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Comparison of Performance and Precision of Advia 2120i and XT 2000i Analyzers

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Abstract

A full blood count is a hematology test commonly used by clinicians to screen for disorders such as anemia, infections, and bleeding. A statistical analysis of results from the two instruments used at Kimberley National Health Laboratory Service will be conducted to determine which analyzer produced the most reliable results. This will help minimize the expenses and resources spent on using both analyzers that are designed to give the same outcomes.

The results of external quality control samples from two FBC instruments will be re-evaluated to compare precision and accuracy. An informed decision will be made based on the reliability and accuracy of results according to PTS in use. Statistical QC uses statistics such as mean and SD to monitor and evaluate method performance. ISO 9001 (2015) QMS states that precision is calculated and discussed in terms of standard deviation (SD) and coefficient of variation (CV). A precise and closely clustered data set has a smaller SD and is generally more reliable than one that is widely distributed. The mean measures accuracy. Both analyzers gave precise and accurate results by reproducing repeatable results which were too close to the true value. However, XT2100i showed better performance as compared to Advia 2120i.

Keywords: Full blood count, Precision, Accuracy, XT2100i, Advia 2120i

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Introduction

A full blood count (FBC) is a hematological test done on a whole blood sample. This is a test commonly requested by physicians as part of a general screen in patients, to screen for disorders such as anemia, infection, and bleeding. The full blood count provides information about the type and number of cells in the blood [1]. The three main components of blood are red blood cells (RBC), white blood cells (WBC), and platelets (PLT) all suspended in plasma. Red blood cells are cells that contain a protein known as hemoglobin which carries oxygen and is transported in these red blood cells to the tissues throughout the body [2]. White blood cells are cells that help the body fight against infections and platelets help in the blood clotting process [3].

Red blood cell count can decrease with increased loss of fluid or can be increased due to bone marrow overproduction. Hemoglobin can increase with high red cell production or decrease when the patient is anemic. White blood cells increase when there is infection, inflammation, or overproduction (leukemia) and can decrease because of some medications, some viral or severe infections, or because of bone marrow failure. Platelets increase after bleeding, inflammation, and infection or in patients who have an underactive or absent spleen. Decreased numbers of platelets are associated with immune conditions such as ITP, SLE, some drugs especially chemotherapy, liver disease, and enlarged spleen or bone marrow disorders [4].

For the most accurate and reproducible FBC results, a whole blood specimen collected in an EDTA tube is

analyzed using the most recent technology and advanced automated hematological analyzers. At National Health Laboratory Services (NHLS) Kimberley, there are two of these analyzers used. One analyzer is an Advia 2120i from Siemens and the other one is XT 2000i from Sysmex. These instruments are flow cytometry-based systems that use a light scatter, differential WBC lysis, and reticulocyte count (immature stage of RBC) to provide a full blood count [5]. The unique RBC indices are directly measured using a mathematical principle that provides an equation for the analysis of light scattering [1, 6]. Both these instruments contribute a lot to releasing results at reduced turnaround times, more reproducible results, and lower costs.

In this study, external quality control results of the samples that are already done in this laboratory on these two instruments will be reanalyzed for FBC and differential WBC parameters to compare the precision and accuracy of these results provided by these two analyzers. The thing is, the two analyzers though from different suppliers, are doing the same job. This means there is two times the cost spent on reagents, two times the costs spent on suppliers who service the instruments, and two times the time spent on daily, weekly, and monthly maintenance performed on these instruments. Monthly, external quality control samples handled under the same environmental conditions are tested on each instrument. The results from these samples will be compared for precision and accuracy using the reports from the proficiency testing scheme (PTS) to determine which of these analyzers performs best over the other analyzer. Additionally, the specifications of each instrument according to the manufacturer will be compared which will help in determining the best performer of the two instruments.

Aim

The purpose of this study is to determine and compare the precision and accuracy of the two analyzers used at NHLS Kimberley's hematology department.

Objectives

- Determine the FBC using EQA samples on two different FBC analyzers.
- Perform statistical analysis of the results for precision, reproducibility, and accuracy.
- Determine which analyzer produces the most accurate and precise results.
- Minimise expenses by choosing one analyzer that works best instead of using two to do the same thing.

Problem statement

The use of two analyzers though from different suppliers, that are designed to do the same job can be costly for the company. This means there are double the costs times two costs spent on reagents, and suppliers for service on these instruments and double the time spent on daily, weekly, and monthly maintenance performed on these instruments. So, to limit the costs and resources spent on using both analyzers which basically give the same outcomes (FBC and differential WBC), it is otherwise best to choose only one between the two, and of course, that has to be the one that operates or performs best. Reproducible results at low and high levels of hematologic parameters are essential for effective workflow and reliable results are crucial for patient safety.

