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DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Establishment of Reference intervals for common hematology test parameters from apparently healthy geriatrics in Asella town, southeast Ethiopia

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This is to certify that the thesis prepared by **MOHAMMED HASHIM**, entitled: **Establishing Reference intervals for common hematology test parameters from apparently healthy geriatrics in Asella town, southeast Ethiopia, 2020** and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Hematology and Immunohematology) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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ABBREVIATIONS

CBC	Complete blood count
CD4	Cluster of differentiation 4
CI	Confidence interval
CLSI	Clinical Laboratory Standard Institute
DC	Direct current
DERC	Departmental Ethical Review and Research Committee
EDTA	Ethylene diamine tetra acetic acid
FBC	Full blood count
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B virus
HCT	Hematocrit
HCV	Hepatitis C virus
Hgb	Hemoglobin
HIV	Human immunodeficiency virus
IFCC	International Federation for Clinical Chemistry and Laboratory Medicine
LYM	Lymphocyte
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean cell volume
MPV	Mean platlet volume

NEUT	Neutrophil
PCV	Packed cell volume
PDW	Platlet distribution width
PLT	Platelet
RBC	Red blood cell
RDW	Red blood cell distribution width
RI	Reference interval
SOP	Standard operating procedure
SST	Serum separator tube
WBC	White blood cell
WHO	World health organization

ABSTRACT

Background*:* Reference intervals are an important tool to identify abnormal laboratory test results. Hematology reference values are useful to interpret hematology results and make clinical decisions, but these values have not been established for geriatrics in Asella town.

Objective: To establish reference intervals for common hematology test parameters from apparently healthy geriatrics in Asella town, southeast Ethiopia from January to April 2020.

Methods: A community-based cross-sectional study was conducted from January to April 2020. Interviewer administered questionnaire was used to collect data of socio-demography and other characteristics from 342 eligible geriatrics. Weight, height, blood pressure, MUAC and temperature were measured and 8 milliliter blood sample was collected. Screening tests like HIV, HBsAg, HCV, syphilis, concentration method and wet mount of stool examination and urinalysis were performed. Hematological parameter was measured by Sysmex kx-21 hematology Analyzer. The data were analyzed by SPSS version 21. The non-parametric independent Mann–Whitney U test were used to compare the parameters between two gender groups.

Result: The reference intervals of red blood cell, white blood cell, platelet count, hemoglobin (HGB), and hematocrit (HCT) in male Geriatrics were 3.8–5.85 × 10^{12}/L, 3.1–9.66 × 10^{9}/L, 115.8–353 × 10^{9}/L, 12.4-17.76g/dL and 35.06-50.2%.The respective values for females were 3.94-5.48×10^{12}/L, 3.13-8.4× 10^{9}/L, 137.5-406× 10^{9}/L, 12.5-16.4g/dL, and 36.09-48.2%.By comparing the two genders by non parametric Mann–Whitney U test, most of the hematological parameters showed significant differences among two genders (p-value <0.05).

Conclusion: The reference intervals which were established by this study was different from the existing reference values as well as from other african countries and caucasion population. This difference could be due to difference in dietary pattern, ethnic difference as well as in the methodological used.

Key words: Reference interval, hematological parameters, geriatrics, southeast Ethiopia.

1. INTRODUCTION

1.1 BACKGROUND

The Word Health Organization (WHO), the International Federation for Clinical Chemistry (IFCC) and the Clinical Laboratory Standard Institute (CLSI) define reference range as the group of results obtained by observation or quantitative measurement of an analyte in a selected apparently healthy group of participant, based on well-defined criteria **(**1**).** The reference interval for many laboratory tests is defined by threshold values between which the test results of a specified percentage (usually 95%) of apparently healthy individuals would fall. The threshold or limiting values for the reference interval are usually the 0.025 and 0.975 fractiles of the test result distribution in the reference population. This definition results in exclusion of the 2.5% of individuals with the lowest results and the 2.5% of individuals with the highest results from the reference interval (2). A test result by itself is of little value unless it is reported with the appropriate information for its interpretation. Typically, this information is provided in the form of a reference interval (RI) or medical decision limit (2).

As per Ceriotti definition reference interval "is an interval that, when applied to the society serviced by the established reference interval should correctly include most of the subjects with characteristics similar to the reference group and excludes the others (3)**.** It has been recommended that an RI be established by selecting a statistically sufficient group (a minimum of 120) of healthy reference subjects. However, it is noted in the guideline that "Health is a relative condition lacking a universal definition(4) .

The determined RI are primarily used for accurate interpretation of laboratory test results, identifying abnormal and normality of results, helping in patient diagnosis and clinical managements (5).The hematological test result in clinical laboratory is a decision-making process, and reference intervals (RIs) produced in laboratory have an important role in guiding the clinician in interpreting patient results with reference values established from apparently healthy subject. So careful establishment or determination of RIs by the laboratory for use in the patient population it serves is, therefore, important to ensure their proper utility. before 30 years ago, each laboratory begun to produce its own reference values which were recommended by IFCC and estimate the corresponding RIs according to defined protocol. The selection and recruitment of appropriate

number of reference subjects is difficult, time taking, and needs high price (6). Because of this reason most laboratories in Ethiopia do not have their own reference interval to interpret patient result.

Good ‘‘health-associated’’ reference intervals will, with a clinically acceptable degree of statistical probability, include all those from the reference population who are healthy with respect to the particular measurement being considered and exclude all those with a pathology (disease) for which there is an association with the measurement being considered (7)**.**

RIs are derived from reference distribution, usually of 95% interval, and describe a specific population. The reference individuals form the reference sample group for measurement of the values from the reference population. Through statistical analysis of the distribution of the obtained values, the reference limits are calculated. These limits then define the reference interval and includes them (8).

Several factors including age affect RIs. Aging is commonly associated with a progressive decrement in the functional reserve of multiple organ systems which increase the probability of dysfunction and disease. Hematopoiesis is controlled by the balance between production and destruction of blood cells. Hematopoietic activation becomes imbalanced with aging. Due to this it is important to establish reference interval for geriatrics individuals to give quality of health care service (9).

The RI of hematological parameters of the apparently healthy subjects vary according to the analytical and pre-analytical variability due to the use of different testing systems or several factors such as sex, age, environment, pregnancy, nutritional state, ethnic origin, lifestyle. For that purpose, their determination for every country, even every region, is very crucial (10).

1.2 STATEMENT OF PROBLEM

One of the most common clinical laboratory tests requested by physician to identify health and disease conditions is Full blood count (FBC) or complete blood count (CBC). However, most laboratories do not have their own RI for hematological parameters. They are often obtained from manufacturer's information sheets or outdated publications and may not always be representative of the local population or laboratory setting. CBC parameters vary with age and sex, therefore requiring RI which is specific for the society it served (11).

Mostly, the reference population widely includes young adults, and using this may not be appropriate for an elderly patient. Because there is, significant age related changes observed in hematological parameters (12). Deriving reference values for older patients is particularly problematic, due to this most laboratory had no specific RI for geriatrics population. This is because the geriatric population has a relatively high prevalence of chronic pathologies such as diabetes, dyslipidemia, renal disease and anemia. They also have comorbidities and regularly take prescription medications, making it difficult to find healthy reference individuals to establish reference interval (13-16) .

Reference interval for African populations are not readily available and the values used in most African countries including Ethiopia are usually based on results of measurements in developed countries, taken from the literature or from package inserts that accompany reagent kits. However, these parameters even in the healthy state are affected by many factors including age, gender, ethnicity and altitude (17-19)**.** A few studies that have been conducted, indicated differences in normal values of African populations, even in children and adolescents, compared to those derived from industrialized populations, especially for hematologic indices (19)**.** These differences may suggest the need for the development of locally derived reference values to improve clinical diagnosis and also for monitoring participants in clinical trials. Reference values for the elderly may differ from those in younger people (6).

Hematological reference values for geriatrics in Ethiopians have never been established for several years before the establishment of hematological RI for geriatrics in southwest Ethiopia, although a few attempts at determining hemoglobin and hematocrit levels as well as reference intrvals in some adult populations have been made (20-22)**.** Thus, adopting non-Ethiopian reference values for Ethiopians might be misleading and adopting adult reference value for geriatrics may impede the

detection of pathologies in older population, so it would be useful to establish age-specific reference values. Given this background, a cross-sectional study was performed with the aim of establishing common hematological reference values for geriatrics population in south east Ethiopia; Oromia regional state, Asella town.

