 hematology analyzer for directly measured parameters at SPHMMC, Addis Ababa, April 2015.

Parameters*	Mean	Standard deviation (SD)	Coefficient Variation(%CV)	Manufacturer's Specifications
WBC	**6.865**	**0.1089**	**1.6**	**≤2.5**
RBC	**5.1435**	**0.059**	**1.15**	**≤1.7**
Hemoglobin	**15.605**	**0.1191**	**0.76**	**≤1.2**
Platelet	**311.8**	**12.61**	**4.04**	**≤6**
MCV	**93.115**	**0.542**	**0.58**	**≤1.5**

*WBC $x10^9$/L; RBC $x10^{12}$/L; PLT $x10^9$/L; Hb gm/dL; MCV fL

On the other hand, Cell-Dyn 1800 Precision specifications for the WBC differential parameters are given as a range of tolerance for each of the WBC subpopulations. The specification is based on running within-sample precision runs of N=20 fresh whole blood. The Result tolerances for the WBC differential parameters were determined by obtaining the difference of individual results in N=20 determinations of the same sample from the mean of the determinations. Thus, based on the results and range of tolerances given by the manufacturer, the three part differential values LYM%, MID%, and GRAN% for all runs were within the tolerance limit of the manufacturer (Table 2). As shown in the table, the respective values for LYM%, MID%, and GRAN% and their respective mean and tolerance ranges were: 32.76 (29.66, 35.86), 9.5 (7.9,11.1), and 57.75 (54.25,61.25).

Table 2: Imprecision (within sample) of WBC differential* of Cell-Dyn 1800 at SPHMMC, Addis Ababa, April 2015.

Sr. No.	LYM%	MID%	GRAN%
1	33.6	9.7	56.7
2	32.3	9.5	58.2
3	32.4	9.4	58.2
4	32.7	9.9	57.4
5	32.0	9.3	58.7
6	33.1	9.6	57.3
7	31.6	8.8	59.6
8	32.5	9.4	58.1
9	32.2	9.4	58.4
10	33.3	9.3	57.4
11	33.7	9.8	56.5
12	33.0	9.4	57.6
13	32.5	9.1	58.4
14	32.9	8.9	58.2
15	33.9	9.2	56.9
16	32.5	10.1	57.4
17	32.6	9.5	57.9
18	32.9	9.6	57.5
19	32.8	10.6	56.6
20	32.6	9.5	57.9
Means	32.76	9.5	57.75
Specification	±3.1%	±1.6%	±3.5%
Range of tolerance	29.66-35.86	7.9-11.1	54.25-61.25

* LYM= lymphocyte; MID representing mainly monocytes but includes eosinophils, Basophils and other immature cells if any; GRAN= Neutrophils.

Imprecision values of Sysmex KX-21 analyzer for directly measured (WBC, RBC, PLT, Hb, MCV and WBC subpopulations) as measured by the coefficient of variation are shown in Table 3. From the table we can easily understand that all the parameters of fresh whole blood that were found within the reference range and tested for repeatability study had coefficient of variations (%CV) which lay within the manufacturer specifications.

Table 3: Imprecision (within sample variation) of Sysmex KX-21 at SPHMMC, Addis Ababa, April 2015.

Parameters*	Means	Standard Deviation (SD)	Coefficient Variation(%CV)	Manufacturer's Specifications
WBC	**4.385**	**0.081**	**1.85**	**≤3.5**
RBC	**4.906**	**0.037**	**0.75**	**≤2**
Hemoglobin	**13.925**	**0.078**	**0.56**	**≤1.5**
Platelet	**214.55**	**6.74**	**3.14**	**≤6**
MCV	**90.855**	**0.374**	**0.41**	**≤2**
LYM%	**32.865**	**1.085**	**3.3**	**≤15**
MID%	**11.38**	**1.29**	**11.3**	**≤30**
GRAN%	**55.755**	**0.98**	**1.76**	**≤15**

*WBC $x10^9$/L; RBC $x10^{12}$/L; PLT $x10^9$/L; Hb gm/dL; MCV fL

5.2 Carryover verification

Table 4 summarizes carryover result of Cell-Dyn 1800. It indicates, in percentage, how much a sample with high results may falsely raise results of a cytopenic sample that is analyzed subsequently. This evaluation was performed in triplicate of a sample with high concentration of the analyte (H1, H2 and H3), with a subsequent analysis in triplicate of a background count. The percentage of carryover for each parameter was calculated with the following formula: carryover (%) = |L1 - L3|/(H3-L3) × 100. Where L1 and L3 were the results of the first and third measurement of background counts, and H3 was the third measurement of the sample with high concentration. For determination of carryover using the Cell-Dyn 1800, the samples used were based on the manufacturer's specifications of high target value and the result showed

that all the parameters for carryover study were within the acceptable range of the manufacturer's specification (Table 4).

Table 4: Carryover of Cell-Dyn 1800 at SPHMMC, Addis Ababa, April 2015.

Parameters	H3	L1	L3	Carryover result	Manufacturer's Specifications
WBC	**94,100/µl**	**0.3K/ µl**	**0.1K/ µl**	**0.21%**	**<1%**
RBC	**6.21M/µl**	**0.01M/ µl**	**0.00M/ µl**	**0.16%**	**<0.5%**
Hemoglobin	**22.0g/dl**	**0.1g/dl**	**0.0g/dl**	**0.45%**	**<0.8%**
Platelet	**908,000/µl**	**1000/µl**	**0K/ µl**	**0.11%**	**<1%**

For carryover determination of Sysmex KX-21, all the samples were taken based on the manufacturer specification of high target value and the result revealed that all the parameters tested for carryover study lay within the acceptable range of the manufacturer specification (Table 5).