Literature review

The use of two analyzers though from different suppliers, that are designed to do the same job can be costly for the company. This means there are double the costs spent on reagents, suppliers of service on these instruments, and double the time spent on daily, weekly, and monthly maintenance performed on these instruments. So, to limit the costs and resources spent on using both analyzers which basically give the same outcomes (FBC and differential WBC), it is otherwise best to choose only one between the two, and of course, that has to be the one that operates or performs best. Reproducible results at low and high levels of hematologic parameters are essential for effective workflow and reliable results are crucial for patient safety [3]. Well even if there are two instruments, they can still be from the same supplier, so that one can be used as a backup and then at least it would be using the same reagents that are in stock.

Different types of automated hematology analyzers used to test FBC in Kimberley laboratory which is used for this study are Advia 2120i and XT 2000i which are both automated analyzers designed for laboratories that do medium to large volumes of samples as shown in **Figures 1 and 2** below [7]. Advia uses a flow cytometry light scatter system, myeloperoxidase, and oxazine 750 staining to provide a full blood count, a differential WBC lysis, a WBC differential, and a reticulocyte count. Hemoglobin is measured colorimetrically using a cyanide-free method [8]. This instrument uses five channels to analyze the blood: two of these channels (peroxidase and nuclear density channels) are for WBC and WBC differentials count, one is a hemoglobin (HB) channel for colorimetric measurement of HB concentration, one is a combined RBC and PLT channel and the other channel is for reticulocyte count. CHCM is measured directly based on cell-by-cell analysis, whereas MCHC is calculated based on HB, MCV, and RBC results [9]. The different cytograms derived from these channels are then displayed on the monitor screen of the analyzer and also on the instrument’s printout [8, 10].

Figure 1. Med_dx_advia2120i_right_wautoslide-00003978 [11]

The Sysmex XT 2000i is also an automated analyzer and it uses the impedance method with the use of direct-current detection with hydrodynamic focusing to measure Red blood cell (RBC), Platelet (PLT), Mean platelet volume (MPV), and hematocrit (Hct) [9]. This means it uses fluorescence flow cytometry to measure WBC, differential WBC, optical platelet count, and reticulocyte count. For the measurement by flow cytometry, a thin stream of cells is injected into a flow cell that has a light beam (laser) and as the cells pass through the laser, the light is scattered and then converted into electrical signals through a photodetector. The side scatter in this instance determines the internal complexity of the cells, shape, and density of the nucleus and granules of the cell. Then the forward scatter determines the size of the cell. Fluorescence and scatter measurements are combined to characterize the white blood cell population and hemoglobin is measured photo-colorimetrically also using a cyanide-free method [8]. MVC, MCH, and MCHC are calculated automatically from the impedance counts [9].

Figure 2. https://www.gmi-inc.com/product/sysmex-xt-2000i-automated-hematology-analyzer [12]

Similarly to the Advia analyzer, the total white cell count is performed in 2 channels, the WBC-DIFF channel and the WBC-BASO channel serving as an internal control. As for the Advia analyzer, the WBC-BASO channel is the default method for reporting the total WBC The Sysmex XT 2000i is also an automated analyzer and it uses the impedance method with the use of direct-current detection with hydro dynamic focusing to measure Red blood cell (RBC), Platelet (PLT), Mean platelet volume (MPV) and (Hct) [9]. This means it uses fluorescence flow cytometry to measure WBC, differential WBC, optical platelet count, and reticulocyte count. For the measurement by flow cytometry, a thin stream of cells is injected into a flow cell that has a light beam (laser) and as the cells pass through the laser, the light is scattered and then converted into electrical signals through a photodetector. The side scatter in this instance determines the internal complexity of the cells, shape, and density of the nucleus and granules of the cell. Then the forward scatter determines the size of the cell. Fluorescence and scatter measurements are combined to characterize the white blood cell population and hemoglobin is measured photo-colorimetrically also using a cyanide-free method [8]. MVC, MCH, and MCHC are calculated automatically from the impedance counts [9].

