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**Evaluation of Quality Control in the Hematology
Laboratories in the West Bank - Palestine:
A Consensus Study**

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Evaluation of Quality Control in the Hematology Laboratories
in the West Bank - Palestine: A Consensus Study

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Dedication

To my compassionate mother

To my great father

To my wonderful brothers

To all my teachers who have taught me that Knowledge is Power

Omar Walid Abed AL-Rahman AL-Jabali

Declaration:

I Certify that this thesis submitted for the degree of Master of Medical Laboratory Sciences Hematology Track is the result of my own research, except where otherwise acknowledged, and that this study (or any part of the same) has not been submitted for higher degree to any other university or institution.

Signed

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Abstract

The complete blood count (CBC) is one of the most commonly performed tests in hematology laboratories. It's useful in the diagnosis of many diseases such as anemia, infections and certain cancers. The accuracy and precision of the CBC require the implementation of a quality assessment program which should include two parts, the internal quality control (IQC) and the external quality assessment scheme (EQAS). The IQC program ensures that the laboratory delivers a reproducible results, while the EQAS controls the interlaboratory harmony.

In the West Bank - Palestine, the accuracy and harmony of laboratory tests' results including the CBC results has not been evaluated. Therefore this study aimed to evaluate and reflect the status of accuracy and harmony of CBC results using fresh whole blood samples. Sixty medical laboratories participated in this study. Three blood samples were distributed to the participant laboratories at three rounds with an interval of 22 days in-between. The CBC results were interpreted using the Deviation index (DI) method. The DI score for any test has been interpreted depending on the UK-NEQAS classification.

The CBC results showed large variations among participant laboratories and confirms the need for a national EQAS program. Statistical analysis of CBC results showed that the performance of participant laboratories is the same in the three rounds and there is no improvement in all rounds.

Among the participants, only 18.3% of laboratories have participated in an EQAS program because participation in an EQAS is not enforced by the local health regulations. Concerning the use of blood calibrators, 26.6% of participants use three calibrators while 66.7% of laboratories use only normal calibrator. Laboratories that use three calibrators have on average achieved better performance (based on DI scores) compared to those who use only one calibrator.

Also, 6.7% of the participant laboratories do not run any type of calibrators. Analysis of the frequency of calibrator use showed that 64.0% of laboratories use their calibrators on daily basis and 36.0% of laboratories use it at a lesser frequency.

The inconsistency in the type or frequency of blood calibrator use among participant laboratories indicates a poor understanding of the principles of the work and calibration of cell counter. The study showed a poor harmony of CBC results in the hematology laboratories in Wes Bank and revealed the need for a national EQAS in the hematology laboratories in Palestine to reach a common level of standardization.

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List of Abbreviations

BF	Blood Film
CAP	College of American Pathologist
CBC	Complete Blood Count
CD4	Cluster of Differentiation 4
CD8	Cluster of Differentiation 8
CML	Chronic Myelocytic Leukemia
CV	Coefficient of Variation
DI	Deviation Index
EBM	Evidence Based Medicine
EDTA	Ethylene-Diamine Tetra Acetic Acid
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
ESR	Erythrocyte Sedimentation Rate
HCV	Hepatitis C Virus
HBsAg	Hepatitis B Surface Antigen
Hct	Hematocrit
Hgb	Hemoglobin
HIV	Human Immunodeficiency Virus
HWCs	Health Work Committees
IEQAS	International External Quality Assessment Scheme
IQC	Internal Quality Control
Lab	Laboratory
MAP-UK	Medical Aid for Palestinian – United Kingdom
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Corpuscular Volume
MS Excel	Microsoft Office Excel
NK	Natural Killer Cells
Plts	Platelets
PMNs	PolyMorponuclear Neutrophils
PS	Proficiency Surveillance
PSC	Pluripotent Stem Cell
QAP	Quality Assessment Program
QAS	Quality Assessment Scheme
QC	Quality Control
QCH	Quality Control Hebron
QCN	Quality Control Nablus
QCR	Quality Control Ramallah
RBCs	Red Blood Cells

RDW	Red Blood Cell Distribution Width
RIQAS	Randox International Quality Assessment Scheme
SD	Standard Deviation
UKNEQAS	United Kingdom National External Quality Assessment Scheme
VTE	Venous Thromboembolism
WBCs	White Blood Cells
WHO	World Health Organization

Definitions

Accuracy: is defined as the best estimate of the result to the true value (Ciesla, 2007).

External quality assessment scheme: the assessment of results from measurements produced at a certain site by comparing the results obtained by other sites or from the same material distributed by an external agency which analyses the data statistically (Lewis, 1998).

Internal quality control: internal quality control comprises all steps of activity from assessing clinical needs, via collection of sample and measurement of a measurable quantity to reporting of results of measurement (Lewis, 1998).

Precision: the reproducibility and repeatability of test samples using the same methodology on two or more occasions (Ciesla, 2007; Shinton et al., 1982).

Quality assessment program: the sum total of a laboratory's activities aimed at achieving the required standard of analysis (Lewis, 1998).

Range: is the difference between the largest and the smallest values in a data group (Stiene-Martin, 1998)

Sample: is a material available for analysis (Lewis, 1998).

Chapter One: Introduction

1.1. Introduction.

Medical laboratory is the first front line in the diagnosis of diseases in the diagnostic medicine. All kinds of laboratory tests need a Quality Control (QC) program which is considered as the foundation stone for the medical laboratory to achieve precise and accurate results. QC is a systematic method that ensures a laboratory maintains standards and reliability in reporting a test result (Saxena et al., 2007). For a medical laboratory that serves a real purpose, the results of the tests must be correct and reliable. The tests themselves must be relevant for the diagnosis and clinical care of patients, and for health screening and epidemiological studies as well (Lewis, 1998).

Clinicians rightly expect that medical laboratories should provide reliable reports of the results of tests which would help them in the diagnosis, monitoring and in the management of their patients (Lewis, 1988). The main task of the medical laboratory is to provide an effective answer to clinical requests and to help clinicians in making decisions for their patients (Sciacovelli et al., 2006). The medical laboratory must be efficient, effective and as economical as possible without sacrificing its standards (Lewis, 1998). To achieve these objectives of good laboratory practice that requires skilled management with critical supervision of the work, the laboratory must include a Quality Assessment Scheme (QAS) (Lewis, 1998). QAS is concerned with all aspects of a laboratory practice. The QAS includes two program components namely Internal Quality Control (IQC) and External Quality Assessment Scheme (EQAS), in addition to the Proficiency Surveillance (PS) and standardization (Lewis, 1998).

The hematology laboratory performs many medical laboratory tests including the Complete Blood Count (CBC), Blood Film (BF), Erythrocyte Sedimentation Rate (ESR) and molecular hematological tests for certain diseases. But the major test in the hematology laboratory is the

CBC which consists of many important hematological parameters depending on how much advanced the cell counter is. CBC with WBCs differential counts is a powerful tool that helps identify specifically which WBC line is affected in a certain disease. CBC is considered one of the most frequently ordered laboratory tests in medicine (George-Gay and Parker, 2003). It helps diagnose the causes of a lot of diseases as a screening test, but also may help to confirm that cause like an infection if present, and suggests a potential need for further testing (<http://www.labtestsonline.com>). The main nine components of CBC are the Red Blood Cells (RBCs), Hemoglobin (Hgb) , Hematocrit (Hct), Red Blood Cell Indices which include Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH) and Mean Corpuscular Hemoglobin Concentration (MCHC), Red Blood Cell Distribution Width (RDW), White Blood Cells (WBCs), and Platelets (Plts) counts (Dixon, 1997). Mean Platelet Volume (MPV) is another useful hematological parameter used in monitoring recovery in thrombocytopenia, but it is less commonly used by clinicians for treatment of other diseases (Buttarelli and Plebani, 2008).

CBC needs a blood sample drawn from a vein in the arm of an adult or sometimes from a finger or a heel in babies, and it is used to determine the general health status and to screen for and monitor a lot of diseases as part of a routine medical examination. A major cause of error is the fact that in a busy medical laboratory, where many samples are handled in a day, it may not be possible to give sufficient attention to every sample (Lewis, 1988). Still the results must be presented, without undue delay, to the clinician or public health worker who has requested the tests. The report should be legible and readily understood to provide help for a clinical diagnosis and for management of a patient or for health care of a population at large (Lewis, 1998). Many diseases or disorders result in increase or decrease of the different parts of the blood that can be detected by the CBC test which is used as a broad screening test. In hematology, the target value is the consensus median value of the participant medical laboratories using the same kind of cell counter, (Martins et al., 1995). In the West Bank, there are many types of cell counters which are used and thus need another formula to work out its performance. There are two methods used in EQAS. These are the consensus method and the assigned value method (Lewis, 1998). This study adopts the consensus method.

1.2. Problem statement.

As a primary test, CBC is used for evaluating hematologic disorders, diagnosing infections, monitoring chemotherapy and radiation, and for the treatment of infection. However, it can be a powerful tool in the hands of the informed clinician (George-Gay and Parker, 2003). So the evaluation of the QC for the CBC test is essential. Nowadays, only the nine basic hematological parameters are involved in the international EQAS programs, like United Kingdom National External Quality Assessment Scheme (UK-NEQAS) (<http://www.ukneqas.org.uk>), Randox International Quality Assessment Scheme (RIQAS) (<http://www.riqas.com/>) and the College of American Pathologists (CAP) (<http://www.cap.org/apps/cap.portal>).

In the West Bank, it seems that the variation in the hemogram results among the medical laboratories is large enough, and the harmony of the results is poor which unveils a need for implementing a national quality control program. Therefore, there is a strong demand for implementing EQAS in the West Bank in order to ensure harmonization of results among medical laboratories. This harmonization would enable all medical laboratories to achieve results which are in agreement with each other and then identify the outlier laboratories. The success of the scheme implementation will provide an opportunity to widen the scope of the participant medical laboratories.

1.3. Justifications.

This study is expected to show the need for a national EQAS in the hematology laboratories and to reach a common level of standardization. It will also help in the development of a plan for harmonizing CBC test results in the West Bank. In addition, it will contribute to the implementation of an EQAS in the West Bank by establishing a basic scientific background for a QC plan. This would suggest that only medical laboratories involved in quality assessment programs should be licensed to perform laboratory tests, which would guarantee better patient care and management, and enhance the reliability of the medical laboratory tests (Sah et al., 1999).

Local EQAS programs run by the department of Medical Laboratory Sciences at AL –Quds University has evaluated a few hematological parameters in the CBC, but this study is the first that covered the nine hematologic parameters. Another contribution that this study offers is providing the participating medical laboratories with a free access to an EQAS. Since the application of this consensus study provides the participating laboratories with feedback on the consistency and precision of their performance. These medical laboratories are commonly unable to afford the international EQAS programs.

1.4. Goals.

CBC is a one simple automated test and each hematological parameter in the CBC test is a specific test and has its medical value in the diagnostic medicine. A routine hemogram is the most frequent test done for any person seeking medical help and most other (specialized and not-so-specialized) hematology tests are planned based upon the information obtained from the hemogram (Varma, 2007) .

This study will reflect the status of harmony of the results, consensus and accuracy in hematology laboratories in the West-Bank. It will also evaluate the performance of Palestinian medical laboratories in the routine hematological parameters of WBCs, RBCs and Plts counts and the red cell indices which include the MCV, MCH and MCHC. Also, the Hgb, Hct and RDW will be assessed to see if the consensus, accuracy and precision of the results currently achieved in the Palestinian medical laboratories meet the medically useful criteria for analytical performance in hematology laboratories. The evaluation of the quality control in the hematology laboratory in West Bank is essential since there is no national EQAS running in the medical laboratories at present.

The outcome of the study will provide new updates in the field of QC, since no sufficient local studies are done recently in this filed. This study aims to provide a profound understanding of the medical diagnostic value of the CBC for medical laboratory scientists and clinicians as there has been a great acceleration in the medical information during the last two decades.

1.5. Automated hematology: where do we stand?

The hematology laboratory is an essential component of the hospitals - based medical laboratories as well as private laboratories in West Bank, as in many other hospitals and laboratories around the world (Bunyaratvej et al., 1999). At macro scale, hematology laboratories particularly the CBC test have served a large number of populations in West Bank. It is the responsibility of the technician or the technologist in charge in the hematology laboratory to ensure that the tests which are performed are relevant, and that the results are reliable, reproducible and as accurate as possible (Lewis, 1998).

Numerous studies have established that CBC is a key test for identifying many diseases of hematological and non- hematological origins, and clinicians rightly expect that the medical laboratories should provide reliable reports of the results, which would be very helpful in the diagnosis and in the management of their patients (Lewis, 1988). EQAS can be used to obtain a correct value for an analyte or a biochemical material. But the QA is concerned with all steps from specimen collection to transmission of the report to the clinician, and the participation in an EQAS will help produce reliable and accurate reporting of patient results.

In 1932, Wintrobe developed a set of calculated indices that estimated the erythrocytes size and hemoglobin content based on RBCs, Hgb and Hct which are MCV, MCH and MCHC (George, 2005). Automation leads to many new advances in the hematological concepts and provide rapid and accurate RBCs, WBCs and Plts counts that establish new hematologic parameters, which are hoped to yield information that help in the diagnosis and treatment of some certain hematologic and non-hematologic disorders (Ward, 2000). During the first decade of the twenty one century, the advances in biochemistry, molecular biology and immunology led to introducing many new parameters that are found in the advanced cell counters, new instruments were made and new technologies were introduced like the flow cytometry technology. With the explosion of new instruments appearing in the market, and since there are many cell counters producing companies in the world that produce many kinds of cell counters, medical laboratories in the West Bank like, all laboratories around the world, use these cell counters and it is impossible to prefer any cell counter over another.

1.6. Understanding the complete blood count.

CBC has multiple clinical applications and the test is usually done to investigate diseases like anemia which is the most frequent hematological disorder in childhood (Saxena et al., 2007). CBC evaluates medical conditions that secondarily affect the blood and bone marrow resulting in hematologic manifestations such as infection, inflammation, coagulopathies, neoplasms, and toxic substance exposure (George-Gay and Parker, 2003). The understanding of this test will help both the clinician and medical laboratory scientist identify a disease. For a full usefulness of the test, medical laboratory scientist, clinicians and hematologists must have a scientific background of the basic physiology and the life cycle of the blood cell types. CBC with differential WBCs count is one of the most common laboratory tests performed today and the value of each hematological parameter in the evaluation of a disease helps in diagnosing, treating and monitoring hematological disorders in addition to solving other medical problems (Tefferi et al., 2005).

The clinicians who understand the CBC strength, limitations, and indications will find the test as an effective tool for avoiding more unnecessary tests and more costly tests for their patients. The benefits of the CBC for clinicians are varied. Sandhaus and Meyer (2002) reported that most CBC parameters are usually reported as percentages rather than absolute counts, and many clinicians do not use much of the data provided in the routine CBC. As a consequence of the dynamic changes in hematology laboratory, CBC, differential WBCs count, and reticulocyte count reports have tended to become longer and more complicated, and because of that clinicians might be receiving more data than they want. These excess data are not useful to clinicians and might affect their perception and comprehension of data and contribute to error in medical judgment (Sandhaus and Meyer, 2002).

Still, CBC is an effective and efficient tool to obtain medical information on what is going on in the human body as hematology is a part of the laboratory medicine which is an Evidence Based Medicine (EBM). It is in every clinician's interest to have some understanding of the specific test basics as well as a structured action plan when confronted with abnormal CBC results (Tefferi et al., 2005).

1.7. The physiological basis of the complete blood count: a scientific background.

The CBC is a medical laboratory test that measures the circulating blood cells which are RBCs, Plts and total WBCs with its subtypes (Tefferi et al., 2005). Under the normal conditions, only mature blood cells should be found circulating in the peripheral blood. These mature blood cells are used to give information about the production of all blood cell lines by evaluating the immune system through the measurement of WBCs, and its subtypes the myeloid and lymphoid cells, and the oxygen – carrying capacity , through the measurement of Hgb, Hct and the RBCs indices and the PLTs counts (George-Gay and Parker, 2003).

CBC is the test that measures all blood cell lines. These cell lines are originated from a mother cell which is the Pluripotential Stem Cell (PSC) in a process called hematopoiesis (George-Gay and Parker, 2003). Hematopoiesis or hemopoiesis is the process in which the hematopoietic stem cells that have the ability both for self-renewal and to transform into all other cellular components of the blood, proliferate and differentiate giving rise to all blood cell lines (Dixon, 1997; Proytcheva, 2009).

All blood cells are produced in the bone marrow from the PSC. This PSC undergoes successive stages of differentiation until it becomes committed cells (Dixon, 1997). The formation of blood cells in human is a complex process, and it depends on the human development. In an embryo, the process is divided into three periods which are named depending on the main sites of production. The first period is the mesoblastic period, and it continues for eight weeks from gestation. The first stem cell is derived from the mesoderm of the embryo; then tiny blood islands appear in the yolk sac and their outer cell form the blood vessels and the inner cells forms the hemoblast, the first primitive RBCs (Dixon, 1997; Proytcheva, 2009).

The second period is the hepatic period which takes place in the liver, the main site of the blood formation in this period. This period starts from the second month and continues into the seventh month. Also the spleen begins to produce and contribute in formation of the blood cells (Dixon, 1997; Proytcheva, 2009).

In the third period which begins in the fourth month in the thymus, lymph nodes and the bone marrow are the main sites of blood production. The role of the bone marrow is the formation of all blood cell lines while the role of the thymus and lymph nodes is to complete the final development and activation of the immature WBCs (Dixon, 1997).

The WBCs are derived from both myeloid and lymphoid stem cells. The mature myeloid cells have four forms the basophiles, eosinophils, neutrophils and monocytes. The first three cells are called granulocytes (Dixon, 1997). Granulocytes get their name from the granules present in their cytoplasm and these granules contain biochemical mediators as histamine, serotonin and heparin in basophiles. Additionally, granulocytes contain enzymes capable of destroying microorganisms or down regulating the hypersensitivity reactions by neutralizing the histamine as in eosinophils (George-Gay and Parker, 2003).

Non - granulocytes are another cell type which lack granules in their cytoplasm like the monocytes, the largest of the WBCs, which are considered as the cleanup crew of the human body with the macrophages (George-Gay and Parker, 2003). A granulocytes include the other mature lymphoid cell types or they are called the lymphocytes that include the T cells, B cells and Natural Killer Cells (NK) (Dixon, 1997).

Neutrophils or Poly Morphonuclear Neutrophils (PMNs) constitute about 55 % to 75 % of the leukocytes, whose main role is defending the human body against bacteria. These are found in two pools; the circulating pool and the marginal pool (Dixon, 1997; George-Gay and Parker, 2003). Neutrophils normally remain in circulation for 12 hours in the absence of infection or trauma (Dixon, 1997). The other granulocyte eosinophils make up about 1 % to 4 % of the WBCs and play the main role in killing the multi cellular parasites in addition to detoxifying the antigen antibody reactions, (Dixon, 1997; George-Gay and Parker, 2003).

Basophiles found in circulation are the least granulocytes and they make up about 1 % and they play major role in hypersensitivity reactions; as the mast cells in tissues (Dixon, 1997). They are associated with systemic allergic reactions with unclear mechanism of action (George-Gay and Parker, 2003).

Monocytes are the largest cells of the WBCs (George-Gay and Parker, 2003). Monocytes constitute about 2 % to 8 % of the WBCs and they are considered the clean-up crew which clear the body's foreign microorganisms (Dixon, 1997). Monocytes that enter the tissues are called the macrophages and they are named after the particular tissue that found in (George-Gay and Parker, 2003). The macrophages can destroy the microorganism while keeping its cell surface markers and then pass the information to the lymphocytes ; lymphocytes with this surface molecule always find the microorganism and defend against it (George-Gay and Parker, 2003).

Lymphocytes which are the second line of defense in the body make about one third of WBCs, i.e., 25 % to 45 % (Dixon, 1997). Their major two types are T cells and B cells. The T cells are responsible for the cell mediated immune process and constitute about 80 % of the circulating lymphocytes. The B cells represents 20 % of circulating lymphocytes and are responsible for the humoral immune response in the body and the production of antibodies (Dixon, 1997). The major function of WBCs or the leukocytes is to defend the human body against organisms and injury and are considered as the major players in the inflammatory / infection in the immune response (George-Gay and Parker, 2003). Each WBCs cell type has a unique defensive role and mechanism in defending the body from foreign substance and microorganisms (Dixon, 1997). T cells have several subtypes including, regulators and effectors (George-Gay and Parker, 2003) .

The regulator T cells, which are so called due to their function in turning on or off the immune response, are also divided into subtypes; the helper T cell that is considered the master switch of the immune system and has the cluster of differentiation 4 (CD4) surface molecules, and the T suppressor cell that suppresses the immune response once the immune system controls the infection (George-Gay and Parker, 2003). The second subtype is the effector cells which also have two types; the T cytotoxic cell which has the cluster of differentiation 8 (CD8) that helps destroy cancer cells and virally infected cells. And the memory cells that provide long lasting immunity against particular microorganisms (George-Gay and Parker, 2003). B cells constitute the body's main humoral immunity team, when activated, it transforms into plasma cells which produce the antibodies (Dixon, 1997).

The last cells are the NK cells and they are so called because they do not have T or B markers. NK cells are non specific, but they are very effective against cancer cells and virally infected cells (George-Gay and Parker, 2003).

Erythropoiesis is the production of RBCs from the bone marrow stimulated by low levels of oxygen via an oxygen-sensing system located in the kidney and also involves the erythropoietin hormone (George-Gay and Parker, 2003) .

The single function for RBCs or the erythrocytes, which are small and flexible cells, is to supply the living tissues with oxygen when picked up in the lungs and remove the generated carbon dioxide waste from the cells to the lungs for excretion (Dixon, 1997; George-Gay and Parker, 2003).