1.3 SIGNIFICANCE OF STUDY

Since the use of incorrect reference values may impede the detection of pathological in geriatrics, it will be useful to establish age and gender specific reference intervals. The main significance of this study is to provides appropriate RIs for common hematological parameters for asella town community and the surrounding kebeles. And also, important to give information for policy makers and helps as a base line data to improve the pathological diagnosis, to treat patient, disease prognosis and screening.

Community gets representative reference intervals of hematological parameters for correct interpretation of a particular disease condition and subsequently improved health care quality.In general, since there is a scarcity of information regarding hematological reference interval for Ethiopians geriatrics this study can serve as the baseline for researchers,Ministry of health,local health beaureus and another person with an interest and policymakers.

Therefore, establishing RIs for geriatrics are very important to provide medical information that ensures correct medical decisions. The reliability of the RI can play major role in result interpretation and as a measure of quality by itself since the patient test results are interpreted in comparison with it.

Helps the clinician usually while comparing the reported test result with the locally and age specific reference values to decrease the risk of missing the underlying disease and to reduce the importance of additional investigations and treat patients with specific disease. Decrease the cost for patients for additional investigation.

2. LITERATURE REVIEW

Reference intervals are affected by several factors including age, sex, dietary patters, altitude, race and life style among others. For example, Hemoglobin concentration, hematocrit, and the other RBC indices reflect the same biological parameters and showed similar variability throughout life. Male and female levels were similar in early childhood and increased slowly until 10 years of age before sex differences were observed (23). According to research done in the six official geographical regions in China there were significant gender difference between male and female who were investigated for some hematological parameter. RBC, HGB, and HCT values decrease with age in males and were more reduced in the elderly population and those parameters were increased slightly with age in females. Whereas WBC and NEUT parameters showed slight increase in males above 60 years which might be associated with chronic infection in older people that were not excluded according to exclusion criteria. LYM counts were decreasing with age (24).

But a non-probabilistic and community based cross-sectional study among Elderly subjects in informal social groups in Gravataí a town in the Porto Alegre Metropolitan Area, Brazil indicated no significant difference for total and differential counts of white blood cells and hematocrit or hemoglobin levels in the elderly and young adults. The MCV and RDW were higher in elderly than young adult but, MCHC was lower among elderly population (25)**.**

All hematological parameters are lower in female than male in all age group except for the mean value for platelet which was higher in female than male and the red blood cell indices that did not show difference between sexes and ages according to study in six geographical region in china (24)**.** A study was carriedout in three high altitude towns; Cojata, Ananea and Rinconada which are located at 4355 m, 4660 m and5500 m, respectively, located in Huancane, Peru. Across-sectional study on apparently healthy individuals at the King abdullah university hospital (Kauh) Irbid and ministry of health, Jordan , realized the increment of red blood cell parameters such as Hct , Hgb and RBC which were 18.49g/dl,20.43 g/dl 20.4g/dl of HGB values in three altitude,55.8%,60.2%,60.6% HCT value and 5.95×10^{12}/L,6.48×10^{12}/L,6.5×10^{12}/L for males in three altitude and 17.47 g/dl,18.24 g/dl ,18.14 g/dl of HGB value ,52.3%,54.6%,55% of HCT value and 5.69×10^{12}/L,5.94×10^{12}/L,5.92×10^{12}/L of RBC value for females with altitude in both sexes. But, there was no significant difference between the two sexes for mean corpuscular hemoglobin

concentration (26, 27). White blood cell count was also higher in people who lived above sea level than people who live below sea level (27) .

In addition to altitude Study on Hematological values in 81 non-smoking and 10 smoking men living at sea level Tampa and Florida ,and 36 non-smoking and 32 smoking men living in the plateau of Tuquerres in the southern Colombian Andes at 3000 m above Sea Level, South America, also showed significantly higher values in smoking and non-smoking at high altitude but, the MCV value was lower than those residing at Sea Level (28).

In addition to altitude, smoking is one of the factors affecting hematological parameters RIs. For example, results from study establishing hematological reference value for adult in Gaza strip-Palestine showed that smokers had significantly higher hematological parameters (RBC, Hgb, Hct, MCV, MCH, and WBC) except for PLT where nonsmokers had significantly higher values than smokers. MCHC and RDW did not show any significant differences between smokers and nonsmokers (28, 29). Study among Arab smokers to determine the Effects of Cigarette Smoking on Hematological parameter showed significant difference of median WBC count between male smokers and nonsmokers. Male smokers had higher WBC than non-smoker. But there were no any statistically significant difference observed between female smokers and nonsmoker (30).

Also, a crossectional study in Africa, on Sudanese in Khartoum state to determine Normal range of white blood cells and differential count of Sudanese in Khartoum state and establishment of Immunohematological reference interval in Central African Republic demonstrated absence of significant difference between males and females in the WBCs count. But the count for the older age group was slightly lower than the adult age group. According to this study, WBC count was different among obese and underweight individuals (31, 32).

The distribution of RBC parameters (median hemoglobin, hematocrit, and RBC) was statistically different by gender in the establishment of reference interval among adult population in Central African Republic and in Population based cross-sectional study in Uganda which was also true for geriatrics. The female had lower values than men for red cell parameter which was similar to the above reviewed articles (32, 33). A study in central Africa also showed no gender-specific differences for platelets (32). But significantly higher values among adult female individuals than male was detected in Population-based hematologic and immunologic reference values establishment for a healthy individuals in Uganda (33).

Population based cross-sectional study in Uganda were again showed significant differences in hematologic parameters by age. The counts of total white blood cell (WBC) and differential count decreased with age but, Hgb, RBC counts, Hct levels, and MCVs increased with age until age 13 years. No Significant differences by gender were observed for any of the indices for children less than 12 years of age (33)**.** None of the values for the leukocyte count showed significance differences by gender in all age group (33)**.**

Another study in Nigerians among apparently healthy geriatrics shows similarity of hematological parameters between two sexes except value for RBC parameter count which were lower in females than male. There were also significant difference between the male young and geriatrics in all the parameters except MCH and which is also true for female except for MCH, MCHC and RBC which were similar for both groups (34)**.**

Hgb and MCV increased with age across the full age range of study subjects as shown in a cohort study in Gambia from age 15 years and values of Hgb in males were significantly higher than for females. There was no significant difference in Hgb between the two sexes under 15 years age and in adults or children for WBC count observed. Median values for platelet counts were highest in the under-fives and decreased significantly with age. Males have lower counts when comparing with females and this difference was statistically significant among adults (35)**.**

Caucasians had higher WBC and neutrophil counts than Africans and Afrocaribbeans. But there were no significance differences between Caucasian/Afrocaribbean for WBC count in women. Africans and Afrocaribbeans both of them had lower eosinophil counts than Caucasians. But, platelet, Monocyte and lymphocyte counts were similar in the different ethnic groups (36)**.**

Study at Gondar university hospital on Hematological reference intervals determination from adults, showed a significant gender differences for the RBC parameter. The finding agree that males have higher values than female for RBC parameter. But there were no significant differences between genders with regard to WBC parameters, platelet counts, MCV and RDW. The significant difference in RBC between male and female is well established and may be due to biological and physiological factors such as the influence of the hormone androgen on erythropoiesis and blood loss during menstruation in females (37)**.**

Study on Haematological and CD4+ T cells reference ranges in healthy adult populations in Gojjam zones in Amhara region, showed higher mean absolute count of RBCs and neutrophil in the youngest age groups compared to older. However, the mean absolute value of MCV was significantly lower in younger compared to older age groups. The Mean absolute counts of RBCs and values of MCHC were significantly lower in females than males (38)**.**

A community-based cross-sectional study conducted in southwest Ethiopia for determination of hematological reference interval determination in geriatric age group shows males had higher median and 95% RI for hematological parameters than females, which was RBC count 5.16×10^{12}/L ($4.25–5.99\times10^{12}$/L) for male versus 4.92×10^{12}/L ($3.91–5.72\times10^{12}$/L) for female ($P<0.001$), Hgb of 151g/L (126.4–179g/L) for male versus 142 g/L (119.1–177.8g/L) for female ($P<0.001$), and Hct of 44.5% (38.3%–52.4%) for male versus 42.6 (36.2–51.4) for female ($P<0.001$). The other hematological parameters show no significant difference between male and female. There was also statistically higher WBC parameter count in children than adult and geriatrics in both sexes. But none of the values for the WBC subset shows any differences between the adults and the geriatrics males Except for eosinophils. There were significant differences in PLT counts between all age groups in male and female. Platelet counts decreased with age increment (39) .