The purpose of measuring full blood count (FBC) is to review the overall health of the patient as part of the routine medical examination and to screen for a variety of diseases, diagnose medical conditions, and monitor a medical condition and treatment [13]. The components of FBC measured include red blood cells, hemoglobin, hematocrit, mean cell volume, mean cell hemoglobin, mean cell hemoglobin concentration, red cell distribution width, white blood cells, platelets, and mean platelet volume [14]. The results of the component vary according to the gender and age of the patient [14]. Below **(Table 1)** are normal references [14, 15] for adults since in this study the samples to be used will only be those of adults:

Table 1. Parameter reference ranges and significances

Parameters/ Components	Significance		Reference range
	Low results	High results	
RBC	-Anaemia -Haemolysis -Bone marrow suppression	-High altitudes -Prolonged exercise -Polycythaemia	Male: 4.35 – 5.65 x10^9 Female:3.92 – 5.13 x10^9
HB	-It is an Oxygen carrier protein -result for the same reasons as RBC	-Result for the same reasons as RBC	Male:13.5 – 17.5 g/dl Female:11.5 – 15.5 g/dl
HCT	Measures the volume of cells as a percentage of the total volume of cells and plasma in the blood -Haemorrhage -Excessive intravenous fluid infusion	-Dehydration	Male:0.40 –0.52 % Female:0.36 – 0.48 %

MCV	Measures the average size of RBC -Iron deficiency Anaemia -Lead poisoning -Thalassemia	-Megaloblastic anemia -Liver disease -Post- splenectomy -Hypothyroidism	Both male & female: 80 – 95fl
MCH	Measures the average weight of hemoglobin per RBC -Iron deficiency anemia		Both male & female: 27 – 34 pg
MCHC	-The average concentration of hemoglobin per RBC	-Spherocytosis	Both male & female: 30 – 35 /dl
RDW	Quantitative uniformity of individual cell size	-Post-blood transfusions	Both male & female: 11.5 – 14.5 %
WCC	Respond to inflammatory process or injury	-Leukemia	Both male & female: 4.0 -11.0 $x10^9$
PLT	Helps to control bleeding -Severe bleeding -Aplastic anemia -Drug-induced Leukemia	-Thrombocythemia -Malignancy -Chronic leukemia	Both male & female: 150 – 400 $10x^{12}$
MPV	Measures the mean platelet volume	Diseases associated with large platelet formation	
Neutrophils	Destroys and digests bacteria	-Inflammation -Infections -Necrosis	Both male & female: 45 – 74%
Lymphocytes	Fight viral infections		Both male & female: 16 – 54%
Monocytes	Removes foreign materials such as injured or dead cells and microorganisms.	Viral or bacterial infections	Both male & female: 2 – 8%
Eosinophils	Respond to allergens	-Allergic reactions -Parasite infections	Both male & female: 0 – 7%
Basophils	Involved in allergic and stressful situations and contribute to preventing clots in microcirculation	-CML -Tissue basophils increase in gastrointestinal, respiratory, and skin infections	Both male & female: 0 – 2%

Hoffbrand, A., Moss, P. (2011) [16]

Both analyzers are easy to use, but the sample volume required for the Sysmex analyzer is much less in comparison to Advia (85µl v.s 200µl) [9]) which is an advantage over the other. Amongst other advantages and specifications of Advia 2120i is that it streamlines workflow by eliminating the majority of manual steps commonly performed to maximize productivity such as:

- Differentiate microcytic anemias with advanced RBC and reticulocyte technology.
- Automates hematology workflow without the need for large track-based systems, expensive stains, or reflexive testing.
- Delivers gold-standard flow cytometry peroxidase methodology for optimum results.
- Maximizes the effectiveness of costly platelet transfusions with accurate results the first time—even at very low platelet levels.
- Simplifies maintenance with Unifluidic Technology through reduced fluidics, eliminated pinch valves, and automated daily cleaning.
- Practical Automation with the ADVIA 2120i System offers a unique high-volume hematology solution that allows your lab to enhance productivity without sacrificing quality.

Sysmex XT 2000i Analyzer on the other hand has:

- Throughput: Stand-alone: 80 samples/hour TWIN: 160 samples/hour
- Aspiration Volume: Sampler or manual closed mode: 150µL manual open mode: 85µL capillary mode: 40µL

- Data Storage: 10000 samples (incl. graphics) 5000 patients' information 1000 selective test orders
- Quality Control: Comprehensive QC files including "Current" and "New" lot feature 1 XbarM file with 300 data points Online QC
- Interfaces: Host line printer graphic printer