RBCs are produced from the RBC progenitors in the bone marrow. Those progenitors go through a chain of phases that lead to production of mature cells called RBCs or erythrocytes (Dixon, 1997). RBCs are considered as Hgb containers. They lack nuclei and thus cannot split and their lifespan is only 120 days in the peripheral blood (George-Gay and Parker, 2003).

The process of metabolism in RBCs depends on many factors like amino acids, vitamin B12 and folic acid which are needed for cell development and DNA synthesis. Iron is needed in Hgb synthesis; four atoms of iron are required for each complete Hgb molecule (Dixon, 1997; George-Gay and Parker, 2003). The RBCs production is a complex process that includes many biochemical and metabolic pathways like heme and Hgb synthesis, acquisition of iron, amino acids, vitamins and growth factors in the bone marrow and the formation of alpha and beta chains that forms Hgb (Dixon, 1997). In a CBC test, Hgb considered a general indicator of anemia or polycythemia (Tefferi et al., 2005). Hgb molecule is a heme-portion complex of two pairs of similar polypeptide chains. Hgb synthesis needs amino acids, vitamin B6 and iron (Dixon, 1997; Irwin and Kirchner, 2001). Each Hgb molecule has two alpha and two beta globin chains in human adults while iron and vitamin B6 are involved in the formation of heme, responsible for the color of the human blood (Dixon, 1997; George-Gay and Parker, 2003).

Hct is a parameter that is calculated in most automated blood cell counters, and it represents the percentage of the total volume of RBCs relative to the total volume of whole blood in a blood sample (George-Gay and Parker, 2003). Hct is considered as an indirect measure of the oxygen carrying capacity in blood while Hgb provides a direct measure of oxygen carrying capacity of blood and seems to be more sensitive to determine anemia but still not a gold standard. Additionally Hct is considered one of the factors that play a vital role in blood viscosity (Quinto et al., 2006). The relationship between both Hgb and Hct is expressed by the hematologic parameter MCHC which is one of the red cell indices (Quinto et al., 2006).

The smallest cells found in the blood are the platelets or thrombocytes and their lifespan is from nine to twelve days (George-Gay and Parker, 2003). They are derived from the myeloid stem cells and produced in the bone marrow through a series of stages, and like the RBCs, they lack nucleus (George-Gay and Parker, 2003). Seventy percent of the Plts are found in the circulation and the remaining part is in the spleen (George-Gay and Parker, 2003). Plts play a vital role in the homeostasis since Plts have two main functions; the first is to help in closing the bleeding site by forming a plug along with the coagulation factors, and the second is the vascular repair (Dixon, 1997).

1.8. The clinical usage of the complete blood count in diagnostic medicine.

Automated WBCs and RBCs counts were used first in 1960s, and today a single instrument can perform the entire CBC with few sampling errors (Dixon, 1997). CBC has multiple clinical applications in medicine, and it is the key that clinicians use once they start to look for any abnormality or disease. CBC contains a lot of valuable medical information about the human body obtained from the hematological parameters of an instrument. The hematological parameters reach up to eighteen parameters in some instruments.

The clinician should use the CBC to evaluate the human body since the CBC is a panel of tests that help in the diagnosis of any hematological disease or other non-hematological disorders. CBC is usually used as a screening test for patients who are asymptomatic and have no physical signs or have symptoms of a disease (George-Gay and Parker, 2003).

The evaluation of each hematological parameter of the CBC is essential. A non-hematologist should be able to address some, but not all CBC abnormalities (Tefferi et al., 2005). The basic nine components of a CBC that are tracked in this study are WBCs, RBCs, Plts, Hgb, Hct, RDW as well as the Red Cell indices, MCV, MCH and MCHC. In the evaluation of each hematological parameter it is very essential for the clinician and the medical laboratory scientist to figure out potential diseases as any abnormal increase or decrease in the value of a given parameter could indicate the presence of a specific disease.

The evaluation of the WBCs or the leukocytes begin with examining of the total WBCs count and then examining the differential WBCs counts (Tefferi et al., 2005). Leukocytosis is an increase in the WBCs count, and any count above 11,000 / μ L is considered a Leukocytosis, which appear in infections, inflammations and in cancers or marrow disorders (George-Gay and Parker, 2003; Tefferi et al., 2005). The severe increase of the total WBCs above 100,000 / μ L as in Leukemia, will affect the circulation by increasing the blood viscosity and may lead to Venous Thromboembolism (VTE) (George-Gay and Parker, 2003). The decrease in the total WBCs below 4,500 / μ L is called Leucopenia. Most commonly it is manifested as neutropenia or lymphopenia, and it may indicate bone marrow failure or it could be due to the immunosuppressive therapy (George-Gay and Parker, 2003; Tefferi et al., 2005).

The evaluation of the WBCs subtypes includes granulocytes and agranulocytes. The increase in neutrophils count in blood is called Neutrophilia, and it indicates a bacterial infection, or in the case of severe elevation, it may relate to the Chronic Myelocytic Leukemia (CML). One of the principles in the differentiation of Neutrophilia is to distinguish between the type of elevation, a shift to the right will mean that there is an elevation in the segmented neutrophils which appears in cases such as burns, hemorrhage or injuries, but a shift to left means that there is an elevation in the band neutrophils, and there are immature cells released in the blood circulation as a result to acute bacterial infection or some cancer. The second type of granulocytes is eosinophils, and their increase or Eosinophilia is an indicator of multi cellular parasitic infection. The third type of granulocytes is basophiles and their increase or Basophilia is seen in allergy (George-Gay and Parker, 2003; Tefferi et al., 2005). Lymphocytes increase is called Lymphocytosis and it can be seen in viral infections such as

cytomegalovirus or mumps in addition to acute leukemia. While the increase in monocytes is called Monocytosis and appears in certain cancers and in the chronic infections (Tefferi et al., 2005).

The evaluation of the RBCs, Hgb, Hct and the red blood indices is also very important. RBCs count assesses the oxygen carrying capacity of blood, but it is also critical to evaluate the bone marrow function especially in marrow failure diseases. An increase in the levels of the RBCs is called Erythrocytosis and it results from many causes such as polycythemia vera, or dehydration while the increase in RBCs count is related to Hgb and Hct (George-Gay and Parker, 2003). The initial screening method for iron deficiency in clinical practice is the evaluation of Hgb or Hct, but additional laboratory tests are needed (Beutler et al., 2003). Hgb is a direct measure of anemia while Hct is an indirect parameter of measurement for anemia (Carneiro et al., 2007; George-Gay and Parker, 2003; Tefferi et al., 2005). The classification of many types of anemia depends on Red Cell Indices. Clinicians should first look at the MCV which allow placement of anemia into one of the standard classification of macrocytic, normocytic or microcytic anemia by narrowing down the diagnosis of the many types of anemia (Irwin and Kirchner, 2001). MCV describes the RBC by size or volume which is, the volume in femto-liters, of the average circulating RBCs (George, 2005).

MCV less than 75 fl is usually correlated with thalassemia can help in the assessment of the diseases by differentiating the type of anemia from thalassemia (Muncie and Campbell, 2009). MCH which measures the average weight of Hgb in an RBC is correlated to MCV. They increase or decrease together, and this tells the medical technologist that the cell counter works correctly (George-Gay and Parker, 2003). While MCHC measures the average concentration of Hgb in an RBC per unit volume, and is considered a marker for some diseases like spherocytosis.

Erythrocyte indices are helpful for monitoring iron status, and assessing the need for iron supplementation during erythropoietin therapy for anemia of renal failure (Goodnough et al., 2000).

Plts count is a valuable parameter in evaluating the Plts status in the blood. In a patient with thrombocytopenia, or a decrease in the Plts, the CBC test may unveil a need for blood transfusion for a patient before some surgical procedures, or otherwise compel the clinicians to cancel a main or alternative surgery for that patient (George-Gay and Parker, 2003). Other types of thrombocytopenia include drug induced or spurious thrombocytopenia which is caused by Ethylene-Diamine Tetra Acetic acid (EDTA) -induced platelet clumping (Tefferi et al., 2005). Thrombocytosis, which is the elevation of Plts greater than 1,000,000 / μ L in the circulation, may be seen in a response to physical stress, infection or in myeloproliferative disorders (George-Gay and Parker, 2003).

The last hematological parameter in this study is the RDW which is the coefficient of variation of MCV, and it represents the degree of size variation, or anisocytosis in the erythrocyte populations (Sandhaus and Meyer, 2002). The use of RDW in the diagnosis of Thalassemia is important as the molecular methods for the detection of the mutations are costly and not widely available. RDW may assist in differentiating iron deficiency anemia and sideroblastic anemia from Thalassemia, because RDW is elevated in these diseases more than in Thalassemia (Muncie and Campbell, 2009).

Many new updates in hematology appear continuously. In Schizas study (2007), the researcher used the CBC hematological parameters to predict positive findings in anemic patients at endoscopy; the study found that in unexplained iron deficiency anemia, when the Hgb is less than 11 g/dl, the Hgb and Hct are useful hematologic parameters in endoscopy while MCV is not. Another relationship between disease and CBC was tackled in a recent study that observed that men with Hct and Hgb in the upper 20th percentile are associated with increased risk for VTE compared to men in the lower 40th percentile while MCV was not associated with VTE (Braekkan et al., 2009). The increase in Hct is associated with increased blood viscosity, reduced venous return and increased platelet adhesiveness (Braekkan et al., 2009). The MCV and MCH at birth are quite reliable parameters for the prediction of alpha Thalassemia trait in neonates (Al-Hilali et al., 2009) which may provide a practical and cost-effective test for screening for neonates' alpha-thalassemia. MCV less than 90 fl may predict the existence of alpha thalassemia.

1.9. Internal quality control and external quality assessment scheme in hematology.

QC is a systematic method that ensures a laboratory maintains standards and reliability in reporting a test result (Saxena et al., 2007). The first national scheme was developed in the early 1960s in the USA by the College of American Pathologists (CAP), and many other national schemes were also established at about the same time in Canada, Australia, the United Kingdom and several European countries (Lewis, 1988).

The two separate but complementary components in a laboratory Quality Assessment Program (QAP), the IQC and EQAS, play a role in achieving a reliable and reproducible report for the medical laboratories. IQC comprises all steps of activity from assessing clinical needs, via collection of sample and measurement of a measurable quantity to the reporting of results of measurement. While EQAS is the assessment of results from measurements produced at a certain site by comparing the results obtained by other sites or the same material distributed by an external agency which analyses the data statistically (Lewis, 1998).

Although EQAS is costly, it helps reduce health care costs. This statement wouldn't sound paradoxical if we take into consideration the gross losses which poor QC entails. Needless to mention the value of clinician trust that QC guarantee. Quality control will result in reducing time and labour costs, and most importantly providing accurate patient diagnosis and treatment.

IQC is concerned essentially with precision or reproducibility of results on a daily basis whilst EQAS is concerned with inter-laboratory and inter-method or inter-instrument harmony (Ciesla, 2007; Lewis, 1998). The main aim of the activities of an EQAS in laboratory medicine is to sustain improvements in the quality of services provided by participating laboratories for the benefit of patients (Sciacovelli et al., 2006). The understanding of the quality control of the CBC is very important; since CBC is one of the most common laboratory tests in medicine (George-Gay and Parker, 2003). Clinicians tend to accept the results of the electronic blood cell counters as accurate because of their high precision.

These counters simplify and speed the performance of blood counts and the calculations of red blood indices, but they are still imperfect and need IQC and EQAS (Herishanu and Berliner, 2002). In our modern era, IQC program for a routine hemogram should use commercial brand specific blood controls which are compatible with the cell counter brand since each blood control is designed for its machine. While what should be measured in the EQAS is the laboratory's accuracy using blind samples that are analyzed as if they were patients samples (Lewis, 1998).

With the explosion of new instruments appearing on the market, it is difficult if not impossible to favor a specific instrument over another at purchase time (Ward, 2000). In this context, EQAS play a primary role in the assessment and monitoring of all elements that contribute to the formulation of laboratory measurements (Buttarello and Plebani, 2008). The EQAS is an effective tool for clinical governance in laboratory medicine and now a wide range of instruments are available for blood counting (Sciacovelli et al., 2006).

Initially the instruments were designed to analyze fresh blood and not stabilized cell suspensions which may not undergo the same shape change when diluted in the manufactures specific diluents (Lewis et al., 1991). This leads to the need of the EQAS with IQC that use commercial materials, since hematological test results are used for many clinical purposes including diagnosis, monitoring, screening, research and education (Fraser, 1990). QC has become mandatory in every field of medicine for measuring the quality of patient care and the QAS in hematology is intended to ensure the reliability of the tests done in the hematology laboratory (Sah et al., 1999). Three very important aspects of QC in hematology are calibration of the cell counter, monitoring accuracy and precision of the machine, and verifying the reliability of test results. A combination of commercial controls (three levels) and fresh blood is recommended (Gulati and Hyun, 1986). Nowadays, new parameters have been introduced to the CBC, and for a number of them there is no IQC or EQAS that raises the question whether these new parameters should be used for clinical decisions (Briggs, 2009). In QC, EDTA is considered the anticoagulant of choice for automated cell counters. Blood samples should be analyzed as soon as possible. Storage at 4 degrees Celsius may stabilize the samples for more than seventy two hours (Burgi, 1995; Buttarello, 2004).

1.10. Electronic blood cell counters and automation in hematology.

In the 1960s, the first multichannel automated hematology instrument appeared based on the impedance technology designed by Walter and Joseph Coulter in 1956. Other technologies were developed later like the cell counting by light scattering that appeared in the 1970s (George, 2005). While the automation of the WBCs with differential for the three part differential began in the 1980s and the five part differential count was first introduced in the early 1990s (George, 2005).

During the first half of the twentieth century, CBC was performed using exclusively manual techniques (George, 2005). The routine manual CBC is a labor-intensive test that lacks reproducibility. But rapid, accurate, and relevant laboratory testing is essential in an era of cost-effective medicine (Rappaport et al., 1988). In the past century until the early 1960s, hematologic evaluations were performed manually, and methods were labor-intensive and involved centrifuges, spectrophotometers, counting chambers with etched grids, and stained wedge smears of blood (Varma, 2007).

In the last fifty years, physical sciences have undergone an evolution that led to many great achievements in the field of automated hematology, and CBC is worthy of special interest. Automated hematology 40 years later is still in its infancy, and in the first few decades of the new millennium advancing technology will routinely identify more white cell subtypes and even blast lineage while reducing the need for flags (Ward, 2000).

Advances in technology over the next few decades will lead to sensitive and specific results of the CBC, but at the present time, the need for EQAS is important because automated hematology counters cannot provide these services. Advances in automated hematology instruments in the 1990s were made possible by new, improved, and cheaper computer processing technology and memory. Automated hematology counters have totally changed the landscape of the hematology laboratory since fewer manual techniques are required. The new automated blood cell counters offer accuracy and precision in counting process more than the old, manual methods did.

Nowadays instrument-driven hematology provides much accurate and precise data to clinicians (Ward, 2000). CBC gives information about the production of all blood cells lines and identifies the patient's oxygen-carrying capacity through the evaluation of RBCs indices, Hgb, and Hct. It also provides information about the immune system through the evaluation of the WBCs count with differential in cases such as infection or inflammation (George-Gay and Parker, 2003). The new technology in the coming years will produce high clinical sensitivity which entails a better ability to distinguish between normal and pathologic samples in terms of quantitative anomalies and qualitative alterations like the presence of immature cells (Buttarelo and Plebani, 2008).

Instruments have to undergo evaluation at many levels using guidelines for evaluation in hematology laboratories (Shinton et al., 1982). Also the international consensus group for hematology was developed 83 rules. These rules hoped to be useful to a large number of hematology laboratories worldwide.

Automated blood cell counters are becoming more and more sophisticated and the range of the reportable hematologic parameters available is increasing and giving more data about what is going on in the human body. So medical scientists and clinicians need to keep up to date with the new hematological parameters provided in the CBC (Briggs, 2009).

The entire cell counters that were participated in this study used the coulter principle. The blood cells are sized and counted by detecting and measuring changes in electrical resistance when a particle passes through a small aperture. This principle is called the electrical impedance principle of counting cells (Figure 1). A blood sample is diluted in an isotonic solution, a good conductor of electrical current, and the cells are pulled through an aperture by creating a vacuum. And then two electrodes made an electrical current (Ciesla, 2007).

The external electrode is located in the blood cell suspension. The second electrode is the internal electrode and is located in the glass hollow tube, which contains the aperture. Low-frequency electrical current is applied to the external electrode and the internal electrode. DC current is applied between the two electrodes.

Electrical resistance or impedance occurs as the cells pass through the aperture causing a change in voltage. This change in voltage generates a pulse. The number of pulses is proportional to the number of cells counted. The size of the voltage pulse is also directly proportional to the volume or size of the cell (Ciesla, 2007).

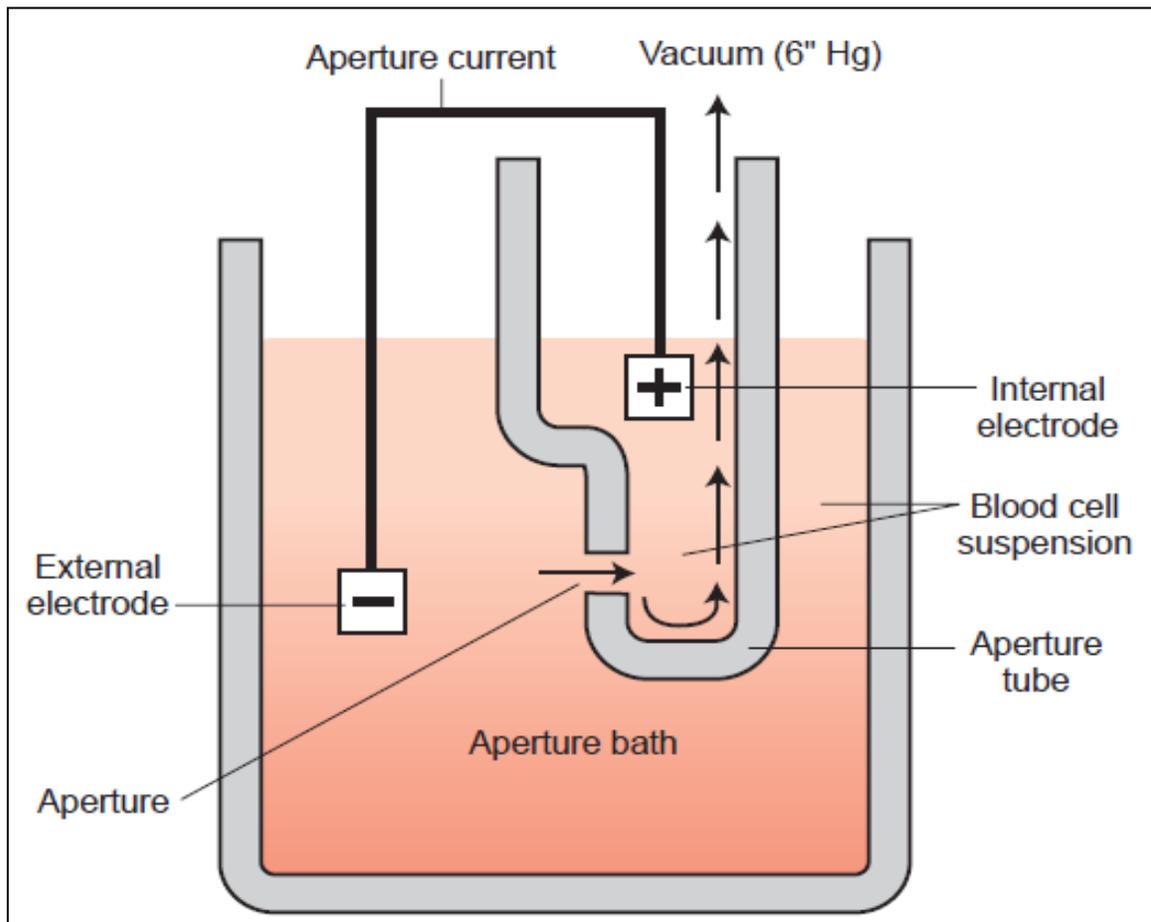


Figure (1.1) Coulter principle of electric impedance (adapted from, Ciesla, 2007)

1.11. Literature review.

Many studies have been done since the first national scheme was developed in the early 1960s (Lewis, 1988). The WHO International External Quality Assessment Scheme (IEQAS) in hematology was started in January 1978 with 11 members, following a WHO interregional workshop on quality assurance and standardization in Thailand (Lewis, 1988). The organization of IEQAS has been based on UK-NEQAS which has over 550 participants in the general hematology laboratory section, which was started in the 1968 (<http://www.ukneqas.org.uk>; Lewis, 1998).

UK-NEQAS has strongly participated in the progress and development of the EQAS programs around the world. In some IEQAS surveys the consensus obtained in the UK-NEQAS is used when the same material is tested in both programs. When the material used for IEQAS differs from that used by the UK-NEQAS, the reference values of IEQAS materials are determined by the WHO Collaborating Centre at the Royal Postgraduate Medical School, London, using reference methods and reference standards in accordance with the protocols of the International Committee for Standardization in Hematology (Lewis, 1988).

For the qualitative procedures, correct results are similarly based on the UK-NEQAS peer consensus or the results from a group of references. In the beginning of EQAS for the basic laboratory tests in the developed countries, the participating laboratories cannot expect any financial support by any organization, nor public health, nor private assurance (Hu et al., 2002). For example in Spain, the spanish hematology EQAS started in 1984 with fifty six medical laboratories, a number which rose to three hundred thirty two in 1989 (Vives-Corrns et al., 1991).

For evaluation of results, laboratories are divided into four to eight groups depending on the methodologies used. Individual's results are assessed against a consensus value (Mean), Deviation Index (DI) from the mean, Coefficient of Variation (CV %) and Youden diagram for all results and groups of each parameter.