3. OBJECTIVES

3.1 GENERAL OBJECTIVE

To establish reference intervals for common hematology test parameters from apparently healthy geriatrics in Asella town, southeast Ethiopia from January to April 2020.

3.2 SPESIFIC OBJECTIVE

- To determine gender specific Reference Interval for common hematological parameter among geriatrics population from January to April 2020.
- To compare the hematological reference interval established from geriatrics and already existing reference interval drived from manual book of sysmexkx-21 machine.

4. HYPOTHESIS

No significant difference between hematological RI for apparently healthy geriatrics (≥ 60) versus currently applicable reference value in the laboratory setting taken from hematology machine and used in our health facility.

5. METHODS AND MATERIALS

5.1 STUDY AREA

The study was conducted at Asella town that is found in Oromia regional state, southeast Ethiopia which is 175 km away from Addis Ababa. The town is located approximately 7°57′N latitudinal and 39°7′E longitudinal with an elevation of 2,430 meters above sea level. The 2007 Ethiopian census reported that the total population of Asella was 101,739 and almost half of them 51,159 (50.5%) are males and the rest are females. There were 23,215 households under 8 kebeles and majority of the inhabitant, (67.43%) are followers of Ethiopian orthodox Christianity, while 22.65% population were Muslim and around 8.75% population were protestant (40).No census was conducted for geriatrics alone in Asella as shown in the 2007 Ethiopian census (40).

5.2 STUDY DESIGN AND PERIOD

Population based cross-sectional study was conducted to Establish Reference intervals for common hematology test parameters from apparently healthy geriatrics in Asella town from January to April, 2020

5.3 SOURCE AND STUDY POPULATION

5.3.1 SOURCE POPULATION

The source population were all population of Asella town.

5.3.2 STUDY POPULATION

The study populations were all apparently healthy geriatrics who are volunteer to participate and fulfill the inclusion criteria.

5.4 ELIGIBILITY CRITERIA

5.4.1 INCLUSION CRITERIA

The participants should be feeling subjectively well and older than 60 years of age lives for at least one year in the Area.

5.4.2 EXCLUSION CRITERIA

Participants with known chronic illnesses like diabetes, hypertension, Arthritis, history of TB, history of chronic liver or kidney disease, history of being a hospitalilised in patient, known history of hematological disorder like malignancy and those who are taking pharmacologically active

agents, smokers, known carrier state for HBV, HCV, Syphilis or HIV were excluded from the study.

5.5 VARIABLES OF THE STUDY

5.5.1 DEPENDENT VARIABLES

Reference Interval of common hematological parameters are the dependent variable.

5.5.2 INDEPENDENT VARIABLES

Factors that are used as independent variables are age and sex in this study.

5.6 MEASUREMENT AND DATA COLLECTION

5.6.1 SAMPLE SIZE DETERMINATION

The sample size was determined according to the CLSI recommendation to use well-defined exclusion and portioning criteria for the selection of the reference individuals. Thus, based on this guideline, the minimum sample size required for RI determination will be 120 healthy individuals for each partitioning (41).

However, according to previous large-scale studies in other African countries, about 30% (42) did not meet the inclusion criteria for RI determination for various reasons. So, the minimum sample size will:

N (100%-30%) =120

N (70%) =120

N (0.7) =120

N=171, this is one partition so we have to multiply by two which gives 342, the required individuals to achieve a minimum sample size will be 342.

5.6.2 SAMPLING METHOD

Five Kebeles were selected randomly by lottery method from eight kebeles in Asella town and non-probability convenient type sampling techniques was used to recruit all volunteer geriatrics individuals from selected kebeles until sample size is reached.Accordingly, about 34 (sirty four) individuals for one partition and 68 (sisty eight) for two partition were selected from each five selected kebeles.

5.6.3 DATA COLLECTION PROCEDURE

The selection of participant was based on the inclusion criteria. Pretest were done for 5% of study samples and 90% were volunteered. Structured and standardized questionnaires were used to collect information from consenting participants to determine their socio-demographic characteristics and health feature of the study participants.

This was followed by collection of blood samples for full blood count (FBC), Hepatitis B surface antigen (HBsAg) and HCV, syphilis and HIV-1 and collection of stool and urine to determine the health characteristic of study participants. Rapid diagnostic tests were used to detect serological markers of infection. Hematological parameters include: Red Blood Cell Count (RBC), Hemoglobin Concentration (Hb), Packed Cell Volume (PCV), Mean Cell Volume (MCV), Mean Cell Hemoglobin (MCH), Mean Cell Hemoglobin Concentration (MCHC), Platelets Count (Plt), Total and Differential White Blood Cell (WBC) counts.After prescreening, potentially eligible subjects with positive laboratory screening results were excluded based on the exclusion criteria. The interviews and the blood sample collections were performed from January to April 2020.

5.6.4 PRINCIPLES OF EACH LABORATORY ANALYSIS, PROCEDURES AND INTERPRETATION

Sample collection procedure

Each participant was fasted from food and water for at least 8 hours since common clinical chemistry test were also determined from this study participant. Blood from each participant was drawn from the cubital vein into appropriate blood collection tubes using vacuum tube needles aseptically. K2EDTA tubes were used for CBC analyses. SST was used for serology and common clinical chemistry tests. Samples collected in SST tubes was separated by centrifugation for 10 minutes at 3,000 rpm for investigation of anti-HCV, anti-HIV, syphilis and HBsAg levels. All study participant provided urine samples for urinalysis and stool sample for stool examination. Samples were transported and tested within 4 hours after collection. Stool was examined by wet mount and formal-ether concentration method, urine dip stick and microscopy was done for urine analysis. Each procedure and principle of screening test were shown in annexes of last pages.

Principle of Hematological Assay

A complete blood count (CBC) and differential was performed on the blood sample, using Sysmex KX-21N, an automated 3-part differential hematology analyzer. The machine automatically dilutes whole-blood sample of 50 ml in the CBC/Differential mode, lyses and directly measures the WBC, RBC, HGB, HCT, and PLT, LYM #, MIXED #and NEUT #. The remaining parameters are calculated or derived, MCV, MCH, MCHC, MPV, RDW-CV and RDW-SD, and differential percentages LYM%, MIXED%, NEUT%. The KX-21N counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection.

Its principle was impedance principle which was based on the detection and measurement of changes in electrical resistance produced by a particle suspended in a conductive liquid as it is drawn through a small aperture. A blood sample is diluted in saline, which is a good conductor of electrical current. 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. The change in voltage generates a pulse. Each cell momentarily increases the electrical resistance between two electrodes. The amplitude and size of the pulse depends on the cell volume.

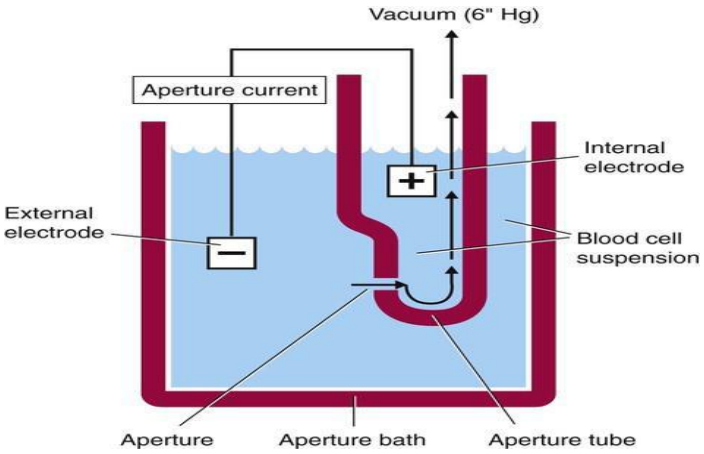

FIGURE 1: ELECTRICAL EMPEDENCE PRINCIPLE OF SYSMEX KX-21

WBC: DC detection method

RBC: DC detection method

HGB: Non-cyanide hemoglobin analysis method

5.7 DATA QUALITY ASSURANCE

To ensure the quality of data, short training was given to data collectors prior to data collection. The data collectors were two laboratory professionals and one health extension. Pre-analytical and analytical aspects must be taken into consideration in the implementation of a RI study.The pre-analytical considerations involve biological (i.e. sampling time in relation to biological rhythms, fasting or non-fasting and physical activity) and methodological factors (i.e. sample collection techniques, type of additives, with tourniquet and sampling equipment, specimen handling, transportation, time and speed of centrifugation, and storage conditions). Analytical aspects include the analytical variability of the method used for the measurement, equipment/instrumentation, reagents, calibration standards and calculation methods. Standard operating procedure (SOP) were followed for pre-analytical, analytical, and post-analytical procedures during hematological tests measurement and sample collection. All samples were analyzed in one laboratory (Arsi University Main Laboratory) with the same hematology analyzer and the same professionals. For Sysmex KX-21 hematology analyzer, daily initialization background check, three levels (tri level) of commercially available whole blood quality control material (high, normal, and low) were used to check the analytical capability of the machine daily on start up. Repeated analysis of randomly selected specimens for reproducibility check (Precision check) was carried out to evaluate instrument performance consistently and accurately. Positive and negative quality control were performed per week and every batch numbers of test kits for HIV, HBsAg, HCV and syphilis tests. Anthropotometric measurement like balance were also tested with previous known individuals.