Table 5: Carryover of Sysmex KX-21 at SPHMMC, Addis Ababa, April 2015

Parameters	H3	L1	L3	Carryover result	Manufacturer's Specifications
WBC	**89,500/µl**	**0.1K/ µl**	**0.0/µl**	**0.11%**	**<3**
RBC	**6.15M/µl**	**0.01M/ µl**	**0.00/µl**	**0.16%**	**<1.5**
Hemoglobin	**22.9g/dl**	**0.0g/dl**	**0.0g/dl**	**0%**	**<1.5**
Platelet	**905,000/µl**	**0/µl**	**0/µl**	**0%**	**<5**

5.3 Linearity Verification

A quantitative analytical method is said to be LINEAR when measured results from a series of sample solutions are directly proportional to the concentration in the test specimens and a straight line can be used to characterize the relationship between measured results and the concentrations of analytes. Linearity testing is required for measured analytes only; so, in this study WBC, RBC, Hemoglobin, and Platelets were tested for Linearity and done as follows.

A. Sample Criteria
    1. A minimum of 5 samples that cover the reportable range of the method were prepared by dilution and used.
    2. When plotted, the values are ideally equidistant from each other.
    3. Manipulated fresh whole blood was used in order to obtain the maximum high target value.

B. Testing
    1. Each sample was run twice.

C. Evaluation of data:
    1. Data were plotted in regression analysis using Excel 2007 and all the necessary calculations were done.
        a. The known values of the standards plotted on the X-axis
        b. The mean of the measured values plotted on the Y-axis.
        c. The slope and intercept were calculated using linear regression.
        d. By using slope and intercept, a predicted Y value for each X value was calculated.
        e. The predicted Y values were plotted against the corresponding known X values on the same graph mentioned in a and b above. And a straight line was drawn to connect all the predicted Y points on the graph.
        f. Each measured Y value was subtracted from the associated predicted Y value.

D. Acceptability criteria: if the difference between the predicted Y and measured Y values is less than the allowable error for each specimen point then the method is said to be linear.

One high target value sample that covers most of the reportable ranges was used to test for linearity verification of WBC and Platelet parameters while another sample of low cell count that covers the rest of lower reportable range was employed. These high target value and low target value samples were diluted into five dilutions that are equidistant to each other i.e. 10%, 30%, 50%, 70% and 90% of the undiluted sample and measured twice on each analyzer. The average

of the two was taken as mean measured value. For RBC and Hemoglobin parameters only one sample of high target value that could cover the whole reportable range was used and diluted the same way.

Linearity of Cell-Dyn 1800

Linearity range verified for high target value (HTV) of WBC count of 91,000/µl presented with an excellent correlation coefficient of 0.999 between theoretical and measured values with a regression equation of y=-0.04+0.898x. However, since correlation coefficient values mislead existence of any bias, we determined the residual plot as recommended in the manufacturer's manual (6, 7). Accordingly, as shown in Table 6 and Figure 1, all the measured values which range between -0.22 to 0.12 lie within the manufacturer specification of residuals that is ±0.3 difference between the measured and the predicted values.

Table 6: Cell-Dyn 1800 WBC* Linearity of high reportable range at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				PROB. OUTPUT	
Observation	Predicted	Residuals		Theoretical	Measured
1	8.94	-0.04		10(9.1)	8.9
2	26.9	0.1		30(27.3)	27
3	44.86	0.04		50(45.5)	44.9
4	62.82	-0.22		70(63.7)	62.6
5	80.78	0.12		90(81.9)	80.9

*WBC, $x10^3/\mu L$

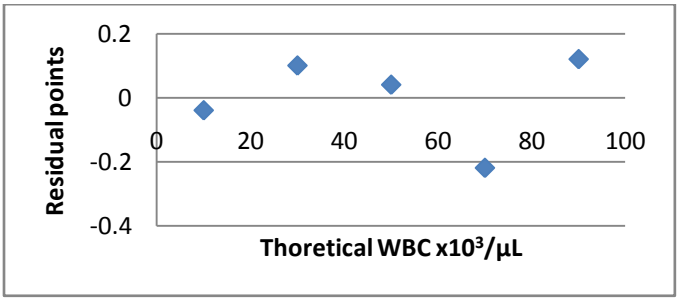

Figure 1: Residual plotting of WBC showing the difference between predicted and measured values on Cell-Dyn 1800 for higher reportable range at SPHMMC, April 2015.

For linearity verification of Cell-Dyn 1800 WBC count of below 10,000/µl, a sample with HTV of 11,000/µl WBC count was used. The result demonstrated an excellent correlation of 0.999

between theoretical values and measured values with a regression equation of y=0.21+0.101x. As stated above, the recommended residual plot was determined and all the measured values lie within ±0.3 of the predicted value (Table 7 and Figure 2).

Table 7: Cell-Dyn 1800 WBC* linearity of low reportable range at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				PROB. Output	
Observation	Predicted	Residuals		Theoretical	Measured
1	1.22	0.08		10(1.1)	1.3
2	3.24	-0.04		30(3.3)	3.2
3	5.26	-0.06		50(5.5)	5.2
4	7.28	-0.08		70(7.7)	7.2
5	9.3	0.1		90(9.9)	9.4

*WBC, $x10^3/\mu L$

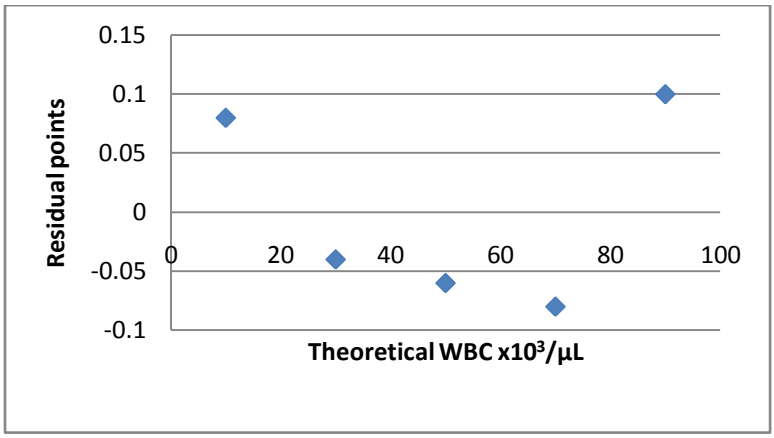

Figure 2: Residual plotting of WBC showing the difference between predicted and measured values on Cell-Dyn 1800 for lower reportable range at SPHMMC, April 2015.