In Germany, Quality control in hematology is performed in Germany for 20 years (Heller, 1995). In France a national system for EQAS was started in the 1970s, and about four thousand eight hundred laboratories are enrolled in the program, and all medical laboratories are financed by a fund that covers all their expenses (Sah et al., 1999). This national program has documented and improved the performance of those laboratories, and has helped the ministry of health to more efficiently manage the problems of laboratory medicine in France (LeBlanc and Goguel, 1990). Since 1970s, automated hematology has been introduced in Asia (Bunyaratvej et al., 1999). Local EQAS in Shanghai has resulted in a reduction of the CV % values of CBC parameters (Xiaobo et al., 2003). Thailand started an EQAS program in 1970s and about 800 out of 1300 laboratories are involved in this program (Opartkiattikul and Bejrachandra, 2002). The results of laboratory tests are evaluated by using participants' consensus values. In Jordan a study by Bilto, 1999, has shown that Jordanian laboratories were far from achieving the analytical goals. The latter study also stressed the need for a national EQAS in hematology, to reach a common level of standardization.

In the West Bank - Palestine the department of Medical Laboratory Sciences at AL-Quds University started an EQAS program in the middle of 1995 with the corporation of the Medical Aid for Palestinian (MAP-UK) and the Higher Council of Health. They launched a limited EQAS that enrolled 72 medical laboratories belonging to governmental hospitals and other nongovernmental organizations (Shehadeh, 2000).. The scheme was suspended in 2001

One of the limitations of this program is that the samples are preserved and not tested immediately; they stay in the medical laboratory for a long time before being tested (Shehadeh, 2000). This affected the blood sample properties in many ways physically, chemically and biologically. Another limited EQAS program was launched at the same time by Health Work Committees (HWCs) in West Bank. The HWCs scheme was similar to Al-Quds University EQAS and has had the same limitations. Even though all possible precautions were taken to achieve reliable results by IQC, potential errors can arise. These are only detectable by EQAS. Since IQC achieves the precision which means the reproducibility but not necessarily the accuracy, it is obvious that both IQC and EQAS are essential tools for the medical laboratory.

Chapter Two: Materials and Methods

2.1. Materials used in this study.

The materials that have been used in the three rounds in this study were a phlebotomy tray and evacuated tube blood collection system as shown in Table 2.1:

Table (2.1) Materials used in the study

Number	Item	Manufacture company
1	Needles	-----
2	Tourniquet and holder	-----
3	Evacuated tube blood collection system	-----
4	1.3 ml plain tubes	-----
5	3.5 ml EDTA tubes	-----
6	70 % isopropyl alcohol swabs	-----
7	Sterile gauze swabs and Adhesive dressings	-----
8	Rack and cork racks	-----
9	Automatic pipette	-----
10	Ice pieces	-----
11	23 Liter refrigerators	Gaiter
12	Thermometers	-----
13	Anti - Human Immunodeficiency Virus (HIV) 1+2 strips	Quick check
14	Hepatitis B Surface Antigen (HBsAg) strips	Quick check
15	Anti - Hepatitis C Virus (HCV) strips	Quick check
16	Fresh venous human whole blood	Three Volunteers

2.2. Preparation and distribution of the questionnaire.

A two parts questionnaire has been prepared. Part one included basic information about the medical laboratory such as its name, laboratory director, address and telephones number, and the second part included eleven questions focusing on the QC components IQC and EQAS in each medical laboratory and the type and version of the cell counter used. The questionnaire was distributed to all medical laboratories.

In Nablus which consists of thirty one medical laboratories, to survey about their acceptance to participate in this study. Twenty one medical laboratories agreed to participate in this study, while four medical laboratories rejected it. Four medical laboratories didn't have automated cell counters and two medical laboratories do not have automated cell counters and they rely on other neighboring laboratories to do CBC and one performs the CBC test manually. For Ramallah, the questionnaire was distributed to all medical laboratories in the city which has twenty six medical laboratories. Nineteen medical laboratories agreed to participate in this study, while six medical laboratories rejected it. One medical laboratory didn't have an automated cell counter. In Hebron, the questionnaire was distributed to all medical laboratories in the city which has twenty two medical laboratories. Twenty medical laboratories agreed to participate in this study, while two medical laboratories rejected it. All who volunteered to participate in this study have filled the study questionnaires.

2.3. Preparation of the study samples.

The main purpose of this study is to assess the performance of the Palestinian medical laboratories in West Bank on a routine CBC test. Sixty public and private medical laboratories participated in this study. These are distributed throughout the cities of Ramallah, Nablus, and Hebron.

The cycle was repeated three times within the interval of twenty two days between successive cycles. Samples were tested between September and October 2010. The collection, preparation and the distribution of the samples were done in Ramallah city.

On the morning of the testing day, around 70 ml of venous blood was collected from a healthy adult male volunteer. The site of vein puncture was swabbed with Isoporpanol. The evacuated blood collection system was used with 3.5 ml tubes that contain EDTA as an anticoagulant. A rack was used to hold the blood samples upright during process of filling.

Three healthy adult volunteers who donated the blood samples for this study was tested against Anti- HIV 1+2; HBsAg and Anti- HCV and the results were negative for all three viral markers. The blood in 3.5 ml tubes was pooled in a sterile box and mixed. The last step done at the end of the three rounds included testing tubes numbered 1, 20, 40, and 60 on a cell counter (CellDyn 1700) to test the consistency; The results are shown in appendix A.

2.4. Distribution of the study samples.

The pooled fresh blood was distributed into sixty polystyrene plain tubes of 1.3 ml volumes using an automatic pipette in which each tube contained 1 ml of homogeneous blood. The samples were given trial code numbers which were Quality Control Ramallah one, two and three (QCR1, 2 or 3), Quality Control Nablus (QCN1, 2 or 3), and Quality Control Hebron (QCH1, 2 or 3).

Then the plain tubes containing EDTA blood were distributed into three refrigerators. Each refrigerator contained at least three ice pieces to provide a suitable environment for the blood samples and one thermometer that was graduated for both Celsius and Fahrenheit degrees to monitor the changes in the temperature during transportation of samples. Three volunteers took the charge of the transportation process in the three cities at the same time.

Distribution was performed in such a way that within less than four and half hours after blood collection, each participating laboratory received one sample of 1.0 ml of EDTA whole fresh blood. Each medical laboratory was instructed to allow the sample to reach the room temperature before testing it on the laboratory's cell counter and mix it for 10 times before testing it on the laboratory's cell counter.

2.5. Temperature changes during blood samples distribution.

Changes in the blood storage affect the blood samples in QC. The WBCs, RBCs and PLTs numbers are stable for more than 24 hours in the EDTA as an anticoagulant (Burgi, 1995; Buttarello, 2004; Hall, 1991). In this study blood samples were put in the refrigerator with ice pieces for less than four and half hours to ensure a suitable environment. Several variables may affect the blood samples such as the time, temperature and shaking. To provide the optimum environment for the blood samples and to stabilize these variables as much as possible, a cork was used in each refrigerator to prevent the shaking during the transportation of blood samples. For temperature, each refrigerator was provided with a thermometer to record the temperature of the box, while time was recorded by the distributors.

In Ramallah, the temperature of the box in round one was 11°C at the beginning of the distribution of the blood samples. Then the temperature decreased under the effect of the ice to 8°C and it did not rise more than 10°C when the last sample was distributed. The time from the beginning of distribution to the end was about four hours. In round two, the temperature was 4°C then rose in the middle of the distribution to 5°C and kept between 4 – 5°C to the last sample, while the time decreased to two hours since two volunteers participated this time in distribution. The temperature in round three started with 3°C and increased with time to reach 9°C by the end of the distribution, while time was less than three hours.

In Nablus, the temperature of the box in round one was 4°C at the beginning of the distribution of the blood samples. Then the temperature increased in the last few samples to reach 5°C and was kept at the same temperature to the end of sample distribution. The time from the beginning of the distribution to the end was about four hours. In round two the temperature was 5°C then it rose in the middle of the distribution to 6°C and was kept between 5 – 6°C till the end of the last sample and the time was about four hours. The temperature in round three started with 4°C and increased in the last hour to reach 5°C at the end of the distribution, while the time was about four hours. In Hebron the temperature of the box in round one was 3°C at the beginning of the distribution; then the temperature decreased under the effect of the ice to 2°C, rose again to 3°C and was stable to the end of the sample distribution.

The time from the beginning of the distribution to the end was about three hours. In round two, the temperature was 4°C from the beginning of the distribution to the end of the distribution. The time was less than four hours. The temperature in round three started with 3°C and rose with time up to 7°C in some points, and by the end of the distribution it was 6°C while time was less than three hours. Further detailed results are shown in appendix B.

2.6. Methods used in this study.

The method that has been used in this study was the consensus mean method. Samples of the same material are sent to a large number of laboratories where requested tests are performed. Then the participant medical laboratories sent back their results to be analyzed and interpreted using the DI method. The consensus method for the participating medical laboratories was used to analyze the results of the laboratories.

The Mean (\bar{x}) represents the arithmetic mean of test samples and the Standard Deviation (SD) was calculated using the following: $SD = \sqrt{\frac{\sum(x-\bar{x})^2}{n-1}}$ Where; x = individual results \bar{x} = Mean n = total number of results. The data were then adjusted by excluding any values that are $> \pm 2SD$ from the mean. The mean and SD (now termed “weighted”) are then recalculated. For these calculations of SD to be meaningful, there must be at least 15 participants in a set, and at least half of the participant should have sufficiently good performance in comparison with each other to avoid having a weighted SD which is unhelpfully wide.

DI is then calculated for each individual participant, it is also known as the Z- score. DI indicates the difference between the individual laboratory results and the weighted mean and can be used to compare the performance of a laboratory with that of other laboratories as well as with its own performance in previous surveys, and the formula is:

$$DI = \frac{\text{Actual result} - \text{Weighted mean test}}{\text{Adjusted SD}}$$

The DI score for any test has been interpreted depending on the UK-NEQAS classification (UK-NEQAS Quality Assurance in Haematology) as shown in Table 2.2:

Table (2.2) Interpretation of the DI Scores

The DI Result	The Performance	Abbreviation
< 0.5	Excellent	E
0.5 – 1.0	Good	G
1.0 – 2.0	Satisfactory	S
2.0 – 3.0	Serious Error	S.E

The CV % and the clinical significance were calculated for all of the hematological parameters that were measured in this study. The CV % formula is shown below:

$$CV \% = \frac{\text{weighted mean}}{\text{weighted SD}} * 100 \%$$

The CV % was compared for evaluation of the three rounds using Chi-square for goodness-of-fit and its formula is:

$$\chi^2 = \sum \frac{(\text{Observed CV value} - \text{Expected value})^2}{\text{Expected value}}$$

Table (2.3) The limits of the Clinical Significance.

The Hematological Parameters values	Limits	
	Lowest limit (%)	Highest limit (%)
WBCs	- 8 % of the value	+ 10 % of the value
RBCs and Hgb	- 3 % of the value	+ 4 % of the value
Hct, MCV, MCH and MCHC	- 4 % of the value	+ 5 % of the value
PLTs	- 10 % of the value	+ 15 % of the value

Chapter Three: Results

3.1. Questionnaire results.

In order to evaluate or study the quality control in the hematology laboratories in the West Bank – Palestine in the medical laboratories three cities were chosen for this study. The three cities chosen for this study are Nablus, Ramallah and Hebron representing the north, middle and south regions of West Bank.

There are seventy nine medical laboratories in the study regions. These laboratories are distributed as follows: 31 in Nablus, 26 in Ramallah and 22 in Hebron. A questionnaire was sent to the seventy nine medical laboratories in the study regions between June and July 2010. The objective of the questionnaire was to collect basic information about the type of cell counters, work load and the IQC and EQAS measures implemented.

However, only sixty laboratories accepted to participate in the study and filled the questionnaire. While eleven laboratories refused to participate in the study, five laboratories do not have an automated cell counter, two laboratories perform the CBC in other neighboring laboratories, and one laboratory performs the CBC manually.

3.1.1. Analysis of the questionnaire data.

In EQAS participation, it was found that forty nine (81.7 %) of the participant medical laboratories do not run an EQAS in their laboratories, while only eleven medical laboratories (18.3 %) run an EQAS (Table 3.1.1).

Table (3.1.1) Distribution of the participating medical laboratories according to their participation in EQAS programs. Where n is the number of medical laboratories.

Medical laboratory location	Participation in an EQAS			
	Yes		No	
	n	%	n	%
Nablus	2	18.0	19	38.8
Ramallah	7	64.0	12	24.5
Hebron	2	18.0	18	36.7
Total	11	100	49	100

3.1.2. The types of cell counters available at the participants' medical laboratories.

The participant laboratories have different brands as well as different versions of cell counters. The most commonly used cell counter was CellDyn and it was available in 23 (38.3%) laboratories (Table 3.1.2). The second most commonly cell counter is Medonic followed by Sysmex, while other cell counters are used in a few laboratories (Table 3.1.2).

Table (3.1.2) Types of cell counters used in the participant medical laboratories. Where n is the number of medical laboratories.

Type of the machine	Nablus		Ramallah		Hebron		Total	
	n	%	n	%	n	%	n	%
CellDyn	5	23.8	10	52.6	8	40.0	23	38.3
Medonic	9	42.8	1	5.2	3	15.0	13	21.7
Sysmex	3	14.3	3	15.8	2	10.0	8	13.3
Celtac	1	4.7	3	15.8	3	15.0	7	11.7
Coulter	1	4.7	1	5.3	2	10.0	4	6.7
Advia	1	4.7	1	5.3	0	0.0	2	3.3
ERMA	0	0.0	0	0.0	2	10.0	2	3.3
Micros	1	4.7	0	0.0	0	0.0	1	1.7
Total	21	100	19	100	20	100	60	100

3.1.3. IQC in participant medical laboratories.

The implementation of IQC measure at the laboratory starts with the use of a blood calibrator designed for calibration of the specific cell counter as indicated by the manufacturer. Among our study sample, fifty six medical laboratories reported that they use the blood calibrator regularly; compared to four laboratories that do not use the blood calibrator (Table 3.1.3). The four laboratories that do not use a calibrator, they use samples from the previous day to check for the precision of the cell counter.

Table (3.1.3) Distribution of participant laboratories according to use of blood calibrators, range of calibrator used and laboratory location. L, N and H refer to Low, Normal and High whole blood calibrators. Where n is the number of medical laboratories.

Laboratory location	No. of labs using blood calibrators						Do not use blood calibrator	
	Total labs		L, N & H blood calibrators		N Blood calibrator			
	n	%	n	%	n	%	n	%
Nablus	19	34.0	4	25.0	15	37.5	2	50.0
Ramallah	19	34.0	9	56.0	10	25.0	0	0.0
Hebron	18	32.0	3	19.0	15	37.5	2	50.0
Total	56	100	16	100	40	100	4	100

3.1.4. Frequency of cell counters calibration using certified whole blood calibrators.

Table 3.1.4A shows the frequency of calibrator use in the three cities: Nablus, Ramallah and Hebron. Sixty four percent of the laboratories run the calibrator daily while, 11.0 % twice per week, 16.0 % once per week and 9.0 % of medical laboratories do it occasionally.

Among the 56 laboratories that use the blood calibrator, 16 medical laboratories use low, normal and high blood calibrators while 40 laboratories use only the normal blood calibrator (Table 3.1.4B).

Table (3.1.4A) Frequency of cell counter calibration using certified whole blood calibrators in participant laboratories according to the city. Where n is the number of medical laboratories.

Frequency of use of blood calibrator	Nablus		Ramallah		Hebron		Total	
	N	%	n	%	n	%	n	%
Daily	11	58.0	18	95.0	7	39.0	36	64.0
Twice per week	2	10.5	0	0.0	4	22.0	6	11.0
Once per week	2	10.5	0	0.0	7	39.0	9	16.0
Occasional	4	21.0	1	5.0	0	0.0	5	9.0
Total	19	100	19	100	18	100	56	100

Table (3.1.4B) Frequency of cell counter calibration using certified whole blood calibrators in participant laboratories according to the type of calibrator. Where n is the number of medical laboratories.

Frequency of use of blood calibrator	L, N & H blood calibrator		N blood calibrator		Total	
	N	%	n	%	n	%
Daily	16	100	20	50.0	36	64.0
Twice per week	0	0.0	6	15.0	6	11.0
Once per week	0	0.0	9	22.5	9	16.0
Occasional	0	0.0	5	12.5	5	9.0
Total	16	100	40	100	56	100

3.2. Complete blood count results.

There is a wide range of cell counters available in the Palestinian market. They represent a selection of many international trademarks. In this study, blood samples collected from healthy volunteers were aliquoted and distributed to the participant laboratories at three times or rounds, each separated from the previous one by around three weeks.

The CBC results collected at each round were analyzed for the consensus mean. The consensus mean was then used as a reference for evaluating the performance of participant laboratories based on calculation of the DI. For calculation of the consensus mean \bar{x} and the SD, the data were adjusted by excluding any values that deviate more than $> 2SD$ from the mean. After exclusion, the mean and SD were recalculated and termed “weighted mean and SD” for all participating medical laboratories.

When participating medical laboratories send back their results to be analyzed and interpreted using the consensus mean method and the DI method, the performance of the laboratories was evaluated. Unfortunately, the harmony of the CBC results was poor in general since there was a large difference between the hematologic parameters values recorded before and after the exclusion of the outlier medical laboratories.

Tables 3.2A and 3.2B show the recorded lowest (LV) and highest (HV) values for each of the hematological parameters studied at each round of the study. The difference between the LV and HV reflects a wide variation in the results reported by the participant laboratories even after exclusion of outlier laboratories. Further detailed information of each parameter is shown in appendix C.

Table (3.2A) The lowest and highest hematologic parameters values recorded during the study before the exclusion of the outlier medical laboratories.

Key: LV: Lowest Value, HV: Highest Value, Diff: Difference.

Laboratory Parameters / unit		Round One			Round Two			Round Three		
		LV	HV	Diff	LV	HV	Diff	LV	HV	Diff
WBCs	K / μL	3.7	6.7	3.0	5.1	7.1	2.0	5.7	8.5	2.8
RBCs	mill/μL	4.4	6.7	2.3	4.3	6.9	2.6	3.9	6.4	2.4
Hgb	g / dL	11.5	17.9	6.4	12.9	19.4	6.5	12.5	19.0	6.5
Hct	%	34.1	55.8	21.7	35.4	82.1	46.7	33.6	56.6	23.0
MCV	fL	72.2	87.3	15.1	79.8	159.4	79.6	80.0	95.8	15.8
MCH	pg	23.9	34.8	10.9	26.2	30.8	4.6	25.2	32.3	7.1
MCHC	%	30.4	35.4	5.0	18.1	36.6	18.5	30.0	37.2	7.2
PLTS	K / μL	173.0	349.0	176.0	120.0	298.0	178.0	168.0	297.0	129.0
RDW	%	10.3	16.9	6.6	9.4	16.0	6.6	10.0	17.6	7.6

Table (3.2B) The lowest and highest hematologic parameters values recorded during the study after the exclusion of the outlier medical laboratories.

Key: LV: Lowest Value, HV: Highest Value, Diff: Difference.

Laboratory Parameters / unit		Round One			Round Two			Round Three		
		LV	HV	Diff	LV	HV	Diff	LV	HV	Diff
WBCs	K / μL	4.9	6.3	1.4	5.2	6.4	1.2	6.1	7.8	1.7
RBCs	mill/μL	5.7	6.7	1.0	4.9	5.6	0.7	4.9	5.7	0.8
Hgb	g / dL	14.9	17.9	3.0	13.4	16.0	2.6	14.5	17.3	2.8
Hct	%	44.2	55.8	11.6	35.4	48.7	13.3	44.0	53.0	9.0
MCV	fL	75.2	84.1	8.9	79.8	91.2	11.4	85.1	93.0	7.9
MCH	pg	23.9	27.7	3.8	26.7	30.3	3.6	27.7	32.0	4.3
MCHC	%	30.5	34.8	4.3	30.9	36.6	5.7	31.7	35.7	4.0
PLTS	K / μL	208.0	327.0	119.0	165.0	276.0	111.0	184.0	291.0	107.0
RDW	%	11.5	15.1	3.6	11.2	14.8	3.6	10.9	14.6	3.7

3.2.1. Statistical analysis of the CBC results.

The results of the CBC were analyzed and interpreted using the consensus mean method and the DI method. The mean, SD were calculated, and then the weighted mean and weighted SD were recalculated after excluding the outlier laboratories and used to calculate the DI which evaluates the performance of the medical laboratories. The CV % for each parameter after trimming of the outlier medical laboratories was calculated in all rounds and was found $>2\%$ implying poor performance. The CV % for each parameter was tested by Chi-square for goodness-of-fit to compare the performance of medical laboratories in the three rounds and assess if there is an improvement in their performance. It was found that their performance was the same in the three rounds ($P > 0.05$) implying no improvement for all parameters (Table 3.2.1D). Furthermore, their performance was assessed by calculating the clinical significance among the participating laboratories (S M Lewis, 2006). It was found that there were many laboratories outside the allowable limits even though the laboratories with performance $> \text{mean} \pm 2 \text{ SD}$ were already excluded. The variability was at most in RBCs and Hgb and the least was in WBCs (Table 3.2.1C).

Table 3.2.1A shows the values of each of the mean and weighted mean, SD and the weighted SD in addition to the CV % values recorded throughout the study. While table 3.2.1B2 shows the general performance of the medical laboratories and the numbers of the total medical laboratories after the exclusion of the outlier values in round one, two and three. To evaluate the CBC results, the DI and the CV % made the basic tools for evaluation. The calculation of DI and the CV % was done for each hematological parameter. The DI represent the deviation of the individual values from the consensus (or weighted) mean. But the CV % is a measure of the reproducibility. The interpretation of the DI was set into four categories; excellent, good, satisfactory, and serious error as shown in Table 3.2.1B1. The interpretation of the CV % results depends on the increase or decrease of its value. An increase in the CV % value indicates an increase in variability (less reproducibility), while a decrease in the CV % value was considered as an improvement in variability or reproducibility. However, a CV % $> 2\%$ indicates in general poor performance or poor reproducibility.