5.8 DATA ANALYSIS AND INTERPRETATION

All the data was coded and checked for completeness, then was be entered to Epidata, and analyzed using SPSS version 21 statistical software for windows. The data was tested for normality of its distribution by Kolmogorov–Smirnov; therefore, the non-parametric methods for determination of RI were used as recommended by CLSI. Median, central 95 percentile, and 90% confidence interval (CI) were calculated. The 97.5percentile and 2.5percentile were the upper and lower reference limit for the population. The significant difference between sex groups was determined using Mann–Whitney U test.

5.9 ETHICAL CONSIDERATIONS

Ethical clearance was obtained from Departmental Ethical Review and Research Committee (DERC) of Addis Ababa University. Permission was obtained from Asella Town administration where the study participants were selected. Written consent was obtained from each study participants to provide clinical specimen for screening and research purpose. Before the samples were collected, the study participants were informed about the aim of the study and that the study process would have no harm and is important and helps to establish specific reference interval for Asella town geriatrics population and used to interpret hematological parameter. In addition, the confidentiality was kept. Any participants who are not volunteers were not be enforced to be included as study subject and they can stop or refuse to be study participant any moment they want. At the end of study, they were informed about the positive results with different infection and link them to Asella hospital as new patients for further investigation and to get necessary treatment.

5.10 DISSEMINATION OF RESULT

The result of this study will be disseminated or communicated to Addis Ababa University College of Health science, Department of Medical Laboratory Sciences, Oromia Regional health bureaus, Asella teaching and referral Hospital and Arsi University College of Health Science, and other concerned bodies through reports, conference presentations and publication on an appropriate peer reviewed journal.

5.11 OPERATIONAL DEFINITION

Apparently healthy: An individual who has no sign and symptoms and history for any disease and negative result for the screening tests. Apparently healthy also refers to the absence of disease based on clinical signs and symptoms and function, normally assessed by routine laboratory methods and physical evaluation.

Geriatric: Individual sixty and above (≥60) years age group.

Hematological Parameters: WBC differentials and absolute count, RBC and Platelet parameters.

Reference Interval (RI): The 95-percentile interval between the 97.5 percentile and 2.5percentile which form the upper and lower reference limit from specific reference distribution of reference sample group.

6. RESULT

6.1 SOCIODEMOGRAPHIC CHARACTERISTICS

From a total of 342 geriatrics, 70 individuals (20.5%) excluded with different exclusion criteria. Among 70 individuals, 46(65.7%) were syphilis positive, 6(8.5%) were HBSAg positive, 6(8.5%) were urine chemicals like leucocyte,blood, WBC and RBC positive, 4(5.7%) were glucose positive in urine dipstick, 3(4.3%) were stool examination positive,3(4.3%) were HIV positive and 2(2.9) were HCV positive and only 272 geriatrics took part in the study. Among the 272 individuals, 134 (49.3%) were females and 138 were males. About (36%) of study participant attained primary education level and 73.2% were Orthodox christen followers (Table 1). The mean and range age of the study participants was 65.82 ± 6.4 and 60-90 (30) years.Age categorize were grouped by age standardization of a new WHO standard(43).

TABLE 1: SOCIO DEMOGRAPHIC DISTRIBUTION OF THE STUDY POPULATION.

Variable	Sociodemographic characteristics	Frequency	Percentage
Sex	M	138	50.7
	F	134	49.3
	Total	272	100
Age group	60-64	138	50.7
	65-69	64	23.5
	70-74	38	14.0
	75-79	15	5.5
	≥80	17	6.3
	Total	272	100
Educational status	Illetrate	36	13.2
	Read and Write	37	13.6
	Primary 1-8	98	36.0
	Secondary 9-12	53	19.5
	College Diploma and above	48	17.6
	Total	272	100

Religion	Catholic	2	0.7
	Muslim	58	21.3
	Orthodox christan	199	73.2
	Protestant	13	4.8
	Total	272	100
Occupation	Farmer	32	11.8
	Governmental employee	44	16.2
	House wife	79	29.0
	Others like pension	97	35.7
	Private employee	20	7.4
	Total	272	100

6.2 HEMATOLOGICAL REFERENCE INTERVALS

Frequency histograms were prepared to check for normality of some of the hematological parameters by Kolmogorov–Smirnov and they showed the Gaussian distribution. Exclusion of outlier are also very important to obtain reliable RI.The Horn using tukey method is a more sophisticated method which includes box plot transformation of the data to obtain gaussian distribution followed by identification of the outlier in IQR.At level of < Q1-1.5IQR and values > Q3+1.5IQR ,the outlier were discarded.The following figures showed the Gaussian distribution of the PLT, RBC, and WBC among the males and females in the histogram.

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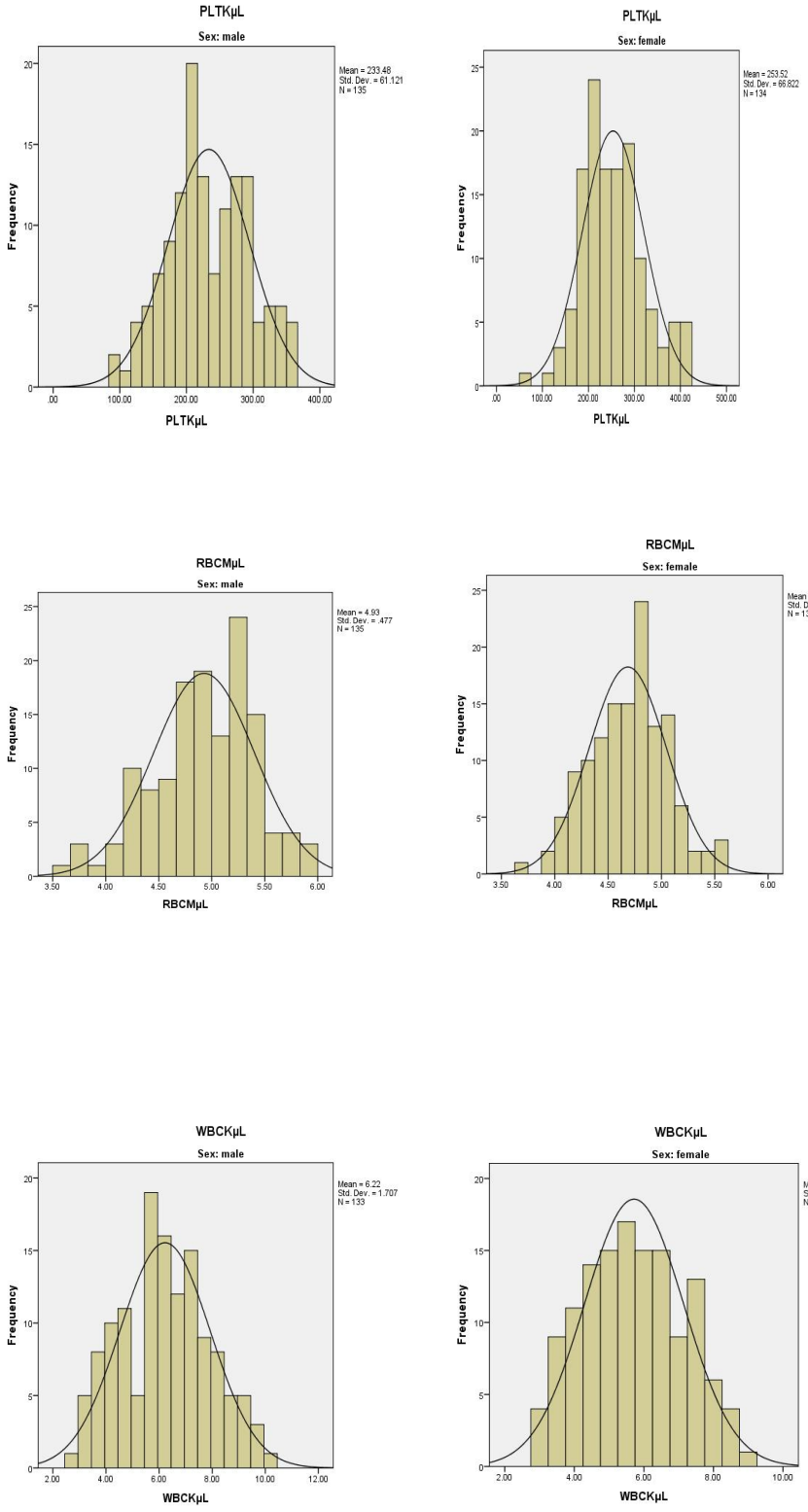

FIGURE 2: FREQUENCE HISTOGRAM FOR SELECTED HEMATOLOGICAL PARAMETERS AMONG MALES AND FEMALES IN HEALTHY GERIATRICS POPULATION IN ASELLA TOWN, SOUTHEAST, ETHIOPIA.