Verification of Cell-Dyn 1800 for Platelet of High target value of 825,000 presented an excellent correlation coefficient of 0.999 and a regression equation of y=3.15+8.205x. As shown in Table 8 and Figure 3, the recommended residual plotting also revealed that all the measured values fall within the assigned specification of the manufacturer ±12.

Table 8: Cell-Dyn 1800 Platelet* linearity of high reportable range at SPHMMC, Addis Ababa, April 2015

Residual output				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	85.2	-10.2		10(82.5)	75
2	249.3	7.7		30(247.5)	257
3	413.4	11.6		50(412.5)	425
4	577.5	-5.5		70(577.5)	572
5	741.6	-3.6		90(742.5)	738

*PLT, $x10^3/\mu L$

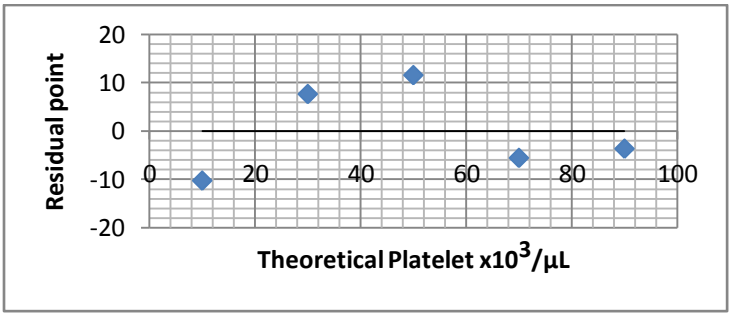

Figure 3: Residual plotting of Platelet showing the difference between predicted and measured values on Cell-Dyn 1800 for higher reportable range at SPHMMC, April 2015.

For Linearity verification of Cell-Dyn 1800 for Platelet count below 80,000/µl, a sample with HTV of 74,000/µl platelet count was used and provides an excellent correlation of 0.986 between theoretical values and measured values with a regression equation of y=1.95+0.685x. The recommended residual plot also revealed that the measured values lie within ±12 of the predicted value (Table 9 and Figure 4).

Table 9: Cell-Dyn 1800 Platelet* linearity of low reportable range at SPHMMC, Addis Ababa, April 2015

Residual output				probability	
Observation	Predicted	Residuals		Theoretical	Measured
1	8.8	-2.8		10(7.4)	6
2	22.5	2.5		30(22.2)	25
3	36.2	2.8		50(37.0)	39
4	49.9	-1.9		70(51.8)	48
5	63.6	-0.6		90(66.6)	63

*PLT, $x10^3/\mu L$

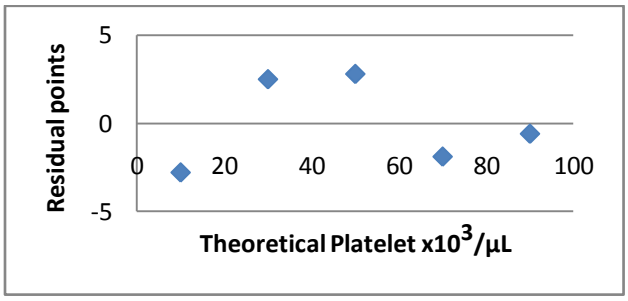

Figure 4: Residual plotting of Platelet showing the difference between predicted and measured values on Cell-Dyn 1800 for lower reportable range at SPHMMC, April 2015.

Linearity verification of Cell-Dyn 1800 for RBC for HTV 6.52M/µl presented an excellent correlation coefficient of 0.998 between theoretical and measured values with a regression equation of y=-0.089+0.0673x. Besides, all the measured values lie within the acceptable range of ±0.1 of the corresponding predicted values using the residual plotting (Table 10 and Figure 5).

Table 10: Cell-Dyn 1800 RBC* linearity at SPHMMC, Addis Ababa, April 2015

Residual output				probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	0.584	0.016		10(0.65)	0.6
2	1.93	-0.08		30(1.96)	1.85
3	3.276	0.044		50(3.26)	3.32
4	4.622	0.088		70(4.56)	4.71
5	5.968	-0.068		90(5.87)	5.9

*RBC, x106/µL

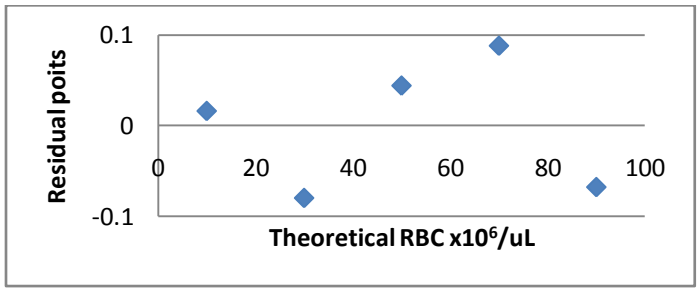

Figure 5: Residual plotting of RBC showing the difference between predicted and measured values on Cell-Dyn 1800 at SPHMMC, April 2015.

Hemoglobin linearity verification of Cell-Dyn 1800 for HTV 22.1gm/dl presented an excellent correlation coefficient of 0.999 between theoretical and measured values with a regression equation of y=-0.41+0.225x. As shown in Table 11 and Figure 6, using the recommended residual plot all the measured values also fall within the acceptable range of the manufacturer specification of ±0.2.