Table (3.2.1A) Mean, SD and Coefficient of Variation of the CBC parameters in all rounds.

CBC Parameter	Round No.	Mean	Weighted Mean	SD	Weighted SD	CV %
WBCs	1	5.5	5.5	0.47	0.36	6.7
	2	5.9	5.8	0.39	0.29	5.1
	3	6.9	6.9	0.50	0.36	5.2
RBCs	1	6.2	6.3	0.32	0.22	3.6
	2	5.2	5.2	0.35	0.16	3.2
	3	5.4	5.4	0.33	0.18	3.4
Hgb	1	16.4	16.4	0.86	0.58	3.6
	2	14.9	14.7	0.99	0.46	3.2
	3	15.9	16.0	0.87	0.51	3.3
Hct	1	49.8	50.0	3.12	2.37	4.7
	2	44.9	43.7	5.93	1.90	4.4
	3	47.8	48.0	3.03	1.92	4.0
MCV	1	79.6	79.4	2.92	2.28	2.9
	2	85.8	84.5	10.00	2.54	3.0
	3	88.8	88.8	2.69	2.06	2.3
MCH	1	26.3	26.2	1.41	0.87	3.6
	2	28.5	28.5	0.97	0.82	2.9
	3	29.7	29.7	1.19	0.89	3.0
MCHC	1	32.9	32.8	1.19	1.04	3.2
	2	33.5	33.7	2.35	1.20	3.6
	3	33.4	33.4	1.33	0.98	2.9
PLTs	1	269.3	269.5	33.00	29.20	10.8
	2	211.8	214.8	32.80	24.99	11.6
	3	238.5	238.7	27.45	25.30	10.6
RDW	1	13.4	5.5	1.20	0.87	6.6
	2	13.1	5.8	1.15	0.87	6.6
	3	13.2	6.9	1.23	0.87	6.6

Table (3.2.1B1) The performance of participating medical laboratories in all rounds after excluding outlier values in percentage. Key: E: Excellent (≤ 0.5 SD), G: Good (0.5-1 SD), S: Satisfactory (1-2 SD), and SE: Serious Error (≥ 2 SD).

CBC Parameters	Round No.	Performance (%)				Participating Medical Laboratories (%)		
		E %	G %	S %	SE %	Labs Included %	Labs Excluded %	Total Labs %
WBCs	1	33.3	23.3	36.7	1.7	95.0	5.0	100
RBCs	1	43.3	26.6	23.3	5.1	98.3	1.7	100
Hgb	1	40.0	30.0	25.0	3.3	98.3	1.7	100
Hct	1	43.3	31.7	18.3	5.0	98.3	1.7	100
MCV	1	25.0	38.3	26.7	3.3	93.3	6.7	100
MCH	1	38.3	25.0	31.7	3.3	98.3	1.7	100
MCHC	1	28.3	28.3	35.0	1.7	93.3	1.7	100
PLTs	1	31.7	28.3	35.0	1.7	96.7	3.3	100
RDW	1	30.0	36.7	23.3	1.7	91.7	8.3	100
WBCs	2	33.8	25.5	30.5	1.7	91.5	8.5	100
RBCs	2	40.7	28.9	22.0	3.4	95.0	5.0	100
Hgb	2	51.0	17.0	22.0	5.0	95.0	5.0	100
Hct	2	39.0	40.7	11.9	3.4	95.0	5.0	100
MCV	2	35.6	34.0	20.3	5.1	98.3	1.7	100
MCH	2	35.6	22.0	30.5	5.1	93.2	6.7	100
MCHC	2	37.3	30.5	23.7	6.8	98.3	1.7	100
PLTs	2	40.7	22.0	27.1	3.4	93.2	6.7	100
RDW	2	42.4	20.3	27.1	3.4	93.2	6.7	100
WBCs	3	31.6	31.6	22.8	3.5	89.5	10.5	100
RBCs	3	40.5	21.0	26.3	5.3	93.1	6.9	100
Hgb	3	42.1	31.6	14.0	7.0	94.7	5.3	100
Hct	3	33.3	19.3	36.8	5.3	94.7	5.3	100
MCV	3	28	26.3	36.8	2.0	93.1	6.9	100
MCH	3	35.0	28.1	24.7	5.3	93.1	6.9	100
MCHC	3	35.0	24.6	28.1	3.5	91.2	8.8	100
PLTs	3	40.4	24.5	28.1	3.5	96.5	3.5	100
RDW	3	28.1	33.3	28.1	1.7	91.2	8.8	100

Table (3.2.1B2) The performance of participating medical laboratories in all rounds after excluding outlier values. Key: E: Excellent (≤ 0.5 SD), G: Good (0.5-1 SD), S: Satisfactory (1-2 SD), and SE: Serious Error (≥ 2 SD). Where n is the number of medical laboratories.

CBC Parameters	Round No.	Performance (n)				Participating Medical Laboratories (n)		
		E	G	S	SE	Labs Included	Labs Excluded	Total Labs
WBCs	1	20	14	22	1	57	3	60
RBCs	1	26	16	14	3	59	1	60
Hgb	1	24	18	15	2	59	1	60
Hct	1	26	19	11	3	59	1	60
MCV	1	15	23	16	2	56	4	60
MCH	1	23	15	19	2	59	1	60
MCHC	1	17	17	21	1	56	1	60
PLTs	1	19	17	21	1	58	2	60
RDW	1	18	22	14	1	55	5	60
WBCs	2	20	15	18	1	54	5	59
RBCs	2	24	17	13	2	56	3	59
Hgb	2	30	10	13	3	56	3	59
Hct	2	23	24	7	2	56	3	59
MCV	2	21	22	12	3	58	1	59
MCH	2	21	13	18	3	55	4	59
MCHC	2	22	18	14	4	58	1	59
PLTs	2	24	13	16	2	55	4	59
RDW	2	25	12	16	2	55	4	59
WBCs	3	18	18	13	2	51	6	57
RBCs	3	23	12	15	3	53	4	57
Hgb	3	24	18	8	4	54	3	57
Hct	3	19	11	21	3	54	3	57
MCV	3	16	15	21	1	53	4	57
MCH	3	20	16	14	3	53	4	57
MCHC	3	20	14	16	2	52	5	57
PLTs	3	23	14	16	2	55	2	57
RDW	3	16	19	16	1	52	5	57

Table (3.2.1C) Clinical Significance of CBC parameters obtained from participating medical laboratories.

CBC Parameters (Limits of clinical Significance)	Round No.	No. of Labs Below lower limit	No. of Labs above higher limit	Weighted mean	Range of clinical significance		Total No. of Labs outsidess the limits		CV %
					the Lower limit	the Higher limit	n	%	
WBCs (8-10%)	1	4	3	5.5	5.0	6.0	7	12	6.7
	2	5	1	5.8	5.3	6.4	6	11	5.1
	3	4	3	6.9	6.3	7.5	7	14	5.2
RBCs (3-4%)	1	12	7	6.3	6.0	6.5	19	32	3.6
	2	9	6	5.2	5.0	5.4	15	27	3.2
	3	10	6	5.4	5.2	5.5	16	30	3.4
Hgb (3-4%)	1	11	9	16.4	15.9	17.1	20	34	3.6
	2	9	7	14.7	14.3	15.3	16	29	3.2
	3	7	7	16.0	15.5	16.6	14	26	3.3
Hct (4-5%)	1	9	9	50.0	48.0	52.5	18	30	4.7
	2	8	4	43.7	41.9	45.9	12	21	4.4
	3	11	6	48.0	46.1	50.4	17	31	4.0
MCV (4-5%)	1	5	3	79.4	76.2	83.3	8	14	2.9
	2	4	4	84.5	81.1	88.7	8	14	3.0
	3	2	0	88.8	85.3	93.3	2	4	2.3
MCH (4-5%)	1	5	7	26.2	25.1	27.5	12	20	3.6
	2	4	3	28.5	27.3	29.9	7	12	2.9
	3	3	3	29.7	28.5	31.2	6	12	3.0
MCHC (4-5%)	1	4	6	32.8	31.4	34.4	10	18	3.2
	2	6	5	33.7	32.3	35.4	11	19	3.6
	3	6	3	33.4	32.1	35.1	9	18	2.9
Plts (10-15%)	1	10	8	269.5	242.5	309.9	18	31	10.8
	2	11	5	214.8	193.3	247.0	16	29	11.6
	3	9	6	238.7	214.8	274.5	15	27	10.6

Table (3.2.1D) The Chi-square results for comparing the CV% of the CBC parameters.

CBC Parameter	<i>P value</i>	CBC Parameter	<i>P value</i>	CBC Parameter	<i>P value</i>
WBCs	<i>P</i> > 0.05	Hct	<i>P</i> > 0.05	MCH	<i>P</i> > 0.05
RBCs	<i>P</i> > 0.05	MCV	<i>P</i> > 0.05	PLTs	<i>P</i> > 0.05
Hgb	<i>P</i> > 0.05	MCHC	<i>P</i> > 0.05	RDW	<i>P</i> > 0.05

3.2.2. Evaluation of the CBC results according to the frequency of cell counter calibration.

The frequency of blood calibrator use was divided into four groups in this study; daily, twice per week, once per week and occasional. The evaluation of the CBC results show that the medical laboratories which run their blood calibrator on daily basis showed a better performance and more medical laboratories in this group showed also excellent performance based on DI (Table 3.2.2A).

3.2.3. Evaluation of the CBC results According to the type of blood calibrator.

Medical laboratories were divided into two groups based on their use of blood calibrators: those used only normal blood calibrator and those who use low, normal and high blood calibrators (Table 3.2.3A and B).

3.2.4. Evaluation of the CBC results according to the type of cell counter.

Eight types of cell counters were participated in this study, previously shown in table 3.1.2. The performance in each round for all hematological parameters was reported. Table 3.2.4 shows the performance and the evaluation according to the cell counter type.

Table (3.2.2A) Evaluation of CBC results in participant laboratories according to frequency of cell counter calibration in percentage. Where n is the number of medical laboratories, AVG: Average percentage of the three rounds.

CBC	Round No.	Frequency of blood calibrator use (%)															
		Daily n = 36				Twice per week n = 6				Once per week n = 9				Occasional n = 5			
		E (%)	G (%)	S (%)	SE (%)	E (%)	G (%)	S (%)	SE (%)	E (%)	G (%)	S (%)	SE (%)	E (%)	G (%)	S (%)	SE (%)
WBCs	1	37.1	34.3	28.6	0.0	40.0	0.0	60.0	0.0	22.0	11.0	56.0	11.0	50.0	0.0	50.0	0.0
	2	36.4	27.2	36.4	0.0	20.0	80.0	0.0	0.0	37.5	12.5	50.0	0.0	40.0	20.0	20.0	20.0
	3	43.8	34.4	18.7	3.1	33.3	33.3	33.4	0.0	22.2	44.5	33.3	0.0	20.0	20.0	40.0	20.0
	AVG	39.1	32.0	27.9	1.0	31.1	37.8	31.2	0.0	27.3	22.7	46.4	3.7	36.7	13.3	36.7	13.3
RBCs	1	41.7	25.0	30.6	2.7	33.3	33.3	16.7	16.7	55.5	22.3	11.1	11.1	50.0	25.0	25.0	0.0
	2	38.2	35.3	26.5	0.0	16.7	33.3	33.3	16.7	75.0	25	0.0	0.0	50.0	25.0	0.0	25.0
	3	55.9	23.5	14.7	5.9	0.0	0.0	100.0	0.0	33.4	33.3	33.3	0.0	0.0	0.0	75.0	25.0
	AVG	45.3	27.9	23.9	2.9	16.7	22.2	50.0	11.4	54.6	26.8	14.8	3.7	33.3	16.7	33.3	16.7
Hgb	1	41.7	27.8	30.5	0.0	0.0	50.0	50.0	0.0	33.3	44.5	11.1	11.1	75.0	25.0	0.0	0.0
	2	58.8	14.7	20.6	5.9	0.0	33.3	50.0	16.7	50.0	25.0	25.0	0.0	75.0	0.0	25.0	0.0
	3	47.1	35.3	8.8	8.8	0.0	25.0	50.0	25.0	44.4	44.4	11.2	0.0	50.0	25.0	25.0	0.0
	AVG	49.2	25.9	59.9	4.9	0.0	36.1	50.0	13.9	42.6	38.0	15.8	3.7	8.0	2.0	2.0	0.0
Hct	1	44.4	33.3	22.3	0.0	33.3	16.7	16.7	33.3	44.4	44.4	0.0	11.2	50.0	50.0	0.0	0.0
	2	38.3	44.1	17.6	0.0	50.0	16.7	16.7	16.6	42.8	57.2	0.0	0.0	40.0	40.0	0.0	20.0
	3	38.3	20.5	38.3	2.9	0.0	0.0	100.0	0.0	44.4	22.3	33.3	0.0	25.0	50.0	0.0	25.0
	AVG	40.3	32.6	26.1	0.9	27.8	11.2	44.5	16.6	43.9	41.6	11.1	3.7	38.3	46.7	0.0	15.0

Table (3.2.2A) Continued.

CBC	Round No.	Frequency of blood calibrator use (%)															
		Daily n = 36				Twice per week n = 6				Once per week n = 9				Occasional n = 5			
		E %	G %	S %	SE %	E (%)	G (%)	S (%)	SE (%)	E (%)	G (%)	S (%)	SE (%)	E (%)	G (%)	S (%)	SE (%)
MCV	1	29.4	41.2	26.5	2.9	40.0	40.0	0.0	20.0	11.2	44.4	44.4	0.0	25.0	50.0	25.0	0.0
	2	40.0	34.3	20.0	5.7	16.7	50.0	16.6	16.7	50.0	37.5	12.5	0.0	20.0	40.0	40.0	0.0
	3	41.2	20.6	35.3	2.9	0.0	75.0	25.0	0.0	12.5	37.5	50.0	0.0	20.0	20.0	60.0	0.0
	AVG	36.9	32.0	27.3	3.8	18.9	55.0	13.9	12.3	24.6	39.8	35.6	0.0	21.7	36.7	41.7	0.0
MCH	1	47.2	22.2	27.8	2.8	16.7	33.3	50.0	0.0	25.0	25.0	50.0	0.0	40.0	20.0	40.0	0.0
	2	29.4	26.5	41.2	2.9	50.0	0.0	0.0	50.0	66.7	11.1	22.2	0.0	50.0	25.0	25.0	0.0
	3	38.2	32.4	29.4	0.0	100.0	0.0	0.0	0.0	33.4	44.4	22.2	0.0	20.0	20.0	0.0	60.0
	AVG	38.3	27.0	32.8	1.9	55.6	11.1	16.7	16.7	41.7	26.8	31.5	0.0	36.7	21.7	21.7	20.0
MCHC	1	31.5	22.8	45.7	0.0	0.0	60.0	20.0	20.0	37.5	37.5	25.0	0.0	25.0	50.0	25.0	0.0
	2	45.7	22.8	28.6	2.9	16.7	50.0	0.0	33.3	37.5	37.5	25.0	0.0	40.0	20.0	20.0	20.0
	3	44.1	20.6	32.4	2.9	25.0	25.0	25.0	25.0	33.3	33.3	33.4	0.0	0.0	66.7	33.3	0.0
	AVG	40.4	22.1	35.6	1.9	13.9	45.0	15.0	26.1	36.1	36.1	27.8	0.0	21.7	45.6	26.1	6.7
Plts	1	34.3	22.8	40.0	2.9	50.0	16.7	33.3	0.0	33.3	55.5	11.2	0.0	20.0	40.0	40.0	0.0
	2	47.0	20.6	29.4	3.0	33.4	33.3	33.3	0.0	42.8	42.8	14.4	0.0	25.0	25.0	50.0	0.0
	3	40.0	25.7	31.4	2.9	60.0	20.0	20.0	0.0	55.6	22.2	22.2	0.0	25.0	50.0	25.0	0.0
	AVG	40.4	23.0	33.6	2.9	47.8	23.3	28.8	0.0	43.9	40.2	15.9	0.0	23.3	38.3	38.3	0.0
RDW	1	36.4	33.3	27.3	3.0	16.7	33.3	50.0	0.0	33.3	44.4	22.3	0.0	0.0	100.0	0.0	0.0
	2	41.2	26.5	32.3	0.0	16.7	16.7	33.3	16.7	66.6	11.2	22.2	0.0	0.0	33.3	33.4	33.3
	3	38.2	32.4	29.4	0.0	25.0	0.0	50.0	25.0	22.3	44.4	33.3	0.0	0.0	66.7	33.3	0.0
	AVG	38.6	30.7	29.7	1.0	19.4	16.7	44.4	13.9	40.7	33.3	25.9	0.0	0.0	66.7	22.3	11.1

Table (3.2.2B) Evaluation of CBC results in participant laboratories according to frequency of cell counter calibration. Where n is the number of medical laboratories, AVG: Average of the three rounds.

CBC	R No.	Frequency of blood calibrator use															
		Daily n = 36				Twice per week n = 6				Once per week n = 9				Occasional n = 5			
		E	G	S	SE	E	G	S	SE	E	G	S	SE	E	G	S	SE
WBCs	1	13.0	12.0	10.0	0.0	2.0	0.0	3.0	0.0	2.0	1.0	5.0	1.0	2.0	0.0	2.0	0.0
	2	12.0	9.0	12.0	0.0	1.0	4.0	0.0	0.0	3.0	1.0	4.0	0.0	2.0	1.0	1.0	1.0
	3	14.0	11.0	6.0	1.0	1.0	1.0	1.0	0.0	2.0	4.0	3.0	0.0	1.0	1.0	2.0	1.0
	AVG	13.0	10.7	9.3	0.3	1.3	1.6	1.3	0.0	2.3	2.0	4.0	0.3	1.7	0.6	1.7	0.6
RBCs	1	15.0	9.0	11.0	1.0	2.0	2.0	1.0	1.0	5.0	2.0	1.0	1.0	2.0	1.0	1.0	0.0
	2	13.0	12.0	9.0	0.0	1.0	2.0	2.0	1.0	6.0	2.0	0.0	0.0	2.0	1.0	0.0	1.0
	3	19.0	8.0	5.0	2.0	0.0	0.0	4.0	0.0	3.0	3.0	3.0	0.0	0.0	0.0	3.0	1.0
	AVG	15.7	9.7	8.3	1.0	1.0	1.3	2.3	0.6	4.7	2.3	1.3	0.3	1.3	0.6	1.3	0.6
Hgb	1	15.0	10.0	11.0	0.0	0.0	3.0	3.0	0.0	3.0	4.0	1.0	1.0	3.0	1.0	0.0	0.0
	2	20.0	5.0	7.0	2.0	0.0	2.0	3.0	1.0	4.0	2.0	2.0	0.0	3.0	0.0	1.0	0.0
	3	16.0	12.0	3.0	3.0	0.0	1.0	2.0	1.0	4.0	4.0	1.0	0.0	2.0	1.0	1.0	0.0
	AVG	17.0	9.0	7.0	1.7	0.0	2.0	2.7	0.6	3.7	3.3	1.3	0.3	2.7	0.6	0.6	0.0
Hct	1	16.0	12.0	8.0	0.0	2.0	1.0	1.0	2.0	4.0	4.0	0.0	1.0	2.0	2.0	0.0	0.0
	2	13.0	15.0	6.0	0.0	3.0	1.0	1.0	1.0	3.0	4.0	0.0	0.0	2.0	2.0	0.0	1.0
	3	13.0	7.0	13.0	1.0	0.0	0.0	4.0	0.0	4.0	2.0	3.0	0.0	1.0	2.0	0.0	1.0
	AVG	14.0	11.3	9.0	0.3	1.7	0.6	2.0	1.0	3.7	3.3	1.0	0.3	1.7	2.0	0.0	0.6
MCV	1	10.0	14.0	9.0	1.0	2.0	2.0	0.0	1.0	1.0	4.0	4.0	0.0	1.0	2.0	1.0	0.0
	2	14.0	12.0	7.0	2.0	1.0	3.0	1.0	1.0	4.0	3.0	1.0	0.0	1.0	2.0	2.0	0.0
	3	14.0	7.0	12.0	1.0	0.0	3.0	1.0	0.0	1.0	3.0	4.0	0.0	1.0	1.0	3.0	0.0
	AVG	12.7	11.0	9.3	1.3	1.0	2.7	0.6	0.6	2.0	3.3	3.0	0.0	1.0	1.7	2.0	0.0
MCH	1	17.0	8.0	10.0	1.0	1.0	2.0	3.0	0.0	2.0	2.0	4.0	0.0	2.0	1.0	2.0	0.0
	2	10.0	9.0	14.0	1.0	2.0	0.0	0.0	2.0	6.0	1.0	2.0	0.0	2.0	1.0	1.0	0.0
	3	13.0	11.0	10.0	0.0	3.0	0.0	0.0	0.0	3.0	4.0	2.0	0.0	1.0	1.0	0.0	3.0
	AVG	13.3	9.3	11.3	0.6	2.0	0.6	1.0	0.6	3.7	2.3	2.7	0.0	1.7	1.0	1.0	1.0
MCHC	1	11.0	8.0	16.0	0.0	0.0	3.0	1.0	1.0	3.0	3.0	2.0	0.0	1.0	2.0	1.0	0.0
	2	16.0	8.0	10.0	1.0	1.0	3.0	0.0	2.0	3.0	3.0	2.0	0.0	2.0	1.0	1.0	1.0
	3	15.0	7.0	11.0	1.0	1.0	1.0	1.0	1.0	3.0	3.0	3.0	0.0	0.0	2.0	1.0	0.0
	AVG	14.0	7.7	12.3	0.6	0.6	2.3	0.6	1.3	3.0	3.0	2.3	0.0	1.0	1.7	1.0	0.3
Plts	1	12.0	8.0	14.0	1.0	3.0	1.0	2.0	0.0	3.0	5.0	1.0	0.0	1.0	2.0	2.0	0.0
	2	16.0	7.0	10.0	1.0	2.0	2.0	2.0	0.0	3.0	3.0	1.0	0.0	1.0	1.0	2.0	0.0
	3	14.0	9.0	11.0	1.0	3.0	1.0	1.0	0.0	5.0	2.0	2.0	0.0	1.0	2.0	1.0	0.0
	AVG	14.0	8.0	11.7	1.0	2.7	1.3	1.7	0.0	3.7	3.3	1.3	0.0	1.0	1.7	1.7	0.0
RDW	1	12.0	11.0	9.0	1.0	1.0	2.0	3.0	0.0	3.0	4.0	2.0	0.0	0.0	3.0	0.0	0.0
	2	14.0	9.0	11.0	0.0	2.0	1.0	2.0	1.0	6.0	1.0	2.0	0.0	0.0	1.0	1.0	1.0
	3	13.0	11.0	10.0	0.0	1.0	0.0	2.0	1.0	2.0	4.0	3.0	0.0	0.0	2.0	1.0	0.0
	AVG	13.0	10.3	10.0	0.3	1.3	1.0	2.3	0.6	3.7	3.0	2.3	0.0	0.0	2.0	0.6	0.3

Table (3.2.3A) Evaluation of CBC results from participant medical laboratories according to the type of blood calibrator used in percentage. Where n is the number of medical laboratories, AVG: Average percentage of the three rounds.