The means, median and reference interval (2.5– 97.5 percentile) for males and females'geriatric population are presented in Table 2. The reference intervals were calculated, based on the IFCC and the CLSI guidelines. Most of the hematological parameters showed significant differences across gender as tested by Kolmogorov–Smirnov method.The males had higher WBC (3.1-9.66 $\times 10^9$/L versus 3.13-8.4$\times 10^9$/L), RBC (3.80-5.85$\times 10^{12}$/L versus 3.94-5.48 $\times 10^{12}$), HGB (12.4-17.76g/dL versus 12.5-16.4 g/dL), HCT(35.06-50.2% versus 36.49-48.2%), NEU% (24.06-70.5% versus 23.67-67.86 %) and MIX cell number (0.3-1.56 $\times 10^9$/L versus 0.3-1.4 $\times 10^9$/L) than females. Whereas the females had a higher PLT (137.5-406.0 $\times 10^9$/L versus 115.8-353 $\times 10^9$) and LYM % (21.88-64.79% versus 18.84 -59.2%) than male. On the other hand, the MIX% cells, absolute lymphocyte number, RDWCV, PDW and MPV did not show statistically significant differences among the genders (P > 0.05).

TABLE 2: REFERENCE INTERVALS, MEAN, MEDIANS AND 95% PERCENTILES FOR THE UPPER AND LOWER LIMIT IN RELATION TO SEX AMONG HEALTH GERIATRICS IN ASELLA TOWN, SOUTHEAST ETHIOPIA.

Parameter	Sex	Unit	No*	Median	Mean	Min	Max	95% RI		p-value
								2.5th	97.5th	
WBC	M	10^9/L	133	6.1	6.22	2.7	10.2	3.1	9.66	.015
	F		133	5.5	5.71	3.0	9.0	3.13	8.4	
RBC	M	10^{12}/L	135	5.0	4.93	3.6	5.95	3.8	5.85	<0.001
	F		133	4.7	4.68	3.69	5.6	3.94	5.48	
HGB	M	g/dL	133	15.5	15.38	11.7	18.3	12.4	17.76	<0.001
	F		130	14.35	14.29	11.4	17.4	12.5	16.4	
HCT	M	%	134	44.0	43.9	34.0	50.8	35.06	50.2	<0.001
	F		131	41.3	41.5	34.6	51.3	36.49	48.2	
MCV	M	Fl	138	89.0	89.07	79.4	98.6	81.64	98.15	.215
	F		131	88.0	88.49	80.5	98.6	82.39	97.36	
MCH	M	Pg	138	31.3	31.3	26.2	35.6	27.78	34.8	<0.001
	F		129	30.4	30.5	26.9	34.7	27.25	34.1	

MCHC	M	%	133	35.0	35.04	33.2	37.1	33.5	36.56	<0.001
	F		127	34.5	34.5	32.6	36.7	32.72	36.26	
PLT	M	10^9/L	135	224	233	93.0	364	115.8	353	.025
	F		134	246.5	253.5	66.8	412	137.5	406	
LYM%	M	%	138	36.1	37.35	11.9	68.0	18.84	59.2	.002
	F		133	40.2	41.3	17.8	65.3	21.88	64.79	
NUE%	M	%	138	52.5	50.64	20.8	73.6	24.06	70.5	.02
	F		134	48.6	47.4	16.4	69.9	23.67	67.86	
MIX%	M	%	133	11.6	11.77	1.6	22.2	4.6	21.56	.230
	F		133	10.4	11.17	4.9	21.9	5.3	21.0	
LYM	M	10^9/L	134	2.1	2.24	0.6	4.0	1.14	3.6	.554
NUMBER	F		132	2.3	2.28	1.1	4.0	1.2	3.8	
NUE	M	10^9/L	137	3.2	3.3	0.7	6.9	1.14	6.5	.004
NUMBER	F		134	2.85	2.8	0.7	5.5	0.84	5.32	
MIX	M	10^9/L	133	0.7	0.72	0.1	1.7	0.3	1.56	.003
NUMBER	F		132	0.6	0.63	0.3	1.5	0.3	1.4	
RDW CV	M	%	133	13.1	13.02	11.10	14.9	11.47	14.66	.194
	F		129	12.9	12.95	11.4	15.7	11.6	15.6	
PDW	M	Fl	134	12.9	13.2	8.5	18.3	10.33	17.1	.82
	F		129	13.2	13.23	9.3	18.0	10.42	17.3	
MPV	M	Fl	137	10.6	10.61	8.70	13.4	8.84	12.67	.709
	F		133	10.6	10.65	8.5	13.2	9.03	12.96	

Note: *The number of study sample shown in the above table was outlier cleaned data for each parameter.

TABLE 3: ESTABLISHED REFERENCE INTERVALS,90CIS FOR LOWER AND UPPER LIMIT OF HEMATOLOGICAL PARAMETERS IN RELATION TO SEX AMONG HEALTH GERIATRICS IN ASELLA TOWN, SOUTHEAST ETHIOPIA.

Parameters	Unit	Sex	Sample number	Lower limit	Upper limit	Lower 90% CI	Upper 90% CI	P-value
WBC	10^9/L	M	133	3.1	9.66	2.86-3.34	9.42-9.9	.015
		F	133	3.13	8.4	2.93-3.33	8.2-8.6	
RBC	1012/L	M	135	3.8	5.85	3.73-3.87	5.78-5.91	<0.001
		F	133	3.94	5.48	3.89-3.99	5.43-5.53	
HGB	g/dL	M	133	12.4	17.76	12.21-12.58	17.58-17.94	<0.001
		F	130	12.5	16.4	12.37-12.63	16.27-16.53	
HCT	%	M	134	35.06	50.2	34.57-35.55	49.71-50.69	<0.001
		F	129	36.49	48.2	36.11-36.86	47.82-48.57	
MCV	FL	M/F	269	81.95	97.9	81.56-82.3	97.5-98.3	
MCH	Pg	M	138	27.78	34.8	27.55-28.0	34.57-35.03	<0.001
		F	129	27.25	34.1	27.02-27.48	33.87-34.33	
MCHC	Pg	M	133	33.5	36.56	33.38-33.62	36.44-36.68	<0.001
		F	127	32.72	36.26	32.6-32.8	36.11-36.14	
PLT	10^9/L	M	135	115.8	353	107-124	344-361	0.025
		F	134	137.5	406	128-147	396-415	
LYM%	%	M	139	18.84	59.2	17.39-20.3	57.7-60.6	.002

		F	133	21.88	64.79	20.4-23.4	63.3-66.3	
NEU%	%	M	138	24.06	70.5	22.5-25.7	68.9-72.1	0.02
		F	134	23.67	67.86	22.0-25.3	66.2-69.5	
MIX%	%	M/F	266	5.1	21.2	4.7-5.5	20.8-21.6	
LYM NUMBER	10^9/L	M/F	266	1.2	3.6	1.1-1.3	3.54-3.66	
NEU NUMBER	10^9/L	M	137	1.14	6.5	0.9-1.3	6.3-6.7	.004
		F	134	0.84	5.32	0.68-1.0	5.16-5.48	
MIX NUMBER	10^9/L	M	133	0.3	1.56	0.26-0.34	1.52-1.6	.003
		F	132	0.3	1.4	0.26-0.34	1.36-1.44	
RDWCV	%	M/F	262	11.6	14.74	11.56-11.7	14.66-14.82	
PDW	FL	M/F	263	10.4	17.1	10.2-10.6	16.9-17.3	
MPV	FL	M/F	270	8.97	12.9	8.8-9.06	12.8-12.99	

In the above table, the determined RI for MCV, MIX%, LYM NUMBER, RDWCV, PDW and MPV were combined since they were not significance among males and females. But for the rest parameter the RI were established separately because, they were significance among two genders.