Table 11: Cell-Dyn 1800 Hemoglobin* linearity at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	1.84	0.16		10(2.21)	2
2	6.34	-0.14		30(6.63)	6.2
3	10.84	-0.04		50(11.05)	10.8
4	15.34	-0.14		70(15.47)	15.2
5	19.84	0.16		90(19.89)	20

*Hb, gm/dL

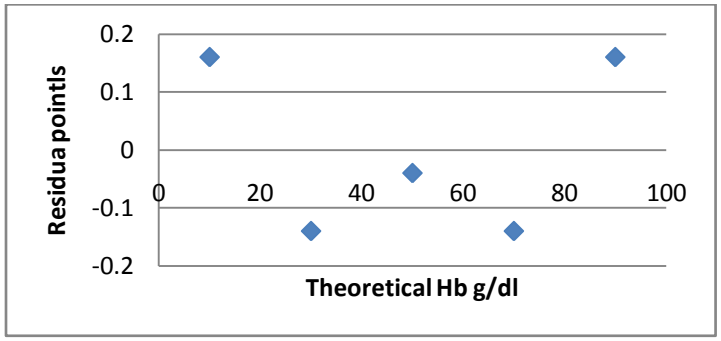

Figure 6: Residual plotting of Hemoglobin showing the difference between predicted and measured values on Cell-Dyn 1800 at SPHMMC, April 2015.

Linearity Results for Sysmex KX-21

Linearity verification of Sysmex KX-21 for high target value of 93,000/µl WBC count presented an excellent correlation coefficient of 0.999 between theoretical and measured values with a regression equation of y=-0.46+0.93x. In addition, uaing the recommended residual plot all the measured values lie within the acceptable limit of the manufacturer specification of ±0.3 (table 12 and Figure 7).

Table 12: Sysmex KX-21WBC* linearity of high reportable range at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	8.84	0.16		10(9.3)	9
2	27.44	-0.24		30(27.9)	27.2
3	46.04	-0.04		50(46.5)	46
4	64.64	0.16		70(65.1)	64.8
5	83.24	-0.04		90(83.7)	83.2

* WBC, x103/µL

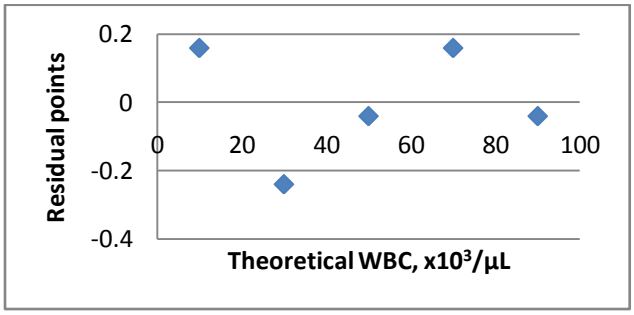

Figure 7: Residual plotting of WBC showing the difference between predicted and measured values on Sysmex KX-21for higher reportable range at SPHMMC, April 2015.

Verification of Sysmex KX-21 for the low WBC count of 10,500/µl showed an excellent correlation coefficient of 0.997 between theoretical and measured values with a regression equation of y=-0.08+0.104x. As shown in Table 13 and Figure 8 all the residuals lie within the acceptable range of the specification of ±0.3.

Table 13: Sysmex KX-21 WBC* linearity of low reportable range at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	0.96	-0.06		10(1.05)	0.9
2	3.04	-0.04		30(3.15)	3
3	5.12	0.28		50(5.25)	5.4
4	7.2	-0.2		70(7.35)	7
5	9.28	0.02		90(9.45)	9.3

*WBC, $x10^3/\mu L$

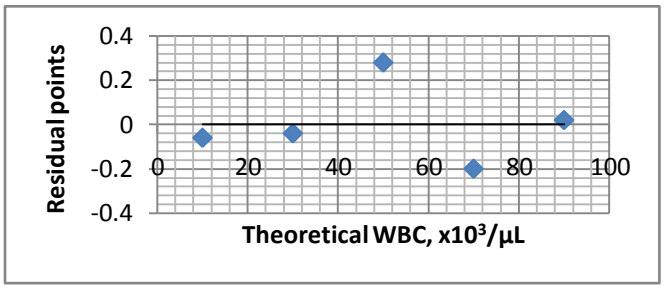

Figure 8: Residual plotting of WBC showing the difference between predicted and measured values on Sysmex KX-21for lower reportable range at SPHMMC, April 2015.

Verification of Sysmex KX-21 for Platelet of High target value of 889,000 presented an excellent correlation coefficient of 0.999 and a regression equation of y=-8.1+9.03x. Again all the measured values found within the assigned specification of the manufacturer ±10 as shown in the plot and table (Table 14 and Figure 9).

Table 14: Sysmex KX-21 Platelet* linearity of high reportable range at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	82.2	-2.2		10(88.9)	80
2	262.8	8.2		30(266.7)	271
3	443.4	-3.4		50(444.5)	440
4	624	-9		70(622.3)	615
5	804.6	6.4		90(800.1)	811

*PLT, x10^3/µL

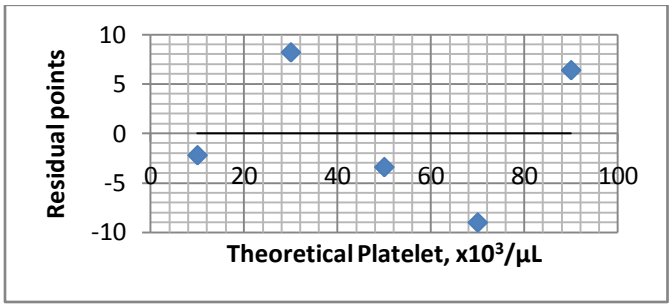

Figure 9: Residual plotting of Platelets showing the difference between predicted and measured values on Sysmex KX-21for higher reportable range at SPHMMC, April 2015.

Linearity verification of Sysmex KX-21 for low Platelet count of 90,000/µl provided an excellent correlation coefficient of 0.973 between theoretical values and measured values with a regression equation of y=1.85+0.855x and all the measured values lie within ±10 of the predicted value as the specification.