CBC parameter	Round No.	Type of blood calibrator use (%)							
		L, N & H n = 16				N n = 40			
		E %	G %	S %	SE %	E %	G %	S %	SE %
WBCs	1	26.7	33.3	33.3	6.7	39.5	21.0	39.5	0.0
	2	54.0	23.0	23.0	0.0	29.0	31.6	36.8	2.6
	3	46.7	20.0	33.3	0.0	32.3	41.2	20.6	5.9
	AVG	42.5	25.4	29.9	2.2	33.6	31.3	32.3	2.8
RBCs	1	37.5	25.0	31.2	6.3	46.3	25.6	23.0	5.1
	2	46.7	40.0	13.3	0.0	40.6	29.7	24.3	5.4
	3	62.5	18.7	12.5	6.3	34.3	22.9	37.1	5.7
	AVG	48.9	27.9	19.0	4.2	40.4	22.1	28.2	5.4
Hgb	1	31.3	37.5	31.2	0.0	41.0	30.7	25.7	2.6
	2	40.0	13.3	33.4	13.3	56.7	19.0	21.6	2.7
	3	37.5	37.5	12.5	12.5	45.7	34.3	14.3	5.7
	AVG	36.3	29.4	25.7	8.6	47.8	28.0	20.5	3.7
Hct	1	31.3	50.0	18.7	0.0	48.7	23.0	20.6	7.7
	2	33.3	53.4	13.3	0.0	43.3	37.8	13.5	5.4
	3	56.3	18.7	18.7	6.3	30.0	10.0	56.7	3.3
	AVG	40.3	40.7	16.9	2.1	40.7	23.6	30.3	5.5

Table (3.2.3A) Continued.

CBC parameter	Round No.	Type of blood calibrator use (%)							
		L, N & H n = 16				N n = 40			
		E	G	S	SE	E	G	S	SE
MCV	1	43.7	43.7	12.6	0.0	19.4	41.6	33.4	5.6
	2	60.0	26.7	13.3	0.0	28.2	41.0	23.1	7.7
	3	50.0	31.5	18.7	0.0	22.8	25.7	48.6	2.9
	AVG	51.3	34.0	14.9	0.0	23.5	36.0	35.0	5.4
MCH	1	37.5	43.8	18.7	0.0	41.0	15.4	41.0	2.6
	2	28.6	21.4	50.0	0.0	43.3	21.6	27.0	8.1
	3	40.0	40.0	20.0	0.0	38.9	27.8	25.0	8.3
	AVG	35.4	35.1	29.6	0.0	41.1	21.6	31.0	6.3
MCHC	1	31.2	12.5	56.3	0.0	27.8	38.9	30.5	2.8
	2	46.7	13.3	33.3	6.7	35.9	33.3	23.1	7.7
	3	26.7	26.7	40.0	6.6	38.9	27.8	25.0	8.3
	AVG	34.9	17.5	43.2	4.4	34.2	33.2	26.2	6.3
Plts	1	33.3	26.7	40.0	0.0	33.3	30.8	33.3	2.6
	2	50.0	21.4	21.4	7.2	40.5	27.0	32.5	0.0
	3	50.0	12.5	31.2	6.3	37.8	32.4	29.7	0.0
	AVG	44.4	20.2	30.9	4.5	37.2	30.1	31.8	0.9
RDW	1	31.2	43.8	25.0	0.0	31.4	37.1	28.6	2.9
	2	40.0	26.7	33.3	0.0	43.3	21.6	29.7	5.4
	3	37.5	37.5	25.0	0.0	29.4	32.3	35.3	3.0
	AVG	36.2	36.0	27.8	0.0	34.7	30.3	31.2	3.7

Table (3.2.3B) Evaluation of CBC results from participant medical laboratories according to the type of blood calibrator used. Where n is the number of medical laboratories, AVG: Average of the three rounds.

CBC	Round No.	Type of blood calibrator use							
		L, N & H n = 16				N n = 40			
		E	G	S	SE	E	G	S	SE
WBCs	1	4.0	5.0	5.0	1.0	15.0	8.0	15.0	0.0
	2	7.0	3.0	3.0	0.0	11.0	12.0	14.0	1.0
	3	7.0	3.0	5.0	0.0	11.0	14.0	7.0	2.0
	Average	6.0	3.7	4.3	0.3	12.3	11.3	12.0	1.0
RBCs	1	6.0	4.0	5.0	1.0	18.0	10.0	9.0	2.0
	2	7.0	6.0	2.0	0.0	15.0	11.0	9.0	2.0
	3	10.0	3.0	2.0	1.0	12.0	8.0	13.0	2.0
	Average	7.7	4.3	3.0	0.6	15.0	9.7	10.3	2.0
Hgb	1	5.0	6.0	5.0	0.0	16.0	12.0	10.0	1.0
	2	6.0	2.0	5.0	2.0	21.0	7.0	8.0	1.0
	3	6.0	6.0	2.0	2.0	16.0	12.0	5.0	2.0
	Average	5.7	4.7	4.0	1.3	17.7	10.3	7.7	1.3
Hct	1	5.0	8.0	3.0	0.0	19.0	9.0	8.0	3.0
	2	5.0	8.0	2.0	0.0	16.0	14.0	5.0	2.0
	3	9.0	3.0	3.0	1.0	9.0	3.0	17.0	1.0
	Average	6.3	6.3	2.7	0.3	14.7	8.7	10.0	2.0
MCV	1	7.0	7.0	2.0	0.0	7.0	15.0	12.0	2.0
	2	9.0	4.0	2.0	0.0	11.0	16.0	9.0	3.0
	3	8.0	5.0	3.0	0.0	8.0	9.0	17.0	1.0
	Average	8.0	5.3	2.3	0.0	8.7	13.3	12.7	2.0
MCH	1	6.0	7.0	3.0	0.0	16.0	6.0	16.0	1.0
	2	4.0	3.0	7.0	0.0	16.0	8.0	10.0	3.0
	3	6.0	6.0	3.0	0.0	14.0	10.0	9.0	3.0
	Average	5.3	5.3	4.3	0.0	15.3	8.0	11.7	2.3
MCHC	1	5.0	2.0	9.0	0.0	10.0	14.0	11.0	1.0
	2	7.0	2.0	5.0	1.0	14.0	13.0	9.0	3.0
	3	4.0	4.0	6.0	1.0	14.0	10.0	9.0	3.0
	Average	5.3	2.7	6.7	0.6	12.7	12.3	9.6	2.3
Plts	1	5.0	4.0	6.0	0.0	13.0	12.0	13.0	1.0
	2	7.0	3.0	3.0	1.0	15.0	10.0	12.0	0.0
	3	8.0	2.0	5.0	1.0	14.0	12.0	11.0	0.0
	Average	6.7	3.0	4.7	0.6	14.0	11.3	12.0	0.3
RDW	1	5.0	7.0	4.0	0.0	11.0	13.0	10.0	1.0
	2	6.0	4.0	5.0	0.0	16.0	8.0	11.0	2.0
	3	6.0	6.0	4.0	0.0	10.0	11.0	12.0	1.0
	Average	5.7	5.7	4.3	0.0	12.3	10.7	11.0	1.3

Table (3.2.4) Evaluation of the CBC results according to the type of cell counter. Where n is the number of medical laboratories.

CBC	Round No.	Cell counter															
		CellDyn n = 23				Medonic n = 13				Sysmex n = 8				Celtac n = 7			
		E	G	S	SE	E	G	S	SE	E	G	S	SE	E	G	S	SE
WBCs	1	9	7	5	0	4	1	6	1	2	1	5	0	2	3	2	0
	2	9	8	3	0	3	5	3	1	6	1	1	0	2	1	4	0
	3	7	5	7	1	4	4	3	0	4	3	0	0	2	5	0	0
	Total	25	20	15	1	11	10	12	2	12	5	6	0	6	9	6	0
RBCs	1	8	6	5	3	5	3	5	0	3	4	1	0	5	0	2	0
	2	11	6	5	0	3	5	2	2	5	1	1	0	4	1	1	0
	3	9	5	5	1	2	1	7	2	3	3	1	0	2	3	1	0
	Total	28	17	15	4	10	9	14	4	11	8	3	0	11	4	4	0
Hgb	1	5	8	9	0	7	4	1	1	5	2	1	0	2	2	3	0
	2	8	3	9	2	8	1	2	1	4	2	1	0	3	2	1	0
	3	6	9	2	3	7	2	3	0	5	2	0	0	2	2	1	1
	Total	19	20	20	5	22	7	6	2	14	6	2	0	7	6	5	1
Hct	1	8	8	4	2	7	3	2	1	4	2	2	0	4	2	1	0
	2	11	9	2	0	6	5	0	2	2	4	1	0	1	2	2	0
	3	8	4	7	1	4	3	4	1	4	1	2	0	0	2	4	0
	Total	27	21	13	3	17	11	6	4	10	7	5	0	5	6	7	0
MCV	1	7	11	4	1	1	6	4	1	2	4	2	0	4	1	2	0
	2	11	9	2	0	2	5	6	0	3	3	2	0	2	3	0	1
	3	8	6	6	0	1	2	9	0	2	4	1	0	2	1	3	1
	Total	26	26	12	1	4	13	19	1	7	11	5	0	8	5	5	2
MCH	1	8	6	9	0	5	2	4	1	3	4	1	0	2	2	3	0
	2	5	6	7	2	7	0	5	0	3	4	1	0	4	1	2	0
	3	5	8	6	1	4	2	3	2	4	0	3	0	2	4	1	0
	Total	18	20	22	3	16	4	12	3	10	8	5	0	8	7	6	0
MCHC	1	7	6	8	0	3	5	3	1	4	1	3	0	1	3	3	0
	2	10	6	3	3	4	5	3	1	4	3	1	0	2	2	2	0
	3	5	4	9	2	3	3	5	0	1	5	1	0	5	1	1	0
	Total	22	16	20	5	10	13	11	2	9	9	5	0	8	6	6	0
Plts	1	8	4	9	0	3	5	5	0	4	3	1	0	2	1	4	0
	2	9	4	8	1	3	5	3	0	7	0	0	0	3	2	1	0
	3	8	1	11	1	3	5	4	0	4	2	1	0	3	3	1	0
	Total	25	9	28	2	9	15	12	0	15	5	2	0	8	6	6	0
RDW	1	8	11	4	0	3	4	3	0	2	4	2	0	2	1	2	1
	2	10	6	6	0	1	3	4	2	6	0	2	0	2	2	3	0
	3	9	8	5	0	1	4	3	1	1	3	3	0	2	1	4	0
	Total	27	25	15	0	5	11	10	3	9	7	7	0	6	4	9	1

Table (3.2.4) Continued.

CBC	Round No.	Cell counter															
		Coulter n = 4				Advia n = 2				ERMA n = 2				Micros n = 1			
		E	G	S	SE	E	G	S	SE	E	G	S	SE	E	G	S	SE
WBCs	1	1	1	2	0	1	0	1	0	0	1	1	0	1	0	0	0
	2	0	0	3	0	0	0	2	0	0	0	1	0	0	0	1	0
	3	1	1	1	0	0	0	1	1	0	0	1	0	0	0	0	0
	Total	2	2	6	0	1	0	4	1	0	1	3	0	1	0	1	0
RBCs	1	2	1	1	0	2	0	0	0	1	1	0	0	0	1	0	0
	2	0	2	2	0	0	2	0	0	0	0	2	0	1	0	0	0
	3	3	0	1	0	2	0	0	0	1	0	0	0	1	0	0	0
	Total	5	3	4	0	4	2	0	0	2	1	2	0	2	1	0	0
Hgb	1	2	1	1	0	1	1	0	0	1	0	0	1	1	0	0	0
	2	2	2	0	0	2	0	0	0	2	0	0	0	1	0	0	0
	3	1	2	1	0	1	1	0	0	1	0	1	0	1	0	0	0
	Total	5	5	2	0	4	2	0	0	4	0	1	1	3	0	0	0
Hct	1	1	0	3	0	0	2	0	0	1	0	1	0	1	0	0	0
	2	2	1	1	0	0	1	1	0	1	1	0	0	0	1	0	0
	3	1	1	2	0	1	0	1	0	0	0	1	1	1	0	0	0
	Total	4	2	6	0	1	3	2	0	2	1	2	1	2	1	0	0
MCV	1	0	0	1	0	0	1	1	0	1	0	1	0	0	0	1	0
	2	2	0	0	2	1	0	1	0	0	1	1	0	0	1	0	0
	3	1	1	1	0	1	1	0	0	0	0	1	0	1	0	0	0
	Total	3	1	2	2	2	2	2	0	1	1	3	0	1	1	1	0
MCH	1	2	0	2	0	1	1	0	0	1	0	0	1	1	0	0	0
	2	1	0	1	1	1	0	1	0	0	1	1	0	0	1	0	0
	3	2	2	0	0	2	0	0	0	0	0	1	0	1	0	0	0
	Total	5	2	3	1	4	1	1	0	1	1	2	1	2	1	0	0
MCHC	1	0	1	1	0	0	0	2	0	2	0	0	0	0	1	0	0
	2	2	0	2	0	0	0	2	0	0	2	0	0	0	0	1	0
	3	3	0	0	0	1	1	0	0	1	0	0	0	1	0	0	0
	Total	5	1	3	0	1	1	4	0	3	2	0	0	1	1	1	0
Plts	1	1	2	1	0	1	1	0	0	0	1	1	0	0	0	0	1
	2	1	1	2	0	1	1	0	0	0	0	1	1	0	0	1	0
	3	3	1	0	0	0	2	0	0	0	0	1	0	1	0	0	0
	Total	5	4	3	0	2	4	0	0	0	1	3	1	1	0	1	1
RDW	1	0	0	3	0	1	1	0	0	2	0	0	0	0	1	0	0
	2	2	1	1	0	2	0	0	0	1	0	0	0	1	0	0	0
	3	1	2	0	0	2	0	0	0	0	1	0	0	0	0	1	0
	Total	3	3	4	0	5	1	0	0	3	1	0	0	1	1	1	0

Chapter Four: Discussion

4.1 Discussion.

The CBC plays an important role in the diagnosis of a wide range of diseases as well as prognosis of the health status in general. In order to fulfil this role, the results of CBC need to be as accurate as possible and show minimal interlaboratory variation. Therefore a need for laboratories to become more responsive to the needs of physicians making request by providing help in the presentation and interpretation (Kotila, 2006).

In this study the interlaboratory and accuracy of hematology cell counters in participating laboratories were evaluated using fresh whole blood samples. Three samples from three healthy volunteers were collected and distributed directly after collection to sixty laboratories participating in this study. All participants were asked to run these samples in the same way they run their own patients' samples.

The CBC results were analyzed using the MS excel program to calculate the mean, SD, DI and the CV %. The implementation of a quality assessment program at the medical laboratory is an essential criteria toward implementing the good laboratory practice required by the regulatory authorities. The quality assessment program should include two parts, the IQC and the EQAS. The IQC program ensures that the laboratory delivers a reliable and reproducible results, while the EQAS controls the interlaboratory harmony.

QC in automated hematology and related topics are extensively researched but there is still less knowledge on automation in other areas of Haematology (Kotila, 2006). Analysis of the data collected from sixty participant laboratories showed that only 11 (18.3 %) laboratories participate in an EQAS program while 49 (81.7 %) were not (Table 3.1.1). The EQAS programs were provided either by local programs like Al-Quds University or Health Work Committees (HWCs) or international programs like UK-NEQAS, RIQAS and CAP.

The reason that most laboratories do not participate in an EQAS is the high cost of the international programs. While the local programs lack sustainability and cover a small number of laboratories and usually the large laboratories or those that are affiliated with non-governmental organizations or charitable societies. Additionally, the participation in an EQAS is not obligatory for the licence of a medical laboratory in Palestine.

In West Bank there are a wide range of cell counters used; CellDyn is the most commonly used in Ramallah and Hebron, while Medonic is the most commonly used one in Nablus (Table 3.1.2). This study also showed that CellDyn (38.3 %) and Medonic (21.7 %) account for about 60.0 % of the cell counters used in participating laboratories. The choice of the cell counter mostly depends on the cost of the machine and availability of a reliable agent for the machine as well as benchmarking with other peer laboratories. Although the different machines vary in terms of the technology used for analysis of blood samples, they should essentially deliver comparable results for the same sample. In order to achieve this, the machines must be properly, carefully and regularly calibrated.

The implementation of IQC at the laboratory starts with the use of a blood calibrator designed for calibration of the specific cell counter as indicated by the manufacturer. The proper calibration of cell counters requires the use of normal whole blood calibrators to calibrate the machine and the low and high blood calibrators are used to check the linearity of the machine which cover the range of values that can be found in patients' samples.

The use of the three types of calibrator is essential because the kinetics of the analysis method and the performance of the machine is not the same over the normal, low and high range (S M Lewis, 2006) Therefore, it's always essential to calibrate or train the machine to perform properly over the values expected in patients' samples. Among our study sample, it was observed that the number of the medical laboratories that use only normal blood calibrator is higher than those who use three blood calibrators (low, normal and high blood calibrators).

The reason for the use of only normal calibrator is probably due to the cost needed to obtain the three blood calibrators compared to the purchase of one calibrator. Four (6.7 %) of the sixty medical laboratories do not use any type of blood calibrators, instead they select a patient sample from another laboratory and repeat it several times to check the reproducibility or precision of the machine, but this does not control the accuracy of the results. On the other hand, 26.6 % of laboratories use low, normal and high blood calibrators while 66.7 % of the medical laboratories use only normal calibrator (Table 3.1.3). This practice can be attributed to the lack of basic knowledge about the operation of the cell counter and thus these laboratory technicians require special attention and further education to better understand their machines properly.

Another reason for not using a calibrator is the cost of the calibrator, but this is not justified because the analysis of a selected sample several times is also expensive and may even exceeds the price of the calibrator. Additionally, the cost of a false or inaccurate result is more costly than the blood calibrator because it affects adversely the image of the laboratory and may provoke a legal action against the laboratory. The performance of laboratories using three calibrators (L, N and H) based on DI calculations was better than those who use only normal calibrator. On average for WBCs as an example 42.5 % of laboratories that use three calibrators achieved excellent results compared to 33.6 % of laboratories who use normal control only (Table 3.2.3A).

The frequency of using of blood calibrator is an important factor in IQC. The cell counters have to be calibrated daily before running the patients' samples and the calibration may be repeated more than once in the same day based on the number of samples as well as per the manufacturer instructions. About two-thirds of the medical laboratories (64.0 %) use the blood calibrator on daily basis especially in Ramallah (95.0 %), but the percentage was much lower in Nablus (58.0 %) and Hebron (39.0 %), data shown in Table 3.1.4A. The results also show that a significant number of laboratories in Hebron and Nablus use the calibrator once or twice per week. While 5 laboratories (9.0 %) use the calibrator occasionally (Table 3.1.4B).

The occasional use of the calibrator can be attributed to the lack of knowledge concerning machine calibration. Laboratories that use three calibrators 16 out of 60 laboratories (26.6 %), all of them use it on a daily basis. The latter finding also indicate that, the technicians of laboratories who realized the need to have three levels of the calibrator (low, normal and high) have also rightly realize the need for machine calibration on a daily basis. Additionally, most of these laboratories participated in EQAS programs.

An attempt to decrease the expenses may also play a role in the infrequent or occasional use of the calibrator. Another factor that may explain the use of only normal calibrator or the infrequent or occasional use of the calibrator is the low sample load since all large laboratories or those with a high work load use three calibrators and they use it on a daily basis. While most laboratories that use the normal calibrator alone are intermediate in size and about 50 % of them use the calibrator on a daily basis.

The laboratories that use one calibrator not on a daily basis or do not use a calibrator are usually small laboratories with a low work load. For medical laboratories to produce reliable and reproducible results there should be intra- and inter-laboratory harmony of results. So that patients, who may have to repeat the analysis at different times or at different laboratories, should receive a quality service that helps in the management of the disease status and do not complicate the diagnosis or leads to inappropriate management.

The results of this study showed that there are large differences in the values of CBC parameters before exclusion of outlier laboratories. Trimming of the raw data to exclude outlier laboratories has decreased the differences between lowest and highest values, but the differences are still large. The decrease in the difference between lowest and highest values was random and it did not show any pattern over the three rounds (Tables 3.2A & B). This study shows a large variation in the CBC results and a poor harmony in the results over the three rounds of the study. The high variability in the CBC results is due to several reasons. First some laboratories (6.7 %) do not calibrate their cell counters and one-third of medical laboratories (36.0 %) do not calibrate their cell counters on a daily basis (twice or once per week and occasionally).