TABLE 4: ESTABLISHED REFERENCE INTERVAL, EXISTING REFERENCE INTERVAL (MANUAL BOOK OF SYSMEX KX-21 DRIVED RI) AND PERCENT OF MISCLASSIFIED OF STUDY PARTICIPANTS FROM EXISTING REFERENCE INTERVAL AMONG HEALTHY GERIATRICS POPULATION IN ASELLA TOWN, SOUTHEAST ETIOPIA.

Parameters	SEX	Number	Established RI (2.5-97.5) percentiles	Existing RI M=124 F=117	% of individuals outside the existing RI
WBC	M	133	3.1-9.66	2.6-8.8	6.76
	F	133	3.13-8.4	3.1-10.3	N/A
RBC	M	135	3.8-5.85	3.6-5.3	15.5
	F	133	3.94-5.48	3.2-4.6	58.64
HGB	M	133	12.4-17.76	11.3-15.7	57
	F	130	12.5-16.4	9.9-13.6	76
HCT	M	134	35.06-50.2	32.6-47.5	14.9
	F	131	36.49-48.2	30.2-42.3	38.16
MCV	M	138	81.64-98.15	80.3-103.4	2.17
	F	131	82.36-97.36	78.6-102.2	2.29
MCH	M	138	27.78-34.8	26-34.4	3.6
	F	129	27.25-34.1	25.2-34.7	N/A
MCHC	M	133	33.5-36.56	31.8-36.3	4.5
	F	127	32.72-36.26	31.3-35.4	10.23
PLT	M	135	115.8-353	134-377	4.4
	F	134	137.5-406	128-434	N/A
LYM%	M	138	18.84-59.2	17.5-47.9	17.39
	F	133	21.88-64.79	15-45.8	31.57
MIX%	M	133	4.6-21.56	1.9-24.6	N/A
	F	133	5.3-21.0	1.3-25.9	N/A
NEU%	M	138	24.06-70.5	38.3-69	23.9
	F	134	23.67-67.86	43.7-77.1	33.58
LYM NUMB	M	134	1.14-3.6	0.8-2.7	23.13
	F	132	1.2-3.8	0.9-2.8	16.66

MIX NUMB	M F	133 132	0.3-1.56 0.3-1.4	0.1-1.5 0.1-1.6	2.25 N/A
NEU NUMB	M F	137 134	1.14-6.5 0.84-5.32	1.2-5.3 1.6-6.9	8.0 13.43
RDW-CV	M F	133 129	11.47-14.66 11.6-15.6	10.8-14.9 10.6-15.7	N/A N/A
PDW	M F	134 129	10.33-17.1 10.42-17.3	9.8-18.0 9.8-18.0	0.74 0.77
MPV	M F	137 133	8.84-12.67 9.03-12.96	8.1-12.4 8.1-12.4	2.18 5.26

Note: N/A =Not available

As shown in table 4, the reference interval was compared with the existing reference interval which is derived from manufacturer and the manual book of Sysmex kx-21 (50). These values are currently use in our laboratory. The lower limits of the NEU%, and absolute NEU count in both females and males, platelet count in males, were comparably lower than the existing RIs. Both the lower and the upper limits showed an increment with the WBC, and MCH in males, RBC, MCHC and HGB, HCT, LYM%, LYM Numbers and slightly mixed count cell values in both males and females when compared with existing reference interval. MCV, PLT, MIX%, PDW in both females and males, NEU% in females showed a mild decrease in the upper limits as compared to the laboratory RI. In addition, HGB showed the maximum percentage of the study individuals (76% in the females and 57% of the males) outside the existing reference values, followed by RBC (58.64% of the females and 15.5% of the males).

7. DISCUSSION

There is a scarcity of RI studies on the elderly in Africa. Existing publications on RI in Africa are generally limited to specific sub-populations: usually children or individuals ≤ 60 years.

Most of the hematological parameters showed significant differences across gender geriatrics groups. Statistically significant gender-based differences were found for the following parameters and hence, separate reference intervals for the two genders should be considered. WBC (3.1-9.66 $\times 10^9$/L versus 3.13-8.4$\times 10^9$/L), RBC (3.8-5.85$\times 10^{12}$/L versus 3.94-5.48 $\times 10^{12}$/L), HGB (12.4-17.76g/dl versus 12.5-16.4 g/dl), HCT (35.06-50.2 % versus 36.49-48.2%), NEU% (24.06-70.5%) versus 23.67-67.86 %) and MIX cell number (0.3-1.56 $\times 10^9$/L versus 0.3-1.4 $\times 10^9$/L) which was higher value in males and PLT (137.5-406 $\times 10^9$/L versus 115.8-353 $\times 10^9$/L) and LYM % (21.88-64.79% versus 18.84 -59.2%) higher value in females.

Gender difference in RBC, HGB and HCT observed in this study were similar with study in six geographical region in china and a reference interval study in Canada that shows female had lower values than male (23, 44), which were also true in another study conducted among Healthy Ugandan Population, where RBC parameters such as RBC, HGB and HCT value shows decearement among female (33).

The mean of HGB concentration (18.49 versus 15.38 g/dl), HCT(55.8 versus 43.9%), RBC(5.95 versus 4.93×109) among male of two study area and mean of HGB (17.47 versus 14.29 g/dl), HCT(52.3 versus 41.5 %) and and RBC (5.69 versus 4.68$\times 10^9$/L) of females among study in three high altitude towns; Cojata , Ananea and Rinconada which are located at 4355 m, 4660 m and5500 m, respectively, located in Huancane, Peru and our study.These findings reflected that RBC parameters are affected by altitude. The finding in the current study was lower while comparing with the study in three high altitude towns; Cojata, Ananea and Rinconada which are located greater than 4355 m, 4660 m and5500 m, respectively that was higher than our study area which was located 2430 above sea level (26).

Having higher mean value of PLT count in females than males in this study again was similar with other study from Chennai, Southern India aimed to establish Reference Intervals for the Hematological Parameters among individuals aged from (18-70 years) which includes geriatrics population (45).

This could be due to a hormonal influence in their regulation. The process by which megakaryocytes proceed to proplatelet formation and platelet production is reportedly under the influence of autocrine estrogen (46). Additionally, estrogen-receptor antagonists inhibit platelet production *in vivo*, supporting a role of estrogens in platelet production (47)**.**

Males have also higher mixed count and neutrophil% than females appeared to be consistently lower in females than in males across all age groups which was similar with study on aging and the hematological profile of Austrialian community (12)**.** The difference in mixed count may be due to the presence of allergic and parasitic diseases in the apparently healthy elderly subjects which is not excluded during screening test like parasitic examination or while filling questionnarries falsely making negative for individuals with allergic condition (35).

Compared with other reference values established in canada Health Measures Survey the current established reference interval was lower for lower limit of PLT (115.8-353×109/L) versus (151.8-324×109/L) for males and (137.5-406×10^9/L) versus (153.2-361×10^9/L) for females. And also have lower both upper and lower limit WBC (3.1-9.66×10^9/L versus 3.8-10.4×10^9/L) for males and (3.13-8.4×10^9/L versus 3.8-10.4×10^9/L) females and NEU number (1.14-6.5 ×10^9/L versus 2.0-6.4×10^9/L) for males and lower both upper and lower limit of NEU number (0.84-5.32×10^9/L versus 2.0-6.4×10^9/L) for females(23).

The lower and upper limit of the WBC, PLT and RDWCV in both males and females, upper limit of RBC, HCT and HGB in females, upper and lower limit of HGB and HCT in males and upper limit of MCV in both females and males decreased slightly when compared with other reports done in south west Ethiopia. But lower limit of RBC, HCT and HGB in females, lower limit of MCV in both sexes and lower limit of absolute neutrophil again shows slight increament (39). This difference in hematological parameters in one country could be due to difference in geographical factor, habit of life style, age group, dietary pattern and altitude on the Hematological parameter. The overall decrease could be due to the gradual loss of androgens, which stimulate increased production of erythrocytes(48, 49)**.**

The upper limit of WBC in both males and females, the upper and lower limit of RBC, HCT and HGB in males, the upper limit of HGB a and HCT in females were lower when compared with the established adult reference interval of Ethiopians. But had higher value for the upper and lower

limit for RBC, lower limit of HGB and HCT for females, upper and lower limit of PLT for both males and females than adult population (21).

8 STRENGTH AND LIMITATION

8.1 STRENGTH

The strength of this study was recruited more study participant required for the establishment of RI than CLSI which recommended minimum number of 120 individuals for one partition.