The results obtained will then be compared for precision and accuracy using the reports from the proficiency testing scheme. Proficiency testing is a method used to monitor individual laboratories' continual performance for specific tests or measurements (Clinlabnavigator.com, 2019) also known as an interlaboratory comparison. To measure this performance, one or more artifacts are sent to different participating laboratories to measure a set of gauge blocks. The results obtained from these laboratories are then compared against the reference values that were specifically measured. The reference value is determined in various ways with the use of a reference laboratory being the most common one. The reference laboratory is chosen by the HN proficiency method where A2LA accredited laboratories (meaning the laboratories that are accredited for the measurand in question) are assessed by a technical advisor for the proficiency test based on knowledge of the laboratory and uncertainty that he/she can quote for the measurand to choose the most competent laboratory to provide reference values for each test [1, 17]. For the HN proficiency testing, the results reported by the reference laboratories are compared to the reference value by calculating the En value using this method:

$$E_n = \frac{V_{lab} - V_{ref}}{\sqrt{U_{lab}^2 + U_{ref}^2}} \quad (1)$$

[1]

If the results of proficiency testing are $-1 \leq En \leq 1$ then the results are successful meaning the participating laboratory agrees with the reference value within the stated uncertainty of the two at least 95% of the time. Consequently, the unsuccessful results will be those whose En is < -1 or En> 1, then such laboratory is expected to investigate the reason for the disagreement and implement corrective action [15].

In the study [9], the performance of the two analyzers was compared using veterinary samples, and the conclusion thereof was that generally, the Sysmex analyzer showed a good to excellent agreement with the Advia analyzer, which is in accordance with previous studies comparing the Sysmex analyzer to the Cell-Dyn 3500 [18, 19]. Bauer (2011) states that the difference between the analyzers observed herein is unlikely to have an impact on the clinical interpretation of data except for the BH, MCHC, and PLT. In this study, it will be proven that this is not the case because the interpretation of results is very crucial to the patient's health.

It is part of the functions of the NHLS quality assurance division to provide proficiency testing schemes (PTs) for all laboratory specialties to measure laboratory performance against established and best practice criteria. Accreditation of PTs is used as a decisive measure of competency with similar international proficiency testing schemes that satisfy technical requirements are met including the accuracy of results, integrity of data, and preservation of the confidential nature of participant results.

Materials and Methods

The study was conducted at NHLS Kimberley in the hematology department. It is an experimental type of research where previously analyzed results of the NHLS external quality control samples conducted based on the quantitative method for precise measurement of analytes were used and reanalyzed. In this study, different samples from the proficiency testing scheme were analyzed for FBC and differential WBC parameters on both Advia 2120i and XT 2000i analyzers. These samples are distributed to the laboratory monthly for peer group comparison to compare the precision and accuracy of the results produced by the laboratory [20].

In this study, the reports sent back from the proficiency scheme for the period of 2018/19 (from April 2018 to March 2019) for the two analyzers under investigation, will be compared for precision and accuracy using the reports sent back from the PTs scheme as a guide. Additional manufacturer specifications of each instrument were also compared which helped in determining whether one is advanced over the other. It was precisely determined which instrument is most capable of reproducing repeatable results and the accuracy was determined by how close the obtained results were to the true value.

Since existing data were to be analyzed, there were no major financial implications. A consent letter from the NHLS academic affairs and research department was provided which permits the usage of this data for the period of the research project.

Results and Discussion

Table 2. XT data results

XT Data Results										
Months	Parameters									
	WBC	RBC	HB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV

April	0,05	0,01	0,20	0,02	0,12	0,12	0,21	0,31	0,32	0,15
May	0,09	0,27	1,04	0,06	0,14	0,55	0,45	0,32	0,52	0,21
June	0,24	0,84	0,41	1,24	1,04	0,29	0,94	1,94	0,38	0,58
July	0,42	0,12	0,19	0,05	0,09	0,37	0,15	0,34	1,10	0,17
August	0,29	0,44	0,57	0,04	0,22	0,90	0,27	0,51	0,14	0,53
September	0,52	0,99	0,44	0,93	0,48	0,28	0,61	0,31	0,32	0,32
October	1,39	0,17	0,67	0,14	0,11	0,65	0,51	0,47	0,95	0,05
November	0,22	1,08	0,97	1,22	0,61	0,02	0,54	0,05	0,27	0,36
December	1,76	0,68	0,27	0,31	0,02	0,73	0,45	0,51	0,32	0,64
January	1,55	1,62	0,92	1,56	0,54	0,88	0,99	0,04	0,71	0,05
February	1,53	0,71	0,47	0,19	0,17	0,23	0,03	0,04	1,01	0,40
March	0,76	0,00	0,40	0,32	0,32	0,23	0,17	0,35	0,37	0,05
Mean	0,735	0,578	0,546	0,507	0,322	0,438	0,443	0,433	0,534	0,293
STD	0,641	0,500	0,295	0,565	0,297	0,296	0,302	0,504	0,325	0,212
CV	0,872	0,866	0,541	1,114	0,922	0,677	0,681	1,166	0,609	0,725