The last point reveals that the quality control is not part of the medical laboratory philosophy as well as a lack of or negligence and/or ignorance of the basic principles of the operation of the cell counters. It also reveals the need for a national legislation that links the license of the medical laboratory to the implementation of IQC and participation in an EQAS. Secondly, some medical laboratories do not calibrate their cell counters appropriately, where they perform calibration depending on the range reported in the machine leaflet instead of the calibrator chart allowable percent, i.e., they fail to follow the instructions for calibration as provided by the cell counter manufacturer and calibrator supplier.

The main objective of laboratory testing is to provide medically or clinically significant results that leads to the appropriate diagnosis of the disease status and improves the management of the patient. It is essential that the laboratory results such as the CBC should be as accurate as possible. The term clinically significant result means that each CBC parameter has an allowable range that allows the test value to deviate slightly from the true value without affecting the clinical decision or judgment of the patient's health status. In this study, applying the criteria of the term "clinical significance of results" on the CBC results obtained from the participating laboratories, it was shown that 11-34 % of laboratories provided results that lie outside the allowable range (Table 3.2.1C).

The performance of the medical laboratories in RBCs, Hgb, Hct and Plts was the poorest compared to other parameters (Table 3.2.1C). For example, evaluation of WBCs data showed that 11-14 % of laboratories lie outside the range because it has a wide reference range ($4-11 \times 10^9/L$). While evaluation of Hgb showed that 26-34 % of laboratories lie outside the range. Also Hgb should be one of the most precisely measured values because of the availability of an accurate and simple measurement method. Testing the harmony of the laboratory results at one time point may be biased, therefore three samples were sent to the participant laboratories, each separated from other samples by about three weeks. Analysis of the data over the three rounds was supposed to give a better overview of the performance of the laboratories.

The performance of the participant laboratories was also analyzed based on the DI, which is also used by the UK-NEQAS and WHO. The results of this study indicate that the overall performance of the medical laboratories was poor in general and the same in all three rounds. To further analyze the performance of laboratories statistically, the CV % of each CBC parameter was analyzed by Chi square for goodness-of-fit.

Based on the CV %, there was no statistically significant change in the performance of the laboratories over the three rounds of the study and the slight changes seen over the three rounds in the values of the CBC are due to random changes. Although, for WBCs as an example 33.3 %, 33.8 % and 31.6 % of laboratories have achieved excellent results in round one, two and three, respectively, based on DI calculation (Table 3.2.1B1). Additionally, analysis of the performance of laboratories based on the type of cell counter also showed the performance is not affected by the type of cell counter (Table 3.2.4).

4.2 Recommendations.

The evaluation of quality control in the hematology laboratories in West Bank is an essential process. The large variations of the results of the CBC tests that have been shown in this study confirms the need of a national EQAS program for the medical laboratories in Palestine as well as the need for a legislation to link the license of medical laboratories to the implementation of IQC and participation in an EQAS.

The development of a local EQAS should encourage more laboratories to participate due to lower costs and a more accessible technical support and consultation. The harmony of the CBC results is poor, which confirms the problem of lacking a national quality control program. So, the need of the implementation of an EQAS in Palestine is essential for ensuring harmonization of results between medical laboratories. This harmonization enables all medical laboratories to achieve results which are in agreement with each other to reach a common level of standardization. In hematology, CBC is still the key for the diagnosis of a lot of diseases and thus warrants more attention.

Further studies to evaluate the consensus and accuracy of hematology laboratories in Palestine are needed to evaluate the performance of participants over a relatively longer period of time to allow for feedback from participants based on each result and examine their improvement over two or three rounds.

Local universities and institutes or any other nongovernmental organizations can participate with teams experience to improve the status of the Palestinian medical laboratories and introduce better laboratory services to the Palestinian patient. Alternatively, laboratories should all be asked by a national regulatory authority to implement IQC and participate in an EQAS and then evaluate their performance and guide them to improve their performance. Additionally, all laboratory technicians should be asked to participate in continuing education programs specifically targeted to tackle practical aspects of laboratory work.

The history of the last 20 years of EQA programs in clinical cell analysis has shown that every project has germinated first in a soil made of clinical need and scientific enthusiasm, and then it was transplanted in a solid institutional background, where it could mature, get stronger, and disseminate its educational fruits (Brando et al., 2007).

The success of the scheme implementation will provide opportunity to widen the scope of the participant medical laboratories. Since further studies for longer periods are needed the small local studies still provide the necessary stimulus to the continuous improvement of the scientifically aspects of EQAS schemes (Brando et al., 2007). Finally, the success of applying EQAS programs gives for sure an increased confidence in the laboratory results.

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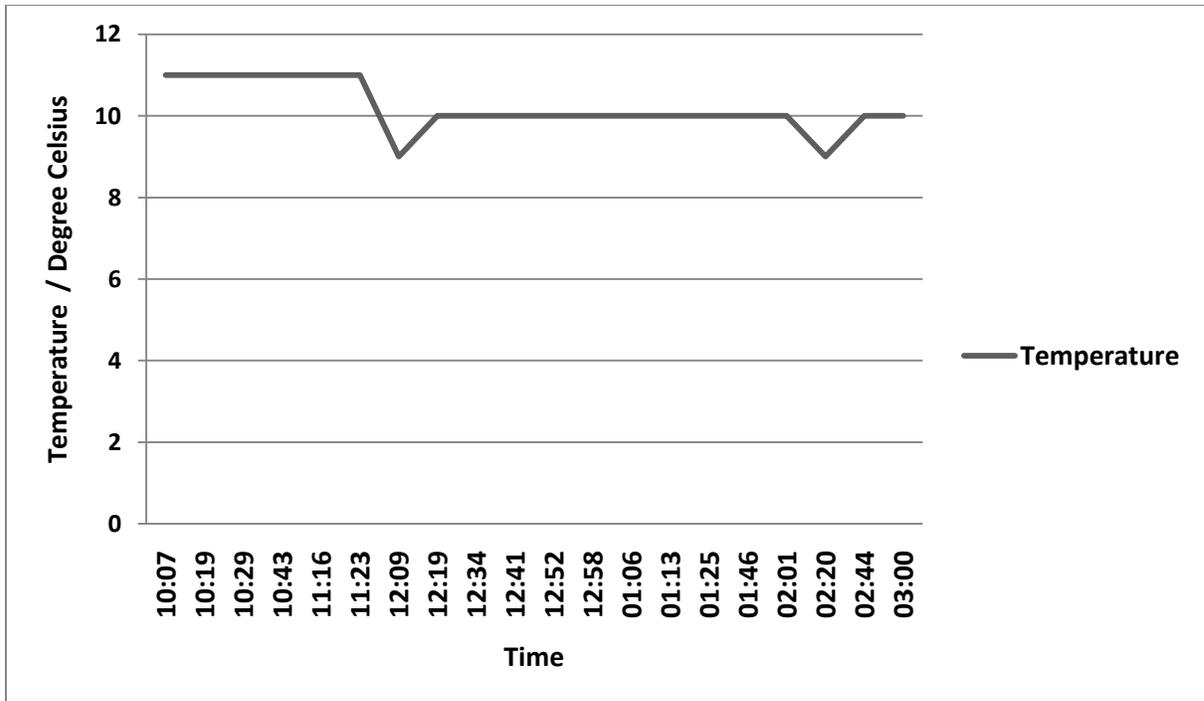
Appendices:

Appendix A

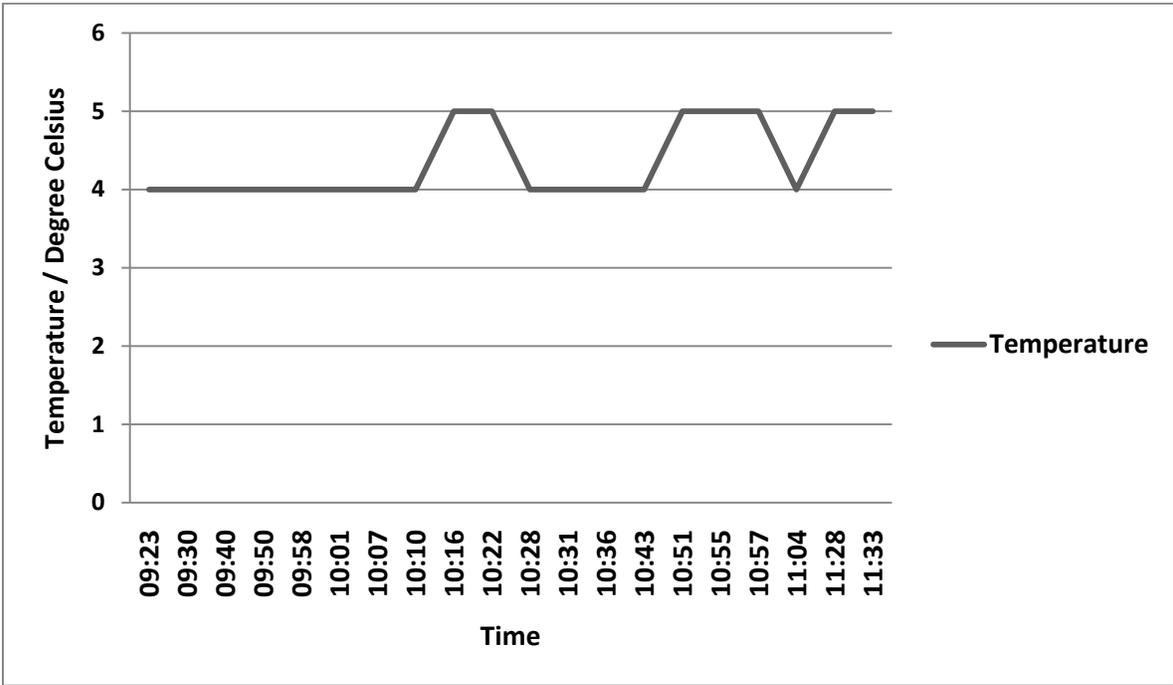
Results of the CBC tests for tubes number 1, 20, 40, and 60 on a CellDyn 1700 machine

CBC Parameter	WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
Tube No.									
1	6.6	5.33	15.3	47.3	88.8	28.7	32.3	176	13.4
20	6.7	5.20	15.1	47.0	88.5	28.5	32.1	173	13.2
40	6.6	5.31	15.2	47.1	88.6	28.6	32.2	179	13.3
60	6.5	5.29	15.3	47.2	88.8	28.8	32.2	177	13.4

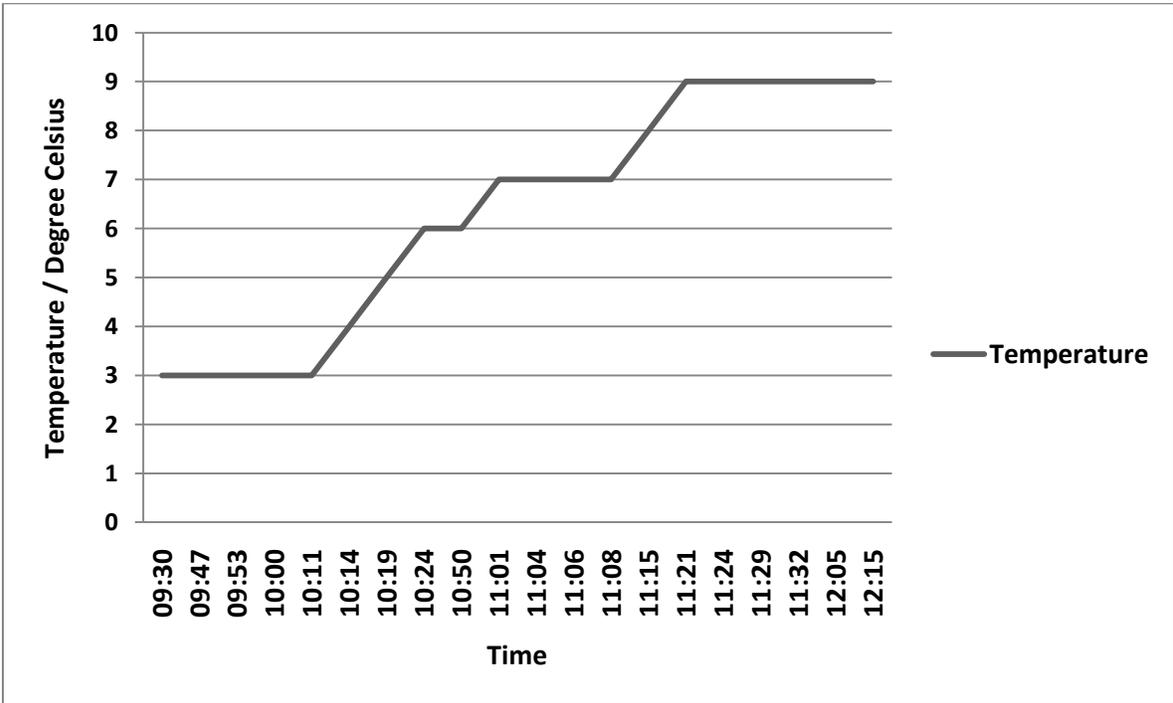
Appendix B The recorded time and temperature of the refrigerators during the study