Assessing disease (acute and chrionic) condition of each participant and select only eligible participant after performing screening test for each study participant with all challenges likes COVID-19 which makes difficulty while some of the data collected after COVID-19 and processing laboratory tests could be also the strength of the study

8.2 LIMITATION

The study had certain limitations. A fundamental limitation is that, the result of this study can not be the Representative of all Arsi Zone geriatrics population. The other limitation is that due to resource reasons, RIs for other hematological parameters such as coagulation profiles and ESR were not done.

9 CONCLUSION AND RECOMMENDATION

9.1 CONCLUSION

Gender and age specific reference intervals are crucial as there were statistically significant gender related differences in the all WBC parameter except relative value for mixed count and LYM number, all RBC parameter except value for MCV and PLT count. The reference intervals which were established by this study was different from the existing reference values as well as from other african countries and caucasion population. This difference could be due to difference in diatray pattern, ethnic difference as well as in the methodological difference. Therefore, this study provided hematological parameters RI which can be used to guide clinicians to manage patient health status by interpreting laboratory result with the established RI for enrollment into clinical trials and potentially improve the quality of health care in the area.

9.2 RECOMMENDATIONS

Since Asella hospital gives service for all Arsi zone including Asella town, the reference interval of hematological parameters should be established for all Arsi zone populations**.** The established reference interval in our study area was different from the one we have adopted (laboratory manual) and have been using it in our facility. Thus, we recommend other health facility to determine their own reference interval using larger scale study for more accurate and reliable interpretation of test result and better patient management.

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ANNEXES

ANNEX I: INFORMATION SHEET IN ENGLISH VERSION

Principal Investigator: Mohammed Hashim (BSc, MSc candidate)

Title of the Research Project: Establishment of hematological parameters reference intervals for apparently healthy geriatrics in Asella town, South East Ethiopia.

Name of the Organization: Addis Ababa University College of Health Sciences, of Medical Laboratory Department.

Introduction

You are invited to participate as a study subject in a research conducted by MSc candidate, from Addis Ababa University. Your participation is voluntarily. The research teams will include one principal investigator, two advisors; from Addis Ababa University Hematology department. Please take as much time as you need to read or listen in the information sheet.

Purpose of the Research Project

We are asking you to take part in this study because we will try to establish hematological parameters reference intervals for apparently healthy geriatrics in Asella town, South East Ethiopia.

Procedures and the expected participation

If you are willing to participate, you need to understand the purpose of the study and give your consent. Not only this but also specimen collected from you will be used for the research purpose, and the results of your sample will be exposed to some concerned professional staffs as it is needed. The required clinical sample will be collected by medical laboratory technologist. Then, you are requested to give your consent to the sample collector. After consent, a sample will be collected. Moreover, there will be a face-to-face interview for additional questions which will take about 10 minutes.

Potential risks and Discomfort

During collection of specimens from you, appropriate precaution will be taken and all samples will be collected by medical laboratory technologist. If anything happened, appropriate medical care will be provided to you.

Confidentiality

We respect your privacy and confidentiality. Any information that identifies you will not be shared with anyone else outside the study team. The information we will collect from you as part of the

study will be kept in a locked file cabinet, or be protected by a password on the computer only accessible to personnel involved in the study. There is no sensitive issue that you will be asked related with your social desirability but any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Potential benefits to subjects and/or to the society

You will not receive any payment for your participation in this research study as compensation. However, you will get the results for free. In addition, the result of the study will be beneficial for establishment of hematological parameters reference intervals for geriatrics. Hence, you are indirectly benefiting other patients and the society in this respect.

Participation and Withdrawal from the Study

The participation is voluntary and you have the right not to participate in this study. You may withdraw at any time and place without consequences of any kind. You may also reject to give any sample. You can ask any questions regarding to this study and you have a right to get a laboratory diagnosis result free.

Contact information

If you have any questions about this study you can contact the following principal investigators and advisors for further information.

Mohammed Hashim Phone**:** 0917981006 Email: mohedhajo2014@gmail.com

Dr. Aster tsegaye Phone: 0911696085 E-mail: tsegayeaster@yahoo.com

ANNEX II: INFORMATION SHEET IN AMHARIC VERSION

ለጥናቱ ተሳታፊዎች መረጃ

የጥናቱ ዋና

የጥናቱ ርዕስ ፡- እድሜያቸው ከ60 እና ከዚያ በላይ ለሆኑት የጤናማ ሰው ደም ውስጥ የሚገኙ የክሊኒካል ላቦራቶሪ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል መስራት፡፡

ተቋማት፡-አዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ የሕክምና ላቦራቶሪ ሳይንስት/ክፍል

መግቢያ

በአዲስ አበባ ዩኒቨርሲ ቲጤና ሳይንስ ኮሌጅ የሕክምና ላቦራቶሪ ሳይንስት/ክፍል በማስተርስ ድግሪ ተማሪ የመመረቂያ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል፡፡ እባክዎ በዚህ ጥናት ለመሳተፍ ከመስማማት ዎበፊት ከዚህ ቀጥሎ የሚገኘውንም ንባብ በጥሞና ያንብቡና ግልፅ ያልሆነሎትን ማንኛውንም ሀሳብይ ጠይቁ፡፡

የምርምር ጥናቱ አላማ

እድሜአቸው 60ዓመትና ከዚያ በላይ ለሆኑ የጤናማ ሰው ደም ውስጥ የሚገኙ የክሊኒካል ላቦራቶሪ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል መስራት፡፡

የጥናቱ አካሄድ

በጥናቱ ለመሳተፍ ከተስማሙ የጥናቱ አባል/አባላት 10 ደቂቃ የሚወስድ ጥያቄ ይጠይቁዎታል፡፡ክብደት፣ቁመት፣የክንድእና የደም ግፊት ልኬት ይወሰዳል፡፡ሽንትና አይነ ምድር በምንሰጠው እቃ እንድትሰጡ ንእንጠይቃለን፡፡በተጨማሪም 10 ሚሊሊትር (አንድ የሾርባ ማንኪያ የሚሆን) በንፁ ህቫኩቴይነር ብልቃጥ እና መርፌ እንቀዳለን (6 ሚሊሊትር በባዶቲዩብ፣4 ሚሊሊትር ደም እንዳይ ረጋ የሚያደርግ ንጥረ ነገር፣ኢዲቲኤ፣ባለበት ቲዩብ)፡፡የሄማቶሎጂ፣ሴሮሎጂ፣ፓራሲቶሎጂ እና የክሊኒካል ኬሚስትሪ ምርመራዎችን እናካሂዳለን፡፡

የጥናቱ ተሳታፊ ለመሆን የሚጠበቅበዎት ምንድንነው?

በዚህ ጥናት ለመሳተፍ የሚስማሙ ከሆነ ናሙናዎ ለጥናቱ እንዲ ሚዉል መስማማት ይጠበቅብዎታል፡፡ከተወሰደው ናሙና ላይ የሚገኘው መረጃዎች ከዚህ አባላት ውጪ ለሚገኙና ለስራው አግባብነት ላላቸዉ ሰዎች ቢነገር የማይቃወሙ መሆኑን መስማማት ይጠበቅብዎታል፡፡ይሁን እንጂ ይህ አይነቱ መረጃ የርስዎን ማንነት የሚገልጡ መረጃዎችን ማለትም ስም፤አድራሻ ና የስልክ ቁጥር የመሳሰሉትን መረጃዎቸን አይጨምርም፡፡ይልቁንም ለዚህ አገልግሎት ብቻ የሚውል እርስዎን ለማወቅ የሚያስችል መለያ ቁጥር ጥቅም ላይ እንዲዉል ይደረጋል፡፡፡በተጨማሪም ስለ ርስዎ አጠቃላይ የጤና ሁኔታ ለሚቀርቡሎት አንዳንድ ተጨማሪ ጥያቄዎች መልስ መስጠት ይኖርብዎታል፡፡በጥናቱ ለመሳተፍ የሚስማሙ ከሆነ የስምምነት ቅፅ ላይ በጹሁፍ ወይም በጣት ፊርማ ማስቀመጥ ይጠበቅቦዎታል፡፡

በዚህ ጥናት መሳተፍ የሚያስከትላቸዉ ችግሮች ምንድንናቸዉ?