Table 3. ADVIA data results

Advia Data Results										
Months	**Parameters**									
	WBC	**RBC**	**HB**	**HCT**	**MCV**	**MCH**	**MCHC**	**RDW**	**PLT**	**MPV**
April	2,05	0,01	0,52	0,33	0,07	0,45	0,44	0,48	0,44	1,30
May	0,01	1,47	0,84	0,72	0,09	0,39	0,29	0,53	0,79	1,07
June	0,43	0,93	0,50	0,93	0,29	0,45	0,78	0,46	1,22	1,28
July	0,28	0,79	1,38	1,00	0,63	0,61	0,19	0,29	0,99	0,97
August	1,05	2,08	1,54	2,10	0,67	0,74	1,20	0,53	1,26	0,81
September	0,52	1,00	0,16	1,27	0,64	1,25	1,49	0,52	0,91	1,51
October	0,14	0,96	1,29	1,53	0,64	0,04	0,47	0,61	1,94	0,86
November	0,47	0,46	1,08	1,76	1,73	0,82	1,87	0,09	2,42	2,04
December	2,02	0,41	0,29	1,24	1,81	0,29	1,09	0,70	2,04	0,75
January	0,19	1,28	1,42	2,14	1,67	0,26	1,83	0,41	1,63	0,50
February	0,01	0,11	0,09	1,37	2,18	0,29	1,49	0,98	1,88	0,59
March	0,78	0,60	0,99	0,37	0,29	0,43	0,44	0,84	0,64	1,09
Mean	0,663	0,842	0,842	1,230	0,893	0,502	0,965	0,537	1,347	1,064
STD	0,710	0,587	0,518	0,598	0,745	0,318	0,609	0,235	0,627	0,428
CV	1,071	0,697	0,615	0,486	0,834	0,634	0,631	0,438	0,465	0,402

Statistical QC uses statistics such as mean and SD to monitor and evaluate method performance and to also alert the laboratory to a change in the method performance, hence calculated for both data resulting on both instruments **(Tables 2 and 3)**. The most important part of this study includes the focus on performance, precision, and accuracy of the two above-mentioned hematological analyzers, and through calculating the SD, CV, and mean, these will be more evident.

Precision as described by Streiner (2005) tells us how close a group of measurements are to one another. This means that the closer data replicates, the more likely the future results of the same analyte will be. It is then important for an instrument to have good precision because it gives us confidence in future results. ISO 9001 (2015) QMS states that precision is calculated and discussed in terms of standard deviation (SD) and coefficient of variation (CV). A precise and closely clustered data set has a smaller SD and is generally more reliable than one that is widely distributed. With the above results, the overall SD of the results on XT is generally smaller than that on Advia for most analytes and this tells us that XT is more precise than Advia. CV allows us to make easier comparisons of the overall precision. Since

SD typically increases as the concentration of the analytes increases, CV is then regarded as a statistical equalizer.

CV is the ratio of SD to the Target Value (the mean calculated from the peer group performance per analyte), therefore the closer the data per analyte is closer to the target value, the more precise the results are. XT as seen above continuously provides a CV that is greater than that of Advia for most analytes, which means it provides results that are closer to the target value more frequently, which equates to more precise results.

Accuracy refers to the deviation of a measurement from the true value of the quantity being measured [21]. Mean helps us determine the accuracy and is mostly proven by External Quality Control and Internal Quality Control programs [22]. If the instrument report results are within acceptable known sample limits determined by a specific laboratory and do so repeatedly, then, one may conclude that the instrument will report reliable results for unknown patient sample (Doc no.3295 – PathCare Quality Control Manual). XT again proves to generally produce a lower mean for most analytes than Advia. The instrument is therefore more reliable.

Conclusion

For this study, z-score results from the NHLS EQA reports were used to collect data. The target z-score of the NHLS EQA program in South Africa is 2SD and therefore, the performance of both instruments is acceptable. However, as observed from the results above, it can be concluded that XT gives more accurate (mean) and precise (SD) results in comparison to Advia.

The results concluded are based on a technical study of these two instruments. Future studies can however focus more on the financial implications vs technical evaluation to determine the optimal point between the two analyzers.

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