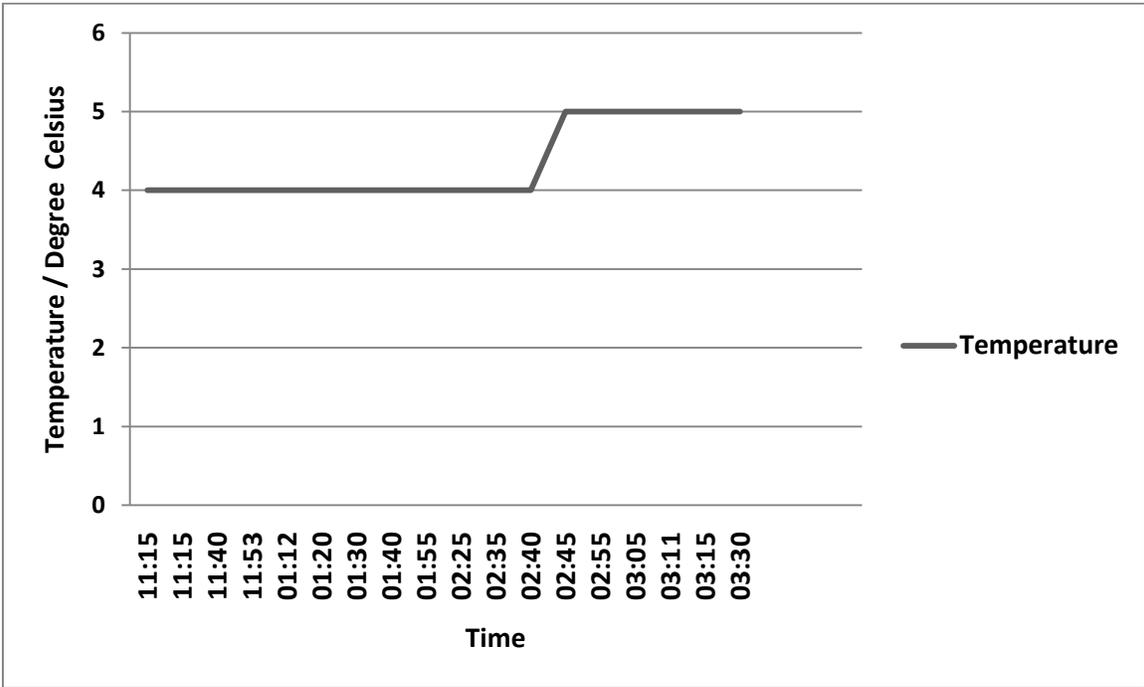
Appendix B1 in Ramallah round one



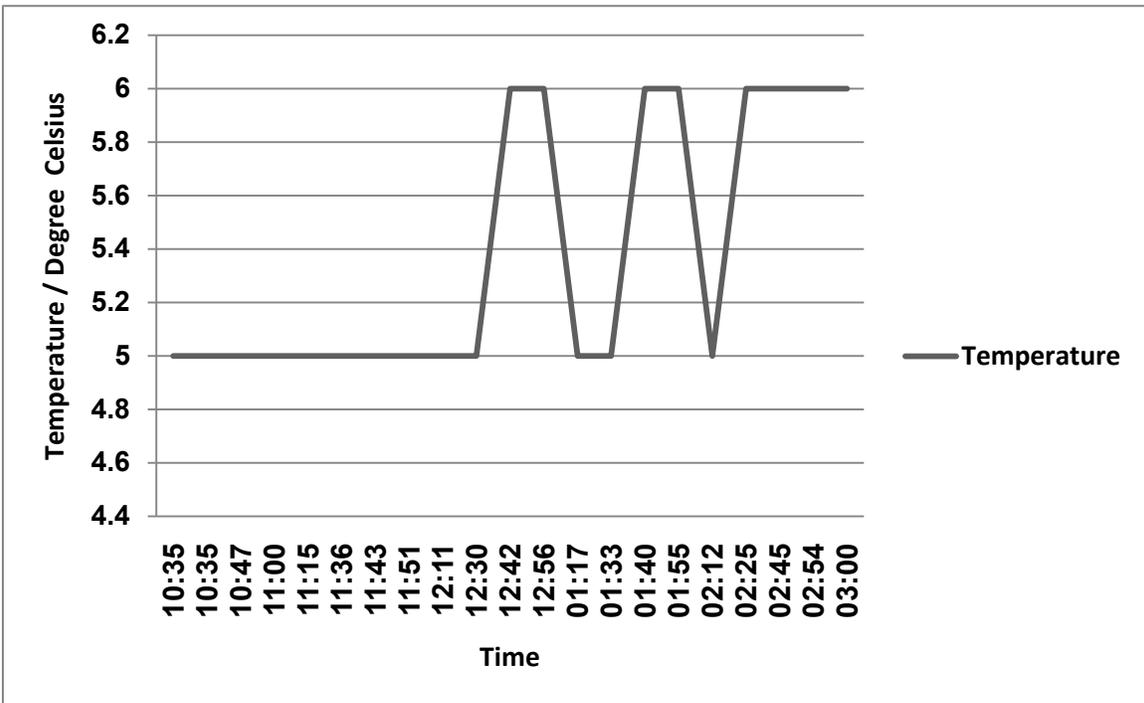
Appendix B2 in Ramallah round two



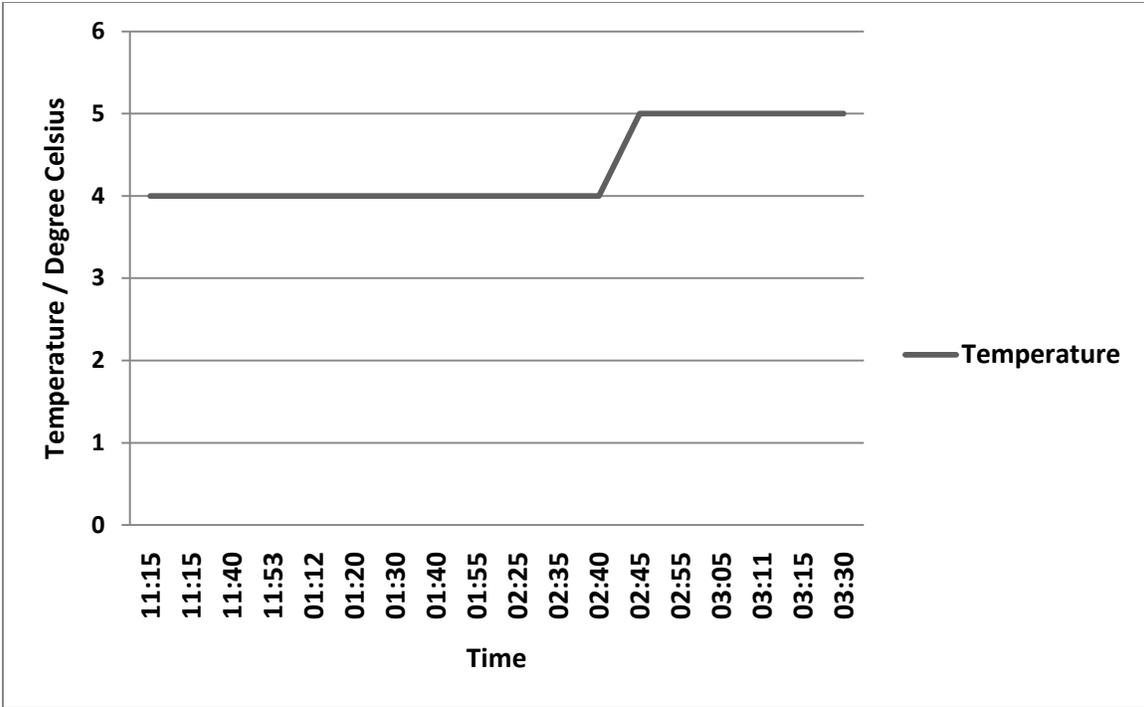
Appendix B3 in Ramallah round three



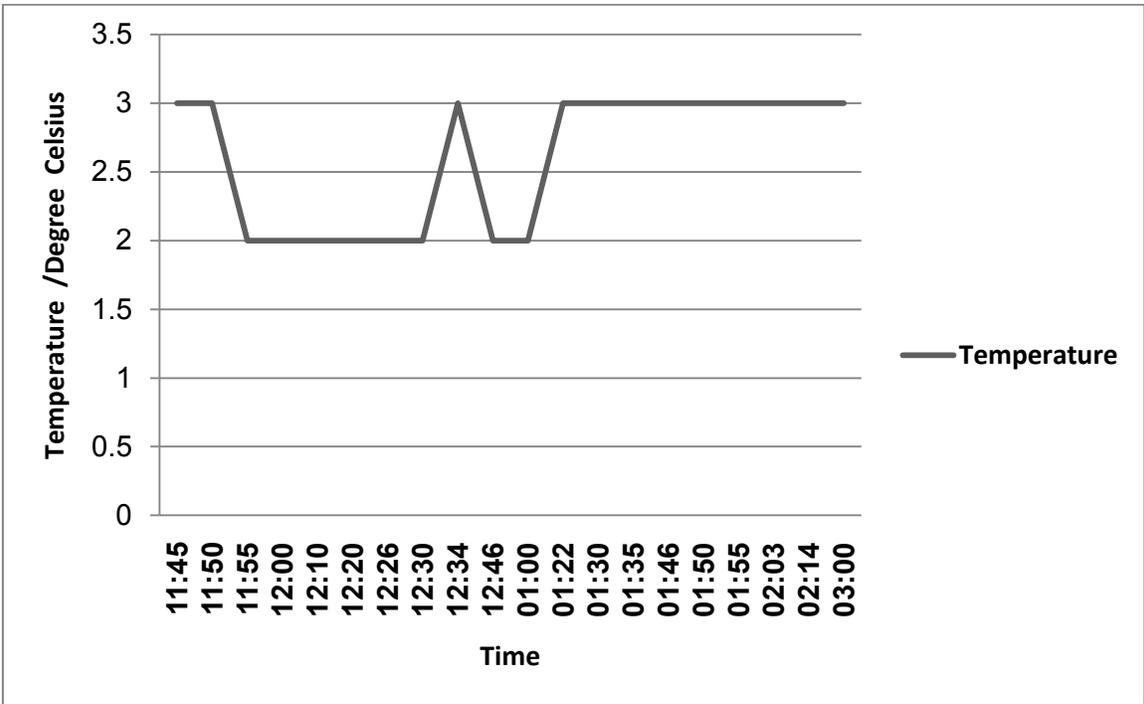
Appendix B4 in Nablus round one



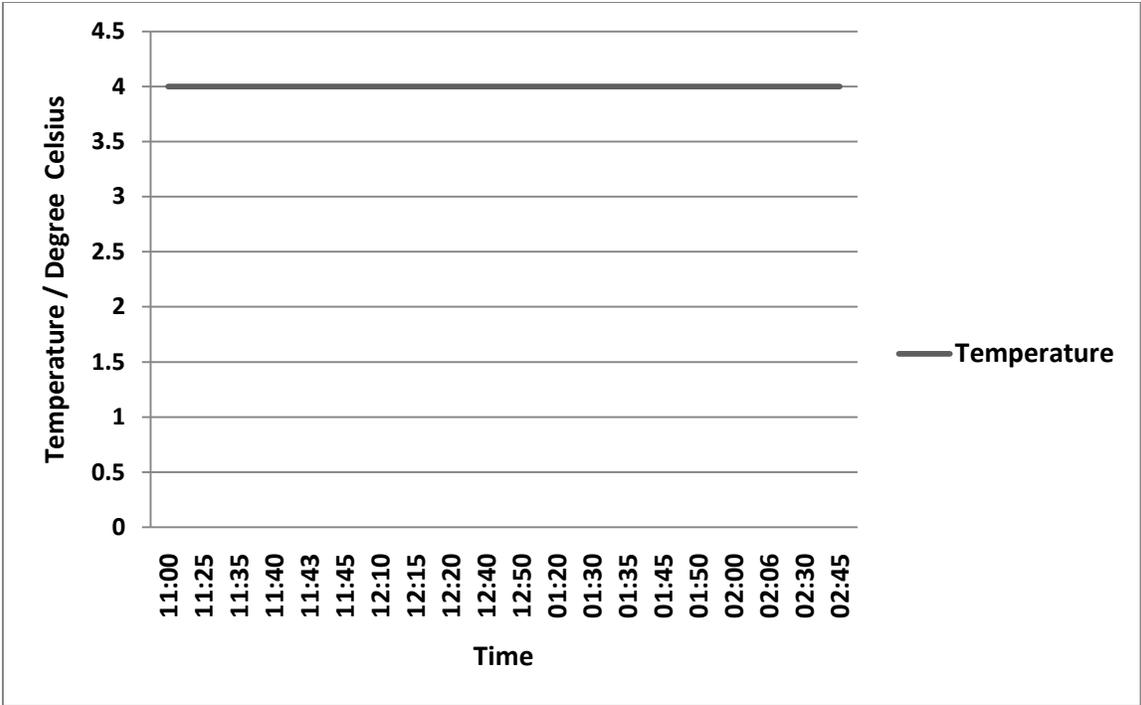
Appendix B5 in Nablus round two



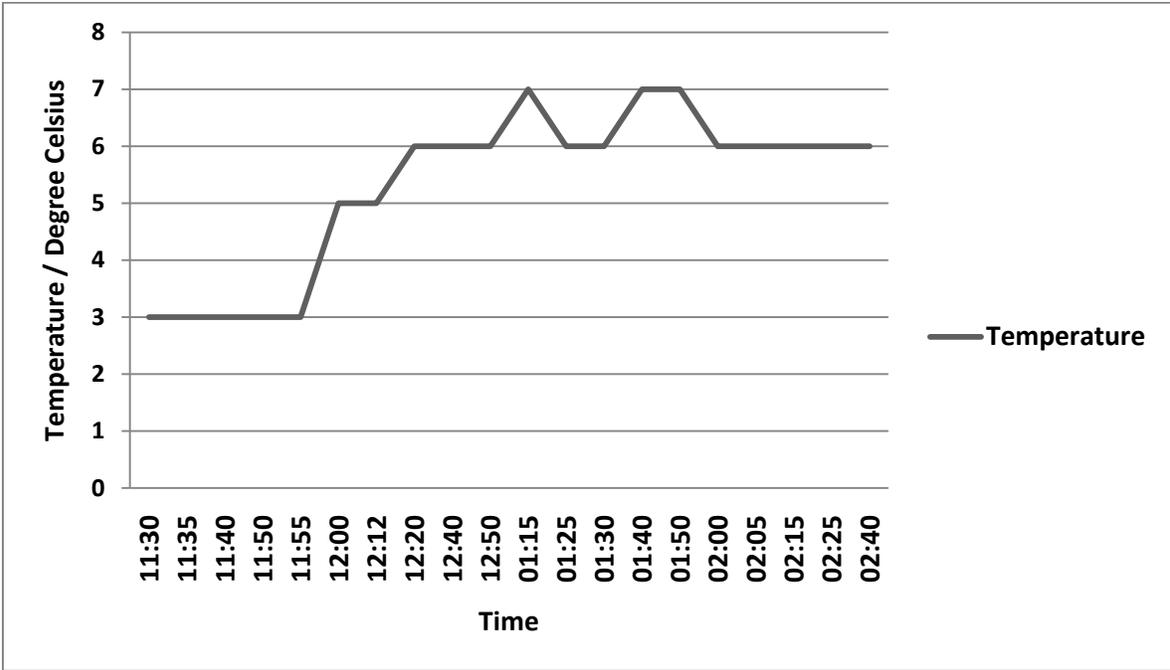
Appendix B6 in Nablus round three



Appendix B7 in Hebron round one



Appendix B8 in Hebron round two



Appendix B9 in Hebron round three

Appendix C The lowest and highest values of the hematological parameters recorded in the three rounds in ascending order.

Round One								
WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
3.7	4.4	11.5	34.1	72.2	23.9	30.4	173	10.3
4.9	5.7	14.9	44.2	75.2	24.3	30.5	208	11.0
4.9	5.7	15.4	44.8	75.9	24.6	31.3	222	11.5
4.9	5.9	15.6	45.8	75.9	24.7	31.4	232	11.7
4.9	5.9	15.6	46.0	76.0	25.0	31.4	232	12.2
5.0	5.9	15.6	46.4	76.1	25.2	31.5	233	12.2
5.0	6.0	15.7	46.9	76.5	25.2	31.5	237	12.2
5.0	6.1	15.8	47.3	77.0	25.2	31.5	238	12.3
5.0	6.1	15.8	47.9	77.0	25.4	31.6	238	12.3
5.1	6.1	15.9	48.0	77.0	25.4	31.7	240	12.4
5.1	6.1	15.9	48.2	77.0	25.4	31.7	242	12.6
5.2	6.1	15.9	48.2	77.2	25.6	31.9	243	12.6
5.2	6.1	16.0	48.3	77.3	25.6	32.0	244	12.6
5.2	6.1	16.0	48.3	77.3	25.6	32.0	244	12.7
5.2	6.1	16.0	48.3	77.4	25.6	32.1	245	12.7
5.2	6.1	16.0	48.4	77.6	25.7	32.1	248	12.7
5.2	6.1	16.0	48.4	77.8	25.7	32.1	248	12.7
5.2	6.2	16.1	48.4	77.9	25.7	32.1	249	12.7
5.3	6.2	16.2	48.7	77.9	25.8	32.1	251	12.8
5.3	6.2	16.2	48.8	78.0	25.8	32.1	251	12.9
5.3	6.2	16.2	48.9	78.0	25.9	32.3	253	12.9
5.4	6.2	16.2	49.0	78.1	25.9	32.3	255	13.0
5.4	6.2	16.3	49.0	78.1	25.9	32.4	257	13.0
5.5	6.2	16.3	49.4	78.4	26.0	32.4	257	13.1
5.5	6.2	16.3	49.6	78.5	26.0	32.4	258	13.1
5.5	6.3	16.3	49.6	78.6	26.0	32.4	258	13.1
5.5	6.3	16.4	49.9	78.9	26.1	32.4	259	13.1
5.5	6.3	16.4	49.9	78.9	26.1	32.5	259	13.1
5.5	6.3	16.4	50.0	79.1	26.1	32.6	262	13.1
5.6	6.3	16.4	50.0	79.3	26.2	32.6	262	13.2
5.6	6.3	16.4	50.1	79.4	26.2	32.7	262	13.3
5.6	6.3	16.4	50.2	79.9	26.2	32.9	263	13.4
5.6	6.3	16.4	50.5	79.9	26.2	32.9	266	13.6
5.6	6.3	16.4	50.6	80.0	26.2	33.0	267	13.6
5.6	6.3	16.5	50.6	80.2	26.2	33.0	268	13.7
5.6	6.3	16.6	50.7	80.4	26.2	33.0	270	13.8
5.7	6.4	16.6	50.7	80.4	26.4	33.0	271	13.8
5.7	6.4	16.6	50.7	80.5	26.4	33.2	275	13.8
5.7	6.4	16.7	50.8	80.7	26.5	33.2	278	13.8
5.7	6.4	16.7	50.9	80.7	26.6	33.3	279	13.9

WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
5.7	6.4	16.7	51.1	80.8	26.6	33.4	286	13.9
5.8	6.4	16.7	51.1	80.8	26.7	33.6	290	13.9
5.8	6.4	16.8	51.1	80.9	26.8	33.7	290	14.0
5.8	6.4	16.8	51.2	81.1	26.8	33.7	292	14.0
5.8	6.4	16.8	51.2	81.1	26.8	33.7	298	14.1
5.9	6.4	16.8	51.3	81.3	26.9	33.9	299	14.1
5.9	6.4	16.8	51.4	81.3	27.1	33.9	303	14.1
5.9	6.5	16.9	51.4	81.4	27.2	34.0	303	14.2
5.9	6.5	16.9	51.5	81.8	27.2	34.1	303	14.2
5.9	6.5	16.9	52.0	82.2	27.3	34.1	305	14.2
5.9	6.5	17.0	52.1	82.7	27.4	34.2	306	14.4
6.0	6.5	17.1	52.5	82.7	27.4	34.4	310	14.5
6.0	6.5	17.1	52.8	82.7	27.5	34.5	311	15.0
6.0	6.5	17.2	52.9	83	27.5	34.6	314	15.0
6.1	6.5	17.2	53.1	83.7	27.5	34.7	315	15.0
6.1	6.5	17.4	53.9	84.0	27.5	34.7	317	15.1
6.2	6.6	17.5	54.0	84.1	27.5	34.8	319	15.1
6.3	6.7	17.5	54.2	86.4	27.6	35.3	322	15.9
6.5	6.7	17.6	54.8	87.1	27.7	35.3	327	16.5
6.7	6.8	17.9	55.8	87.3	34.8	35.4	349	16.9

Round Two								
WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
5.1	4.3	12.9	35.4	79.8	26.2	18.1	120	9.4
5.2	4.9	13.4	41.3	79.8	26.5	30.9	133	10.2
5.3	4.9	13.5	41.4	80.1	26.7	31.2	133	11.2
5.3	4.9	14.0	41.6	81.1	27.0	31.6	165	11.3
5.3	4.9	14.1	41.6	81.2	27.1	31.7	176	11.7
5.3	4.9	14.1	41.9	81.4	27.3	32.2	176	11.8
5.4	4.9	14.3	41.9	81.6	27.4	32.3	176	11.8
5.5	5.0	14.3	41.9	81.7	27.4	32.4	181	11.9
5.5	5.0	14.3	42.0	81.8	27.5	32.6	184	11.9
5.5	5.0	14.3	42.4	82.1	27.5	32.6	186	12.0
5.5	5.1	14.4	42.4	82.2	27.5	32.6	188	12.1
5.6	5.1	14.4	42.4	82.2	27.6	32.6	190	12.3
5.6	5.1	14.5	42.5	82.3	27.6	32.9	191	12.4
5.6	5.1	14.5	42.5	82.3	27.6	33.0	192	12.6
5.6	5.1	14.5	42.6	82.5	27.8	33.0	195	12.7
5.7	5.1	14.5	42.9	82.6	27.8	33.0	195	12.7
5.7	5.1	14.6	43.0	82.9	27.9	33.1	195	12.7
5.7	5.1	14.6	43.0	82.9	27.9	33.1	198	12.7
5.7	5.1	14.7	43.1	83.0	28.0	33.2	202	12.7
5.7	5.1	14.7	43.1	83.4	28.0	33.2	203	12.7

WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
5.8	5.1	14.7	43.2	83.6	28.1	33.3	203	12.8
5.8	5.1	14.7	43.2	83.6	28.3	33.3	204	12.8
5.8	5.2	14.7	43.3	83.7	28.3	33.3	204	12.8
5.8	5.2	14.8	43.3	83.7	28.4	33.3	205	12.9
5.8	5.2	14.8	43.4	83.9	28.4	33.4	207	12.9
5.8	5.2	14.8	43.7	84.0	28.4	33.4	207	12.9
5.8	5.2	14.8	43.8	84.0	28.4	33.4	209	13.0
5.8	5.2	14.8	43.8	84.2	28.5	33.4	210	13.0
5.9	5.2	14.8	43.8	84.4	28.6	33.5	210	13.0
5.9	5.2	14.9	44.0	84.4	28.6	33.6	212	13.1
5.9	5.2	14.9	44.0	84.5	28.6	33.6	214	13.1
5.9	5.2	14.9	44.1	84.5	28.7	33.7	216	13.2
5.9	5.2	14.9	44.3	84.9	28.7	33.7	216	13.2
5.9	5.2	14.9	44.3	85.1	28.7	33.7	218	13.2
5.9	5.2	14.9	44.4	85.1	28.7	33.8	219	13.3
6.0	5.2	14.9	44.4	85.2	28.8	33.9	219	13.3
6.0	5.2	14.9	44.5	85.2	28.8	34.0	220	13.4
6.0	5.3	14.9	44.6	85.5	28.8	34.0	220	13.5
6.0	5.3	14.9	44.8	85.5	28.9	34.1	222	13.6
6.0	5.3	15.0	44.8	85.5	28.9	34.3	222	13.7
6.0	5.3	15.0	44.9	85.9	28.9	34.3	223	13.7
6.1	5.3	15.0	44.9	85.9	29.0	34.4	223	13.7
6.1	5.3	15.1	45.0	86.1	29.0	34.5	223	13.8
6.1	5.3	15.1	45.1	86.2	29.0	34.5	228	13.8
6.1	5.3	15.1	45.1	86.2	29.0	34.5	228	13.9
6.1	5.3	15.1	45.1	86.3	29.1	34.6	229	13.9
6.2	5.3	15.1	45.2	86.4	29.1	34.6	230	13.9
6.2	5.3	15.1	45.3	86.5	29.3	34.9	236	14.0
6.2	5.4	15.2	45.3	86.6	29.4	34.9	242	14.1
6.2	5.4	15.2	45.4	86.8	29.4	34.9	242	14.1
6.2	5.4	15.3	45.4	86.9	29.5	35.0	244	14.1
6.2	5.4	15.3	45.6	87.0	29.5	35.0	244	14.2
6.3	5.4	15.3	45.9	87.9	29.5	35.3	246	14.4
6.4	5.5	15.4	46.8	88.4	29.6	35.3	255	14.5
6.4	5.5	15.5	47.4	88.8	30.1	35.4	258	14.6
6.6	5.6	15.7	48.7	89.8	30.2	35.5	264	14.7
6.6	5.6	16.0	58.0	90.6	30.3	36.0	274	14.8
7.0	6.7	19.4	59.6	91.2	30.5	36.3	276	15.4
7.1	6.9	19.4	82.1	159.4	30.8	36.6	298	16.0

Round Three								
WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
5.7	3.9	12.5	33.6	80.0	25.2	30.0	168	10.0
5.9	4.5	13.1	40.9	82.8	27.1	30.4	184	10.6
6.1	4.9	14.5	44.0	85.1	27.7	30.6	190	10.9
6.2	4.9	14.7	44.1	85.3	28.3	31.7	202	11.5
6.3	5.1	14.9	44.8	85.6	28.3	31.8	203	11.7
6.3	5.8	15.3	45.5	85.7	28.6	32.0	204	11.9
6.4	5.8	15.4	45.6	85.7	28.7	32.1	208	12.1
6.4	5.1	15.4	45.7	85.7	28.7	32.1	208	12.1
6.5	5.1	15.5	45.8	86.0	28.8	32.1	209	12.1
6.6	5.1	15.6	45.9	86.5	28.8	32.2	214	12.1
6.6	5.2	15.6	46.0	86.7	28.8	32.3	217	12.2
6.6	5.2	15.6	46.0	86.7	29.0	32.3	217	12.3
6.6	5.2	15.6	46.0	86.8	29.1	32.4	217	12.3
6.6	5.3	15.6	46.2	87.1	29.1	32.5	218	12.3
6.6	5.3	15.7	46.5	87.3	29.2	32.6	219	12.3
6.7	5.3	15.8	46.6	87.4	29.2	32.7	220	12.5
6.7	5.3	15.8	46.8	87.5	29.3	32.7	222	12.6
6.7	5.3	15.8	46.9	87.5	29.3	32.8	223	12.6
6.7	5.3	15.8	47.1	87.7	29.3	32.9	228	12.6
6.8	5.3	15.8	47.2	87.7	29.3	33.0	229	12.7
6.8	5.3	15.8	47.2	88.2	29.3	33.0	229	12.8
6.8	5.3	15.9	47.4	88.2	29.4	33.1	229	12.8
6.9	5.3	15.9	47.4	88.4	29.4	33.1	230	13.0
6.9	5.4	15.9	47.4	88.4	29.4	33.2	231	13.0
6.9	5.4	15.9	47.4	88.5	29.4	33.2	233	13.1
6.9	5.4	16.0	47.5	88.5	29.5	33.3	235	13.2
6.9	5.4	16.0	48.0	88.7	29.6	33.4	235	13.3
7.0	5.4	16.0	48.0	88.8	29.7	33.5	236	13.3
7.0	5.4	16.1	48.0	88.8	29.7	33.5	236	13.3
7.0	5.4	16.1	48.0	88.9	29.7	33.5	236	13.4
7.0	5.4	16.1	48.1	88.9	29.7	33.5	237	13.4
7.0	5.4	16.1	48.1	89.0	29.8	33.5	239	13.4
7.0	5.4	16.1	48.2	89.1	29.9	33.6	239	13.4
7.0	5.4	16.1	48.3	89.1	29.9	33.6	241	13.5
7.0	5.4	16.1	48.3	89.6	30.0	33.7	244	13.5
7.0	5.5	16.2	48.5	89.8	30.1	33.7	248	13.6
7.0	5.5	16.2	48.6	90.0	30.1	33.7	248	13.6
7.1	5.5	16.2	49.0	90.1	30.1	33.8	249	13.7
7.1	5.5	16.3	49.1	90.1	30.1	33.9	251	13.7
7.1	5.5	16.3	49.3	90.1	30.2	34.0	251	13.7
7.1	5.5	16.3	49.4	90.2	30.2	34.0	252	13.7
7.1	5.5	16.3	49.4	90.2	30.3	34.0	258	13.8
7.2	5.5	16.3	49.5	90.5	30.4	34.1	260	13.8

WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
7.2	5.5	16.3	49.6	90.9	30.5	34.2	261	13.9
7.2	5.5	16.3	49.6	91.0	30.5	34.4	262	13.9
7.3	5.5	16.4	49.8	91.0	30.6	34.4	264	14.0
7.3	5.6	16.4	49.8	91.1	30.7	34.4	266	14.1
7.3	5.6	16.4	49.8	91.2	30.7	34.6	268	14.2
7.4	5.6	16.5	50.0	91.5	30.8	34.6	268	14.3
7.5	5.6	16.6	50.1	91.7	31.0	34.6	273	14.4
7.5	5.6	16.6	50.6	92.0	31.1	34.7	276	14.5
7.5	5.6	16.7	50.6	92.0	31.1	35.0	276	14.5
7.9	5.6	16.8	50.7	92.1	31.3	35.4	280	14.5
7.9	5.7	16.8	51.3	92.1	31.7	35.6	281	14.6
7.9	5.8	16.9	51.5	93.0	32.0	35.7	287	15.6
8.0	6.3	17.3	53.0	94.2	32.2	36.5	291	15.6
8.5	6.4	19.0	56.6	95.8	32.3	37.2	297	17.6

Appendix D: The Questionnaire

دراسة بحثية بعنوان :

Evaluation of Quality Control in the Hematology Laboratories in the West Bank, Palestine: A Consensus Study.

صممت هذه الدراسة لمعرفة مدى توافق نتائج فحص الدم الشامل (CBC) بين مختلف المختبرات الطبية في الضفة الغربية، إن كافة المعلومات ستبقى سرية ويبقى لك خيار المشاركة في هذه الدراسة ، مع العلم ان مشاركتك واجابتك عن الأسئلة أدناه ستعود بالنفع على الباحث وعلى كافة المختبرات الطبية في فلسطين.