Table 15: Sysmex KX-21 Platelet* Linearity of low reportable range at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	10.4	-3.4		10(9)	7
2	27.5	5.5		30(27)	33
3	44.6	-3.6		50(45)	41
4	61.7	4.3		70(63)	66
5	78.8	-2.8		90(81)	76

*PLT, $x10^3/\mu L$

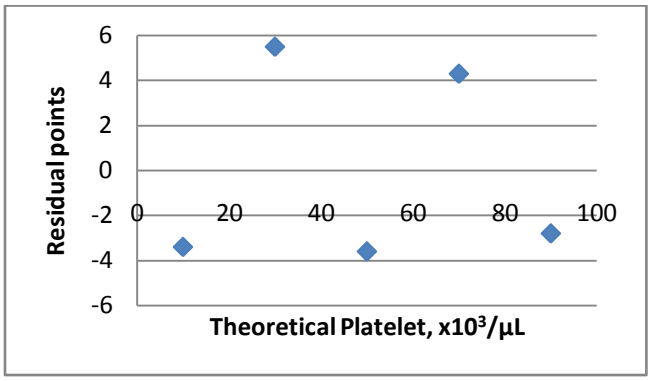

Figure 10: Residual plotting of Platelets showing the difference between predicted and measured values on Sysmex KX-21for lower reportable range at SPHMMC, April 2015.

Linearity verification Sysmex KX-21 for RBC of HTV 6.8M/µl presented an excellent correlation coefficient of 0.999 between theoretical and measured values with a regression equation of y=0.0745+0.063x. As shown in Table 16 and Figure 11 all the measured values lie within the acceptable range of ±0.05 of the corresponding predicted values.

Table 16: Sysmex KX-21 RBC* linearity at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	Measured
1	0.702	-0.012		10(0.68)	0.69
2	1.957	0.003		30(2.04)	1.96
3	3.212	-0.002		50(3.4)	3.21
4	4.467	0.043		70(4.76)	4.51
5	5.722	-0.032		90(6.12)	5.69

*RBC, $x10^6/\mu L$

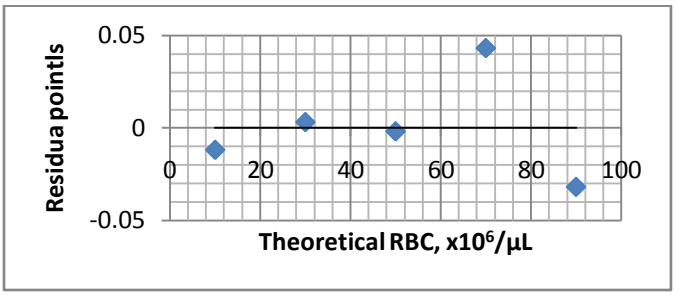

Figure 11: Residual plotting of RBC showing the difference between predicted and measured values on Sysmex KX-21 at SPHMMC, April 2015.

Hemoglobin linearity verification of Sysmex KX-21 of HTV 24.2gm/dl presented an excellent correlation coefficient of 0.999 between theoretical and measured values with a regression equation of y=0.48+0.245x. In addition, all the measured values falls within the acceptable range of the manufacturer specification of ±0.2 (Table 17 and Figure 12).

Table 17: Sysmex KX-21 Hemoglobin* linearity at SPHMMC, Addis Ababa, April 2015

RESIDUAL OUTPUT				Probability output	
Observation	Predicted	Residuals		Theoretical	measured
1	2.93	-0.03		10(2.42)	2.9
2	7.83	-0.03		30(7.26)	7.8
3	12.73	0.17		50(12.10)	12.9
4	17.63	-0.13		70(16.94)	17.5
5	22.53	0.02		90(21.78)	22.55

*Hemoglobin; gm/dl

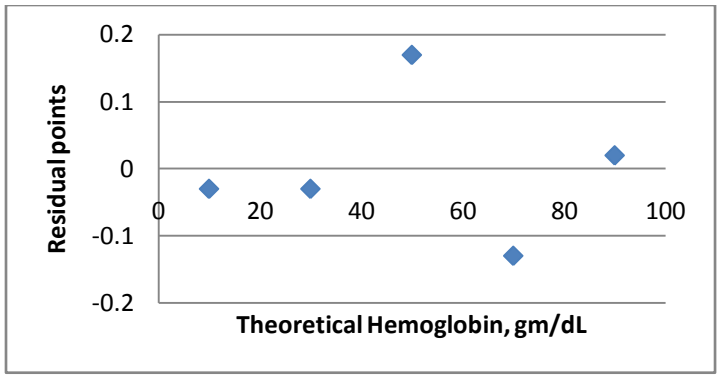

Figure 12: Residual plotting of Hemoglobin showing the difference between predicted and measured values on Sysmex KX-21 at SPHMMC, April 2015.

6. Discussion

This study generally focuses on three specific objectives that aim to evaluate performance of hematologic analyzers against their specifications that are provided with the manual of the manufacturer to the end user laboratory. This study documents within sample precision or repeatability, carryover, and linearity.

Precision is computed to check how the results of a sample that is carried out in similar conditions of same reagent, same location of analyzers and same operator are dispersed. In this study the sample which is used for precision evaluation is a reference sample that run for twenty times and the mean, standard deviation and coefficient variation of the twenty results are calculated and compared with the manufacturer's specification. Accordingly, the coefficient of variation of all the parameters of both analyzers become within the manufacturer's specification. Method of precision evaluation of WBC subpopulations between Cell-Dyn 1800 and Sysmex KX-21 is different; for Cell-Dyn 1800 the specifications for differential counts are given in terms of range of tolerance of percentage for each WBC subpopulations and for Sysmex KX-21 the specifications are given in terms of coefficient of variation(6, 7). But generally both Cell-Dyn 1800 and Sysmex KX 21 surpassed the manufacturer's specifications (7).

The precision specifications of Sysmex KX-21 utilized in the present study and that by Langford et al on Sysmex XT-2000i (9) use same procedure. When results are evaluated against manufacturer's specifications of %CV, both verification studies presented results that surpassed the manufacturer specifications. Cell Dyn 1800 also uses and resulted similar results with the above analyzers even if precision of differential counts are verified using ranges of tolerance. Ghys et al evaluated the precision of Sysmex XS-1000i by using patient samples of different levels and the result showed that within run imprecision was less than 3% except for extreme low level for WBC, hemoglobin and platelets; but all results were within specifications of the manufacturer (19).