رقم المختبر الطبي : التاريخ : الساعة :
اسم المختبر الطبي :
اسم مدير المختبر الطبي :
عنوان المختبر الطبي :
هاتف المختبر الطبي:

-
1. Type and version of your cell counter:
 2. Do you buy blood control for calibration? [Yes] [No]
 3. If No, How do you calibrate your machine?
 4. Do you use only normal control? [Yes] [No]
 5. Do you use normal, low or high controls? [Yes] [No]
 6. What is the brand of blood control you use?
 7. Do you share the blood control with others? [Yes] [No]
 8. Are you participating in EQAS system? [Yes] [No]
 9. If Yes, What is the name of the program?
 10. How often you run the blood control on your machine?
[] Daily [] Once a Week [] Twice a Week [] Occasional
- What is the daily average load of the CBC?

Appendix E The performance of the CBC results of all medical laboratories in the three rounds

Appendix E1The performance of the CBC results of all medical laboratories in round one

Key: E: Excellent, G: Good, S: Satisfactory, and SE: Serious Error.

Lab #	WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
1	Excluded	Excluded	Excluded	Excluded	(S)	(E)	(G)	Excluded	(G)
2	(S)	(E)	(G)	(G)	(G)	(G)	(E)	(G)	(E)
3	(S)	(E)	(G)	(E)	(G)	(G)	(S)	(G)	(E)
4	(S)	(S)	(E)	(G)	(G)	(S)	(S)	(G)	(G)
5	(S)	(E)	(S)	(E)	(E)	(S)	(S)	(E)	(E)
6	(G)	(S)	(G)	(E)	(S)	(E)	(G)	(E)	(E)
7	(G)	(E)	(E)	(G)	(S)	(E)	(S)	(S)	(G)
8	(G)	(G)	(G)	(E)	(E)	(E)	(E)	(E)	(E)
9	(G)	(S)	(S)	(S)	(E)	(E)	(E)	(G)	(G)
10	(E)	(SE)	(S)	(S)	(E)	(G)	(S)	(S)	(G)
11	(E)	(G)	(G)	(E)	(S)	(E)	(S)	(E)	(S)
12	(E)	(E)	(S)	(E)	(E)	(S)	(S)	(S)	(G)
13	(E)	(G)	(G)	(G)	(G)	(E)	(E)	(S)	(E)
14	(E)	(E)	(E)	(E)	(G)	(E)	(G)	(S)	(E)
15	(E)	(G)	(E)	(E)	(SE)	(S)	(E)	(S)	(E)
16	(G)	(S)	(E)	(G)	(E)	(G)	(E)	(S)	(S)
17	(S)	(E)	(E)	(G)	(G)	(E)	(E)	(E)	(S)
18	(S)	(E)	(G)	(G)	(G)	(G)	(S)	(G)	(G)
19	Excluded	(S)	(S)	(E)	(E)	(G)	(S)	(E)	(S)
20	(E)	(G)	(E)	(E)	(S)	(E)	(G)	(SE)	(G)
21	(G)	(S)	(S)	(S)	(G)	(E)	(S)	(G)	(S)
22	(E)	(E)	(S)	(E)	(E)	(S)	(S)	(S)	(G)
23	(E)	(G)	(S)	(S)	(G)	(G)	(E)	(S)	(S)
24	(S)	(G)	(G)	(S)	Excluded	(S)	(S)	(G)	Excluded
25	(E)	(S)	(S)	(E)	(S)	(SE)	(S)	(S)	(E)
26	(S)	(S)	(E)	(S)	(G)	(S)	Excluded	(S)	(G)
27	(S)	(G)	(G)	(G)	(E)	(S)	(S)	(E)	(G)
28	(G)	(E)	(G)	(G)	(G)	(G)	(G)	(E)	(E)

29	(E)	(E)	(E)	(G)	(S)	(E)	(S)	(E)	(E)
30	(S)	(E)	(E)	(G)	(S)	(E)	(G)	(S)	Excluded
31	(G)	(E)	(E)	(E)	(E)	(E)	(G)	(E)	(E)
32	(S)	(G)	(G)	(E)	(G)	(E)	(G)	(E)	(E)
33	(G)	(G)	(G)	(E)	(S)	(S)	(E)	(E)	(S)
34	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(G)	Excluded
35	(S)	(SE)	(S)	(SE)	(G)	(S)	Excluded	(E)	(G)
36	(S)	(E)	(E)	(S)	Excluded	(E)	Excluded	(G)	Excluded
37	(E)	(E)	(E)	(E)	(G)	(G)	(G)	(S)	(G)
38	(E)	(E)	(E)	(E)	(G)	(G)	(G)	(P)	(G)
39	(S)	(G)	(E)	(S)	(S)	(G)	(S)	(E)	(G)
40	(S)	(G)	(E)	(G)	(E)	(G)	(S)	(G)	(S)
41	(SE)	(E)	(E)	(E)	(G)	(E)	(E)	(E)	(E)
42	(S)	(E)	(G)	(G)	(S)	(G)	(S)	(G)	(S)
43	(E)	(G)	(S)	(G)	(E)	(G)	(S)	(S)	(S)
44	(E)	(S)	(S)	(S)	(G)	(E)	(E)	(E)	(G)
45	(G)	(E)	(G)	(E)	(G)	(S)	(G)	(S)	Excluded
46	(S)	(E)	(S)	(S)	Excluded	(S)	(G)	(G)	(S)
47	(G)	(S)	(G)	(G)	(G)	(S)	(G)	(E)	(G)
48	(S)	(E)	(E)	(G)	(G)	(E)	(S)	Excluded	(E)
49	(G)	(G)	(E)	(E)	(G)	(S)	(E)	(E)	(G)
50	(G)	(S)	(E)	(S)	Excluded	(S)	(S)	(S)	(S)
51	(S)	(SE)	(S)	(SE)	(G)	(S)	Excluded	(S)	(G)
52	(S)	(E)	(E)	(E)	(E)	(E)	(E)	(G)	(E)
53	(E)	(S)	(S)	(S)	(S)	(E)	(G)	(S)	(SE)
54	(E)	(E)	(G)	(E)	(E)	(S)	(G)	(E)	(G)
55	Excluded	(S)	(G)	(SE)	(SE)	(G)	(SE)	(S)	(S)
56	(S)	(G)	(E)	(E)	(S)	(S)	(E)	(G)	(G)
57	(G)	(G)	(SE)	(S)	(S)	(SE)	(E)	(S)	(E)
58	(S)	(S)	(SE)	(G)	(S)	Excluded	(G)	(G)	(S)
59	(E)	(E)	(G)	(E)	(S)	(S)	(E)	(G)	(E)
60	(E)	(E)	(E)	(E)	(G)	(E)	(G)	(G)	(G)

Appendix E2 The performance of the CBC results of all medical laboratories in round two

Key: E: Excellent, G: Good, S: Satisfactory, and SE: Serious Error.

Lab #	WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
1	(E)	(E)	(S)	(G)	(G)	(G)	(E)	(E)	(S)
2	(E)	(E)	(E)	(E)	(G)	(G)	(E)	(S)	(E)
3	(E)	(E)	(E)	(G)	(S)	(G)	(S)	(E)	(E)
4	(E)	(S)	(E)	(G)	(G)	(S)	(E)	(G)	(G)
5	(S)	(G)	(S)	(E)	(E)	(E)	(G)	(S)	(G)
6	(G)	(E)	(E)	(E)	(G)	(E)	(E)	(S)	(G)
7	(E)	(E)	(E)	(G)	(G)	(G)	(E)	(S)	(G)
8	(G)	(E)	(E)	(E)	(G)	(G)	(E)	(E)	(E)
9	The Cell Counter was not available								
10	(E)	(G)	(S)	(G)	(E)	(E)	(E)	(E)	(E)
11	(S)	(G)	(E)	(S)	(SE)	(S)	(S)	(S)	(S)
12	(E)	(E)	(G)	(G)	(G)	(E)	(E)	(G)	(E)
13	(S)	(G)	(E)	(G)	(E)	(S)	(G)	(G)	(S)
14	(G)	(G)	(S)	(E)	(E)	(G)	(G)	(S)	(E)
15	(G)	(S)	(E)	(E)	(S)	(S)	(E)	(E)	(E)
16	(E)	(E)	(E)	(G)	(E)	(E)	(E)	(E)	(S)
17	(E)	(S)	(E)	(G)	(E)	(G)	(G)	(E)	(S)
18	(S)	(G)	(E)	(G)	(E)	(S)	(S)	(E)	(E)
19	Excluded	(G)	(S)	(E)	(G)	(S)	(S)	(S)	(S)
20	(S)	(E)	(E)	(G)	(G)	(G)	(S)	(S)	(E)
21	Excluded	(E)	(G)	(E)	(G)	(G)	(S)	(S)	(S)
22	(S)	(S)	(SE)	(S)	(E)	(S)	(S)	(G)	(S)
23	(E)	(G)	(SE)	(E)	(E)	Excluded	(SE)	(E)	(G)
24	(S)	(SE)	(E)	(E)	(S)	Excluded	(S)	(G)	Excluded
25	(S)	(G)	(E)	(E)	(S)	(S)	(E)	(S)	(S)
26	(SE)	Excluded	Excluded	(SE)	(G)	(S)	(SE)	Excluded	(G)
27	(G)	(E)	(G)	(E)	(E)	(G)	(E)	(G)	(E)
28	(S)	(E)	(E)	(G)	(E)	(E)	(E)	(S)	(G)
29	(S)	(G)	(E)	(S)	(S)	(E)	(S)	(G)	(E)

30	(G)	(E)	(E)	(G)	(S)	(E)	(G)	(G)	Excluded
31	(S)	Excluded	Excluded	Excluded	(G)	(G)	(G)	Excluded	(G)
32	(G)	(G)	(S)	(E)	(G)	(E)	(G)	(E)	(S)
33	(G)	(S)	(E)	(E)	(S)	(S)	(E)	(E)	(G)
34	(G)	(G)	(E)	(E)	(E)	(E)	(E)	(S)	Excluded
35	(E)	(S)	(G)	(S)	(E)	Excluded	(SE)	(G)	(G)
36	(S)	(G)	(G)	(E)	(E)	(E)	(E)	(G)	(E)
37	(E)	(E)	(E)	(G)	(S)	(E)	(G)	(S)	(SE)
38	(E)	(E)	(E)	(E)	(E)	(G)	(G)	(E)	(E)
39	(E)	(E)	(G)	(G)	(G)	(E)	(E)	(E)	(E)
40	(E)	(E)	(S)	(S)	(S)	(S)	(G)	(E)	(S)
41	Excluded	(G)	(G)	(G)	(E)	(S)	(S)	Excluded	(E)
42	(S)	(E)	(E)	Excluded	Excluded	(E)	Excluded	(G)	(E)
43	(G)	(E)	(S)	(G)	(G)	(SE)	(SE)	(S)	(E)
44	(E)	(G)	(G)	(G)	(E)	(E)	(E)	(E)	(E)
45	(S)	(E)	(G)	(S)	(SE)	(S)	(S)	(E)	(S)
46	Excluded	(S)	(G)	(E)	(SE)	Excluded	(E)	(S)	(E)
47	(E)	(S)	(S)	(G)	(E)	(E)	(E)	(E)	(E)
48	(G)	(E)	(S)	(E)	(G)	(S)	(E)	(SE)	(G)
49	(G)	(S)	(E)	(G)	(E)	(S)	(G)	(E)	(E)
50	(S)	(S)	(E)	(G)	(E)	(SE)	(S)	(E)	(G)
51	(E)	(E)	(E)	(G)	(G)	(E)	(G)	(E)	(E)
52	(S)	(S)	(E)	(G)	(G)	(S)	(G)	(SE)	Excluded
53	(G)	(S)	(E)	(S)	(G)	(S)	(S)	(E)	(S)
54	(G)	(G)	(S)	(E)	(S)	(SE)	(G)	(E)	(S)
55	(G)	(SE)	(SE)	(SE)	(G)	(E)	(G)	(G)	(SE)
56	(S)	Excluded	Excluded	Excluded	(G)	(E)	(E)	Excluded	(E)
57	Excluded	(S)	(E)	(E)	(S)	(G)	(G)	(S)	(E)
58	(E)	(G)	(S)	(E)	(S)	(E)	(S)	(G)	(S)
59	(E)	(E)	(S)	(E)	(E)	(S)	(G)	(E)	(E)
60	(S)	(E)	(E)	(G)	(G)	(E)	(G)	(E)	(S)

Appendix E3 The performance of the CBC results of all medical laboratories in round three

Key: E: Excellent, G: Good, S: Satisfactory, and SE: Serious Error.

Lab #	WBCs	RBCs	Hgb	Hct	MCV	MCH	MCHC	PLTs	RDW
1	(SE)	Excluded	Excluded	Excluded	(S)	(SE)	Excluded	Excluded	(G)
2	(E)	(E)	(G)	(S)	(S)	(G)	(E)	(S)	(G)
3	(E)	(E)	(G)	(E)	(G)	(E)	(G)	(E)	(G)
4	(E)	(SE)	(E)	(S)	(S)	Excluded	(S)	(S)	(G)
5	(E)	(S)	(SE)	(S)	(E)	(G)	(S)	(G)	(E)
6	(G)	(E)	(E)	(E)	(E)	(G)	(G)	(S)	(G)
7	(G)	(S)	(G)	(S)	(S)	(G)	(S)	(S)	(E)
8	(G)	(E)	(E)	(S)	(G)	(E)	(G)	(G)	(E)
9	(E)	(E)	(G)	(E)	(G)	(E)	(G)	(E)	(E)
10	(E)	(S)	(E)	(G)	(E)	(S)	(S)	(S)	(G)
11	Excluded	(E)	(G)						
12	(G)	Excluded	Excluded	Excluded	(E)	(E)	(E)	(S)	(E)
13	(E)	(G)	(E)	(S)	(S)	(G)	(S)	(E)	(E)
14	Excluded	Excluded	Excluded	Excluded	(E)	(S)	(S)	(S)	(G)
15	(G)	(G)	(G)	(G)	Excluded	(S)	(E)	(S)	(E)
16	(E)	(G)	(G)	(G)	(G)	(E)	(E)	(E)	(S)
17	(E)	(S)	(E)	(S)	(E)	(S)	(S)	(E)	(S)
18	(S)	(E)	(E)	(E)	(E)	(E)	(G)	(G)	(E)
19	Excluded	(G)	(S)	(E)	(S)	(S)	(SE)	(E)	(S)
20	Excluded	(E)	(S)						
21	(S)	(E)	(E)	(G)	(S)	(G)	(S)	(S)	(G)
22	(S)	(SE)	(SE)	(SE)	(E)	(G)	(E)	(E)	(S)
23	(S)	(E)	(SE)	(E)	(E)	Excluded	Excluded	(S)	(S)
24	(S)	(SE)	(E)	(G)	(S)	(SE)	(S)	(E)	Excluded
25	(G)	(G)	(E)	(E)	(S)	(S)	(E)	(G)	(G)
26	(S)	(S)	(E)	(SE)	(S)	(SE)	Excluded	(S)	(G)
27	(G)	(E)	(G)	(E)	(E)	(G)	(S)	(E)	(G)
28	(S)	(E)	(E)	(G)	(G)	(E)	(G)	(G)	(G)
29	(SE)	(E)	(G)	(S)	(G)	(E)	(E)	(G)	(E)

30	(G)	(E)	(E)	(S)	(S)	(E)	(S)	(G)	Excluded
31	(G)	(G)	(E)	(S)	(S)	(S)	(E)	(E)	(S)
32	The Cell Counter was not available								
33	(G)	(S)	(E)	(E)	(S)	(S)	(E)	(G)	(E)
34	(G)	(S)	(G)	(G)	(E)	(G)	(G)	(G)	Excluded
35	The Cell Counter was not available								
36	(E)	(E)	(G)	(S)	Excluded	(G)	Excluded	(E)	Excluded
37	(E)	(S)	(S)	(E)	(G)	(E)	(G)	(G)	(S)
38	(G)	(G)	(E)	(E)	(G)	(S)	(G)	(S)	(G)
39	The Cell Counter was not available								
40	(E)	(E)	(E)	(E)	(E)	(E)	(E)	(G)	(G)
41	(S)	(E)	(E)	(G)	(G)	(G)	(S)	(E)	(G)
42	(G)	(G)	(E)	(S)	(S)	(G)	(E)	(G)	(G)
43	(S)	(S)	(SE)	(S)	(G)	(E)	(S)	(E)	(S)
44	(E)	(G)	(E)	(G)	(G)	(E)	(G)	(E)	(S)
45	(G)	(E)	(G)	(G)	(S)	(G)	(E)	(E)	(S)
46	(G)	(S)	(S)	(S)	(G)	(E)	(E)	(G)	(E)
47	(E)	(E)	(S)	(E)	(E)	(S)	(S)	(S)	(E)
48	(S)	(E)	(G)	(S)	(G)	(E)	(E)	(SE)	(E)
49	(E)	(G)	(G)	(E)	(E)	(S)	(S)	(S)	(E)
50	(S)	(E)	(G)	(G)	(S)	(G)	(E)	(E)	(G)
51	(S)	(S)	(G)	(S)	Excluded	(E)	(G)	(E)	(E)
52	(S)	Excluded	(E)	(SE)	Excluded	Excluded	Excluded	Excluded	Excluded
53	(G)	(E)	(S)	(S)	(SE)	(G)	(G)	(G)	(S)
54	(E)	(S)	(G)	(S)	(G)	Excluded	(SE)	(E)	(S)
55	Excluded	(S)	(S)	(S)	(S)	(E)	(G)	(S)	(SE)
56	(G)	(G)	(G)	(E)	(S)	(S)	(G)	(E)	(S)
57	Excluded	(E)	(S)	(S)	(S)	(S)	(E)	(SE)	(G)
58	(E)	(S)	(S)	(E)	(S)	(E)	(S)	(E)	(S)
59	(G)	(G)	(E)	(E)	(G)	(G)	(E)	(S)	(E)
60	(E)	(S)	(G)	(S)	(S)	(S)	(E)	(S)	(S)

وفيما يتعلق باستخدام أنواع مواد معايرة فحص الدم أظهرت الدراسة أن 26.6% يستخدمون ثلاث أنواع من مواد المعايرة في حين 66.7% يستخدمون نوع واحد فقط. أظهرت الدراسة أيضاً أن المختبرات التي تستخدم ثلاث أنواع من مواد المعايرة أظهرت نتائج ممتازة مقارنة بمن يستعملون نوع واحد بناء على نتائج مؤشر الإنحراف. كما أظهرت الدراسة أن 6.7% من المختبرات لا تستخدم أي نوع من مواد المعايرة. علاوة على ذلك أظهر تحليل النتائج أن 64.0% من المختبرات تعمل ضبط ومعايرة لجهاز فحص الدم يومياً وأن 36.0% من المختبرات تعمل ضبط ومعايرة للجهاز مرتين أسبوعياً أو مرة أسبوعياً أو أحياناً.

إن التناقض في عدد الأنواع المستخدمة في المعايرة أو الفترة الزمنية لكل معايرة بين المختبرات الطبية يشير الى وجود سوء فهم لمبادئ عمل المعايرة لجهاز قياس خلايا الدم. لقد أظهرت هذه الدراسة ضعف التوافق وعدم الإنسجام في مختبرات الدم في الضفة الغربية والحاجة الى برنامج وطني للجودة في مختبرات الدم في فلسطين للوصول الى مستوى مشترك من التوافق.

تقييم الجودة في مختبرات علم الدم في الضفة الغربية - فلسطين ، دراسة توافقية

إعداد : عمر وليد عبد الرحمن الجبالي

المشرف الأول: أ. خالد يونس.

المشرف الثاني: د. محمود سرور.

الملخص

يعتبر فحص الدم الشامل (CBC) الأكثر شيوعاً على الإطلاق في مختبرات الدم. تكمن أهمية فحص الدم الشامل بقدرته على تشخيص حالات فقر الدم، العدوى، وبعض أمراض السرطان. لذلك ولأهمية هذا الفحص وجب إدراج برنامج رقابة الجودة على أن يتضمن البرنامج مستويين أساسيين: أولاً مراقبة الجودة الداخلية وثانياً الإشتراك في برنامج تقييم الجودة الخارجية مما يوفر مراقبة للفحوصات الطبية بشكل مستمر، حيث أن برنامج مراقبة الجودة الداخلية يضمن للمختبر أن ينتج نتائج طبية مخبرية موثوق بها، في حين يضمن برنامج تقييم الجودة الخارجية توفير التوافق والإنسجام لنتائج الفحوصات المخبرية بين المختبرات الطبية.

إن الدقة والإنسجام بين نتائج المختبرات الطبية بما في ذلك نتائج فحص الدم الشامل لم يتم تقييمها سابقاً في الضفة الغربية - فلسطين. ولذلك تهدف هذه الدراسة الى تقييم مدى الدقة والإنسجام لفحص الدم الشامل تم توزيع ثلاث عينات من الدم حيث تكررت دورة اختبار الفحص ثلاث مرات يفصل كل دورة 22 يوماً. بعد الفحص قامت المختبرات المشاركة بإرسال نتائجها ليتم تحليلها وتفسيرها باستخدام مؤشر الانحراف (Deviation Index) وقد أعتمد نظام المملكة المتحدة في الجودة الخارجية (UK-NEQAS) لتفسير نتائج مؤشر الانحراف. في مختبرات الضفة الغربية باستخدام عينات دم طازجة ولقد شارك في هذه الدراسة ستون مختبراً طبياً.

لقد بين التحليل الإحصائي لفحص الدم الشامل أن أداء المختبرات المشاركة ثابت ولم يطرأ تحسن في الأداء في الجولات الثلاث. أظهر تحليل البيانات أن 18.3% من المختبرات الطبية تشترك في برنامج خارجي للجودة الخارجية لأن برامج الجودة الخارجية لا تطبق من قبل الأنظمة الصحية المحلية.