On the other hand, Maciel et al evaluates Sysmex XE 2100D using different level of samples; using normal range sample, low count samples and high count samples the precision was carried out only for WBC and platelet parameters and brought similar result as our study. However,

results for low counts presented a high %CV and did not meet the manufacturer specification (12). Our study uses normal range samples only as it is recommended by the manufacturer user's manual and also since the specifications for low and high count samples are not given it is inappropriate to evaluate these two types of samples using a specification given for normal range samples. That may be the reason why their finding did not agree in case of low and high count samples.

Carryover check to measure the effect of high target value of some parameters on the subsequent cytopenic sample was one of the specific objectives of this study. Carryover evaluation presented result for both Sysmex KX-21 and Cell-Dyn 1800 with all the four directly measured parameters, i.e. WBC, RBC, Platelets and Hemoglobin fall within their respective specifications of the manufacturer. Likewise, a recent study conducted by Maciel et al (12) provided carryover evaluation result of Sysmex XE 2100D all the four directly measured parameters lie below 1%.

This finding also agrees with the finding of from high to low carryover of less than 0.5 for all tested parameters that was reported by Ghys et al for Sysmex XS-1000i (19). Moreover, Langford et al evaluated the effect of high target value of WBC, RBC, Hemoglobin and Platelet on the subsequent cytopenic sample using Sysmex XT 2000i and the result showed an excellent carryover for all parameters in that all become less than their respective specifications in agreement with our finding (9). There are limited studies evaluating Cell_Dyn 1800. Kendall et al reported that background and carryover were shown to be consistent with the performance specification (18).

Linearity was checked for four parameters that are directly measured and most studies use only the linear regression and report their results using correlation coefficients; but almost all users manuals put linearity specification not in correlation coefficient rather they use range tolerance that could measure whether each of the values of the diluted sample fall within those ranges or not (6, 7). Accordingly, this study employs such method and hence linearity of each parameter is checked by not only observing the correlation coefficient rather using range tolerance (residual plot) as recommended in the manufacturer's manual. The residual plot expresses the results as how each measured value of the equidistant dilutions are far from the predicted value which is

computed based on the regression of theoretical and measured values of dilutions of high target values of each parameters that are measured directly by the analyzers.

The correlation coefficient and linear regression of the measured and theoretical values are also calculated but these measurements only tell us how the two variables affect to each other. The study done by Maciel et al on Sysmex XE 2100D presented only correlation coefficient and linear regression equation of the theoretical values and measured values, a limitation shared by most studies, and stated that since all the correlation coefficients are near to one (0.999), the linearity of that parameter is acceptable (12). A study done by Langford et al (9) on Sysmex XT-2000i also presented a linearity result of correlation coefficient of one for WBC and Platelet parameters and stated to have a very good linearity result.

Similarly, the linearity study done by Ghys et al used linear regression only as presented by correlation coefficient and stated that all tested parameters showed an excellent linearity result of $\geq$0.99 even at lower range of tested parameters of platelet and WBC. However, our finding is strong in that even if the correlation coefficients lie between 0.97-0.999, to overcome the limitations of earlier studies (9, 12, 19), the residual plot is performed and each dilution is evaluated against the manufacturer's specifications (6, 7). Consequently, all the parameters and each measured dilutions were evaluated to check whether individual diluted samples surpassed the stated linearity specifications of the manufacturer from the predicted value of each diluted sample. As a result all the parameters and its individual diluted samples surpassed the stated residual plot of the manufacturer.

7. Strength and limitation of the study

Strength:

- Samples run in duplicates
- Linearity test of lower range of WBC and Platelets were covered independently
- Residual tolerance determined

Limitation:

- Limited studies are available on similar analyzer models, making comparison difficult

8. Conclusion and Recommendation

8.1. Conclusion

From this study it is possible to conclude that the verification of Sysmex KX-21 and Cell-Dyn 1800 hematology analyzers for linearity, carryover and precision have produced similar results in accordance with the specifications given by the manufacturer.

Taken together, the findings revealed that the two analyzers fulfilled the manufacturer's specifications. Thus, the analyzers in St Paul's Hospital have to be checked periodically; especially for patients on ART monitoring or patients who may need regular monitoring of hematological parameters.

8.2. Recommendation

- Every analyzer has to be verified for the manufacturer's specifications during installations as per the manufacturer's recommendations.
- When the current study was carried out, two of the hematology analyzers of St paul's Hospital with different models were not functional; thus further evaluation is recommended whenever these instruments become functional to evaluate their performance.

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Annexes

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

Participant Information sheet

St' Paul's Hospital Millennium Medical College

Laboratory Department

You are invited to participate in a study to be conducted in SPHMMC by Tibebe Adinew a master's student of Addis Ababa University at the Department of Medical Laboratory Sciences and working at the hospital's laboratory. Please read the following statements and ask any unclear points before you agree to participate.

Introduction

The topic of the study is "Performance Evaluation of Cell dyn 1800 and Sysmex KX 21 at St.Paul's Hospital Millennium Medical College, 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 collection 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 that will be obtained from the research, either the laboratory will maintain its performance as previous or a kind of interventions or corrections will be made. Hence, you are indirectly benefiting yourself, other patients and the society as a whole from provision of quality laboratory service.

Compensation for participation

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

Confidentiality

Your name and identity on the request paper will be changed to confidentiality code for the purpose of this study. 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.

Tibebe Adinew

Department of Medical Laboratory St' Paul's Hospital Millennium Medical College

Cell phone: +251- 9 12 04 43 71

Email: tibebeadinew@gmail.com

Consent form

This page contains an agreement signature to participate in the study entitled "Performance Evaluation of Cell-Dyn 1800 and Sysmex KX-21 at St. Paul's Hospital Millennium Medical College, 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 on "Performance evaluation of Cell-Dyn 1800 and Sysmex KX-21 at St. Paul's Hospital Millennium Medical College, 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 the phlebotomist and Principal investigator.

6. I understand that my participation is voluntary and can withdraw anytime from the study and this will not affect the service I am getting from the hospital.

Therefore, with full understanding of the situations I agree the leftover samle can be used for this study.

Signature of the participant: _____

Address of the participant: _____

Date: _____

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

በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ህክምና ኮሌጅ ላቦራቶሪ ክፍል

በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ኮሌጂ በህክምና ላቦራቶሪ ክፍል ውስጥ የመመርመሪያዎችን ጥራት ለመጠበቅ በአዲስ አበባ ዩኒቨርስቲ የማስተርስ ተማሪና የሆስፒታሉ ሠራተኛ በሆነው ጥበበ አድነው በሚደረግ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል፡፡ እባክዎ በዚህ ጥናት ላይ ከመሳተፍዎ በፊት ከዚህ ቀጥሎ የሚገኘዉን ምንባብ በጥሞና ያንብቡ/ይመልሱ ፤ ግልፅ ያልሆነ ነገር ካጋጠመዎት ይጠይቁ፡፡

መግቢያ

የጥናቱ አላማ በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ህክምና ኮሌጅ ላቦራቶሪ ክፍል ውስጥ የሚገኙትን የመመርመሪያ እቃዎችን ጥራት መጠበቅ ሲሆን፤ እርስዎ በዚህ ጥናት ላይ የሚኖሮት ተሳትፎ ሙሉ ለሙሉ በበጎ ፈቃደኝነት ላይ የተመሠረተ ነዉ፡፡ በዚህ ጥናት ዉስጥ ላለመሳተፍ ከወሰኑ በዚህ የህክምና ቦታ ዉስጥ የሚሰጥዎት አገልግሎት አይቋረጥም፡፡ በጥናቱ ለመሳተፍ የሚስማሙ ከሆነ የስምምነት ቅጹ ላይ በጹሑፍ ወይም በጣት ፊርማዎትን ማስቀመጥ ይጠበቅቦታል፡፡

የጥናቱ ተሳታፊ በመሆኔ የሚጠበቅብኝ ምንድንነዉ?

የጥናቱ ተሳታፊ በመሆንዎ ምንም ዓይነት ተጨማሪ የደም ናሙና እንዲሰጡ አይጠየቁም። እርስዎ ለምርመራዎ በሚሰጡት ደም ጥናቱ የሚካሂድ ይሆናል እንጂ አዲስ ናሙና እንዲሰጡ አይጠየቁም፡፡

በዚህ ጥናት መሳተፍ የሚያስገኛቸው ጥቅሞች

በጥናቱ ውጤት መሰረት የላብራቶሪ እቃዎችን ደረጃ በማወቅ እንዲሁም አስፈላጊ ሆኖ ከተገኘ ማስተካከያ ይደረግበታል፡፡ ስለዚህም በማሽኖቹ ተሰርቶ የሚወጣው ውጤት ጥራቱን የጠበቀ ይሆናል፡፡ በጥናቱ በመሳተፍዎ ለራስዎ ለሌሎች ህሙማን ብሎም ለህብረተሰቡ ይጠቅማሉ ማለት ነው።

በዚህ ጥናት በመሳተፍ የሚከፈል ክፍያ

በዚህ ጥናት ስለተሳተፉ ምንም ዓይነት ክፍያ አይከፈልዎትም

የተሳታፊዎች ምስጢር ስለመጠበቅ

ለጥናቱ ሲባል በመጠየቂያው ወረቀት ላይ ያለውን የርስዎን ስምም ሆነ ማንነት ወደ ሚስጥራዊ ቁጥር ይቀየራል. እንዲሁም የሰጡት ናሙናም ሆነ መረጃ ከዚህ ጥናት ውጪ ለሌላ አላማ ጥቅም አይውልም፡፡

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

በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ህክም ኮሌጅ ላቦራቶሪ ክፍል

ጥበብ አድነው ሞባይል: +251- 9 12 04 43 71

ኢ-ሚይል: tibebeadinew@gmail.com

የስምምነት መጠየቅያ ቅጽ

የጥናቱ ተሳታፊ መለያ ቁጥር፡ _____

የዚህ ጥናት አላማ በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ሜዲካል ኮሌጂ በህክምና ላቦራቶሪ ክፍል ውስጥ የመመርመሪያዎችን ጥራት መጠበቅ ሲሆን "ጥናቱ የሚካሄደው "በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ሜዲካል ኮሌጅ ውስጥ ይሆናል። እባክዎትን ከዚህ በታች የተዘረዘሩ ነጥቦች በጥሞና ያንብቡ እና በመጨረሻ በተሰጠው ክፍት ቦታ ላይ ይፈርሙ።

1. በቅዱስ ጳውሎስ ሆስፒታል ሚልኒየም ሜዲካል ኮሌጂ በህክምና ላቦራቶሪ ክፍል ውስጥ የመመርመሪያዎችን ጥራት ለመጠበቅ የሚካሄደውን ጥናት ዓላማ ተረድቻለሁ።
2. የምሰጠው ናሙና አስፈላጊው ምርመራ ከተካሄደ በኋላ ለዚህ ጥናት እንደሚዉል አውቂያለሁ።
3. ለጥናቱ የምሰጠው ናሙና እንዲሁም ውጤቱ በሚስጥር እንደሚያዝ ተረድቻለሁ።
4. በጥናቱ በመሳተፌ የሚከፈለኝ ክፍያ እንደሌለ አውቂያለሁ።
5. ሁሉም የሚያስፈልገው ነገር በተመራማሪው በኩል ተብራርቶልኛል።
6. በዚህ ጥናት ላይ የሚኖረኝ ተሳትፎ ሙሉ ለሙሉ በበጎ ፈቃደኝነት ላይ የተመሠረተ መሆኑን፣ በማንኛውም ጊዜ ማቋረጥ እንደምችልና በዚህ ጥናት ዉስጥ በመሳተፌ በዚህ የህክምና ቦታ ዉስጥ የሚሰጠኝ አገልግሎት እንደማይቋረጥ ተረድቻለሁ::

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

የተሳታፊ ፊርማ፡_____

ቀን፡_____

Annex III: 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:

- Stable at room temperature until the expiration date on the container.
- Protect from direct sunlight, extreme heat, and freezing during storage.
- Do not use if reagent has been frozen.

2. Cell-Dyn Lytic Agent:

- Stable at room temperature until the expiration date on the container.
- Protect from direct sunlight, extreme heat, and freezing during storage.
- Do not use if reagent has been frozen.

3. Cell-Dyn Detergent:

- Stable at room temperature until the expiration date on the container.
- Protect from direct sunlight, extreme heat, and freezing during storage.

- Do not use if reagent has been frozen.

4. Enzymatic Cleaner:

- Stable at 2-8°C until the expiration date on the container.
- Do not use if reagent has been frozen.

5. Cell-Dyn Whole Blood QC:

- Unopened QC vials are stable at 2-8°C until the expiration date on the vial. Opened QCvials are Stable at 2-8°C for 7 days after opening. Do not use expired QC.
- Allow QC to sit at room temperature for fifteen minutes before testing.
- Mix QC vial by rolling the vial between palms for 20 seconds.
- Invert the vial and roll it back and forth for another 20 seconds.
- Gently invert the vial 10 times.
- Do not shake.
- Continue to mix in this manner until cells are completely suspended (3-5 times).
- Gently invert the pre-mixed vial 5 times immediately before testing.
- Return vial to refrigerator when testing is complete.

6. Whole Blood Calibrator:

- 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.
- Allow the calibrator to sit at room temperature for fifteen minutes before testing.
- Mix the calibrator vial by rolling the vial between the palms for 20 seconds.
- Invert the vial and roll it back and forth for another 20 seconds.
- Gently invert the vial 10 times.
- Do not shake.
- Continue to mix in this manner until cells are completely suspended (3-5 times).
- Gently invert the pre-mixed vial 5 times immediately before testing.
- Return vial to refrigerator when calibration is complete.

Annex IV: Procedure and reagent of Sysmex KX-21 Hematology Analyzer

Sysmex KX-21 Hematology Analyzer

Procedure

Analysis Mode

Whole blood mode: This is the mode of analyzing collected blood sample in the whole blood status. The tubecap is opened and the sample is aspirated through the sample probe one after another.

Pre-diluted mode: This mode is used in analyzing a minute amount of child's blood, for instance, collected from the earlobe or fingertip. In this mode, blood sample diluted into 1:26 before analysis is used. The sample aspiration procedure is the same as in the whole blood mode.

PROCEDURES IN EACH ANALYSIS MODE

With this instrument, sample mixing, cap removal, and tube setting are performed manually and Sample analysis can be executed when the instrument is in the Ready status.

Whole Blood (WB) Mode

Samples are processed in the following steps:

- Collecting and preparing samples
- Selecting whole blood mode
- Inputting sample No.

- Analyzing samples

Collecting and preparing samples

A specified amount of sample, corresponding to the amount of EDTA anticoagulant, is collected from the vein. Tubes up to 80 mm in height should be used. The volume of sample that can be aspirated is 50µl.

Analyzing samples

- Mix the sample sufficiently
- Remove the plug while taking care not to allow blood scatter
- Set the tube to the sample probe, and in that condition, press the start switch
- The buzzer sounds two times - "beep, beep" - and when the LCD screen displays "Analyzing," remove the tube. After that, the unit executes automatic analysis and displays the result on the LCD screen. Then the unit turns to the Ready status, becoming ready for analysis of the next samples.
- When the LCD screen displays "Ready," prepare the next samples and repeat the above procedures.

Pre-Diluted (PD) Mode

In this mode, a sample is diluted into 1:26 before analysis. This mode is applied in analyzing a capillary blood collected from the earlobe or fingertip. Samples are processed by the following steps:

- Collecting and preparing samples
- Preparing analysis samples in PD mode (dilution of 1:26)
- Selecting Pre-Diluted mode
- Inputting sample no.
- Analyzing samples

Collecting and preparing samples: Dilute samples to the ratio of 1:26 using CELLPACK dispensed beforehand in containers. [Example] 20 µL of blood is diluted in 500 µL of CELLPACK.

Tubes up to 80 mm in height should be used. The volume of sample is as follows:

- Volume of whole blood required Approx. 20 µL or more
- Volume of sample aspirated Approx. 200 µL

Preparing analysis samples in PD mode (1:26 Dilution)

- Clean a container such as erlenmeyer flask, beaker, etc. with CELLPACK and removeany dirt.
- Using a syringe, etc., take CELLPACK into a cleaned container.
- Using a 500 µL transfer pipette, dispense 500 µL of CELLPACK into a micro-tube.
- Using a capillary tube, etc., collect 20 µL of blood and dispense it into the micro-tube.
- Attach the cap and mix well.

When preparing a 1:26 dilution sample, use the tools listed below:

- Diluent (CELLPACK)
- Micro-tube (MT-40, etc.)
- Capillary tube
- A 500 µL transfer pipette
- A container, such as erlenmeyer flask or beaker
- A syringe

Analyzing Samples: to analyze the sample in Prediluted Mode, first switch the analyzer to Prediluted mode and follow the procedure as Whole Blood analysis.

Reagents of Sysmex KX-21

CELLPACK: is ready to use for impedance and photoelectrical analysis of whole blood, its ingredients are: sodium chloride, boric acid, sodium tetra borate, EDTA-2K

STROMATOLYZER WH: is ready to use lysing reagent to analyze the leucocytes by lysing the RBC and left the WBC Free and easy to count; whole blood sample by resistance

measurement and photometric measurement, and its ingredients are: non ionic surfactant, organic quaternary ammonium salt

CELLCLEAN: is a strong alkaline detergent to remove lysing reagents, cellular residuals and blood proteins remaining in the hydraulics of 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