ናሙና በሚሰበሰብበት ወቅት ምንም አይነት የከፋ ችግር አያጋጥምዎትም፡፡ሆኖም ግን ናሙናውን ለመሰብሰብ ልምድ ያለዉ ባለሙያ ስለሚመደብ ና አስፈላጊዉ የጥንቃቄ እርምጃ ስለ ሚወሰድ የህመም ስሜት አይኖርም፡፡

የህክምና መረጃ በሚስጥር ተጠብቆ መቆየት የሚችለዉ እንዴትነዉ?

ስለ ራስዎ የሰጡት ማንኛዉም መረጃ ናከ ተወሰደዉ ናሙና ላይ የተገኘዉ የላቦራቶሪ ዉጤት የሚዉለዉ ለጥናቱ አላማ ብቻ ነው፡፡ይህን ማህደር ሊያገኙ የሚችሉት የተወሰኑ የጥናቱ ተባባሪ ሰዎች ብቻ ናቸው፡፡ ከዚያም በላይ ስለ እርስዎ ያለውን ማንኛውንም መረጃ የተለየ ይለፍ ቃል ባለው የኮምፒውተር የመረጃ ማህደር ውስጥ እንዲቀመጥ ይደረጋል፡፡

በዚህ ጥናት መሳተፍ የሚያስገኛቸው ጥቅሞች ምንድንናቸው?

ይህ ጥናት የማስተርስ ዲግሪ መመረቂያ እንደ መሆኑ መጠን በዚህ ጥናት በመካፈል ዎበ ገንዘብ የሚያገኙት ጥቅም ባይኖርም ከጥናቱ በሚገኘው ውጤት ግን ተጠቃሚነዎት፡፡የእርሶዎ ተሳትፎ የእርስዎን ና የወገንዎትን የደም ምርመራ ሊኬትን ለማከታተል ከፍተኛ ጥቅም ይኖረዋል፡፡

በዚህ ጥናት ተሳታፊ የመሆንዎ መብቶች ምንድንናቸው

በዚህ ጥናት መሳተፍ ሙሉ በሙሉ በእርስዎ ፈቃደኝነት የተመሰረተ በመሆኑ በማንኛውም ሰዓትና ቦታ የማቋረጥ ሙሉ መብት የተጠበቀ ከመሆኑም በላይ እራስዎን ከጥናቱ በማግለልዎ ምክንያት የሚቀርብዎት ምንም አይነት የሆስፒታል አገልግሎት አይኖርም፡፡ከዚህም በተጨማሪ ጥናቱን በተመለከተ ማንኛውንም አይነት ጥያቄ የመጠየቅ ና ገለጻ የማግኘት መብት አለዎት፡፡የላብራቶሪ ምርመራ ውጤቱንም በነጻ ማግኘት ይችላሉ፡፡ነገር ግን እርስዎ በሚሰጡን መረጃ የችግሩን ስፋት ለመከላከል እና ለመቆጣጠር ጠቃሚ ስለሆነ ለሚቀርብልዎት ጥያቄ ቀጥተኛ መልስ ይሰጡን ዘንድ በታላቅ አክብሮት እንጠይቃለን፡፡

ጥያቄ ካለኝ ወይም ችግር ቢያጋጥመኝ ምን ማድረግ ይገባል?

ይህንን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለ ሚያጋጥሙ ድንገተኛ አደጋዎች ወይም ጥያቄ ካለዎት በሚመለከተው አድራሻ ይጠቀሙ፡፡

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ዶ/ር አስቴር ፀጋዬ ሞባይል፡ +251-911-696-085 ኢሜል፡ tsegayeaster@yahoo.com

ANNEX III: INFORMATION SHEET IN AFAAN OROMOO VERSION

Oddeeffaannoo Hirmaattottaa qoraannoo kaanafi kennaammu Qoraataan qoraannoo kanaa obboo Muhaammad Hashim

Mataa dureen qoraannoo kana: Giddu galeessummaa baayina dhiiga hemaatoloojjii fi kilinikaal keemistriinamaa fayyaa umriin isaa 60 fi Sanaa olii magaaala Asallaa bu ‘uurreessuu.

Seensaa:

Qoraannoo baarattootni Yuunvaarsittii finfiinnee koolleejjii fayyaa Diipaartmeenti Meedikaal Laboratorii saayinsii Digrii lammaaffa (Maasteris) eebifaamuuf gaaggeessaan irraati akka hirmaataan carraan isiinif kennaame jiraa. Qoraannoo kanaa irraati hirmaachuuf waalgaluu keessaan dursitaan oddeeffaannoo armaan gadii kanaa xiyyeeffaanan akkaa dubistaani fi gaaffii dhimmaa qoraannoo kanaa ilaalchisee isiinit umaame kamuu akka gaafataan kabaajadhaan isiini gaafanna.

Kaayyoon Qoraannoo kanaa:

Dhigaa namaa fayyaa umrii isaa kudhaa lamaafi sanaa olii keessaati gidduu galeessumaan hangaa argaamaa qoraannoo kilinkaal Laboraatorii reefireensi inteervaali bu ‘uurreessuufi wantoota Quulqullinaa qoraannoo laboratorii ittiin to ‘aatani hoojaachuudha.

Haala Qoraannoon itti addeemsifaamu:

Qoraannoo kanaa keessaatti hirmaachuuf yoo murteessitaan namoon qoraannoo kanaa kan gaaggeessan gaaffiii daqiqaa kudhaan (10) fudhaatu isiin gaafatani ulfaatina dheerina, dhiibbaa dhigaa keessaan safaaruun dhigaa milileetirii kudhaan (10ml) siin irraa fudhaachun milileetiri jaha (6ml) tubii homaa hin qabneeti isaa hafee ammo waan dhignii akka hin ragaane godhuu EDTA tuubit naquun meeshaa ficaanii fi udaan itti fidaan isiinif kennamaa. Qoraannoolee akka hemaatolojjii, seeroolojjii, paraasaytolojjii fi kilinkal keemistrii irraatti addeemsifaama

Qoraannoo kanaa irraati hirmaachuuf waantotaa namaarraa egaamu:

Qoraannoo kanaa irraati hirmaachuuf yoo fedhaan ta ‘ee sammuudni keessaan qoraannoof akka oluu heyaamama ta ‘uu qabduu. Akkasumaasi bu ‘uudhan qoraannoo kanaara argaammuu akkumaa barbaachisuma isaatti qamaa addaa addaa yoo qaaqaabe kaan hin mormiine yoo ta ‘ee. Haa ta ‘uu malee oddeeffaannoo eenyuummaa keessaan ibsuu kaneen akka maqaa teessoo fi bilbilaa keessaan kan daabarsinee hin keeninee ta ‘uu ibsaa. Koodii dhimmaa kanaaf oluu qofaa kan fayyaadamnu ta ‘aa. Daabalataanis dhimmaa fayyaa keessaan ilaalchisee gaaffii isaani gaafannuu deebii keessaan nuuf laachuutu isiiniraa eegamaa.

Qoraannoo kanaarrati hirmaachuun miidhaa qaqaabsisaa?

Yeroo saammudni fudhaatamuu miidhaan isiinira gaahuu hin jiruu. Ogeessii sammuudaa kanaa funaanu gahuumsaa fi muxxaannoo kan qabuu waan ta ‘ee hordooffii barbaachisaa waan godhuuf dhuukkubiin siniiti dhagahamuu hin jiruu.

Bu’aan qoraannoo kana

Oddeeffaannoo isiin irraa guraamesi ta ‘ii bu ‘aan qoraannoo saammuda keessaan kaan oluu dhimmaa qoraannoo kaannaa qofaafi. Gaalmee kanaasi ilaalu kaan daanda ‘aan qamaa qoraannoo kanaa gaaggeessuu qofa. Oddeeffaannoo keessaan komputeeraa keessaa gaalchuun akka qamaa birootif hin saxilaamne passwordii gaargaraan cufaamee kayyaama.

Qoraannoo kanaarratti hirmaachuuni bu’aa maal argaamsisaa?

Qoraannooni kuun masteersii digrii eebifaamuuf kan rawwaatamuu waan ta‘ee kaaffaltiin asirraati hirmaachuu keessaanif kafaalamu hin jiruu. Haa ta ‘uu malee bu ‘aa qoraannoo kanaarra argaammuun fayyaadamoo tatuu. Hirmaannaan keessaanin isiinis ta ‘ee laammiin keessaani hammaa qoraannoo dhigaa laboraatorii bu ‘uurreffamee irraa fayyaadamoo ta ‘uu.

Mirgii qoraannoo kanaarrati hirmaachuu maal fa’aa?

Qoraannoo kanaarrati hirmaachuu fedhaa keessaani irraatti kaan bu ‘urreefame waan ta ‘ee yeroo barbaadaanitti qoraannoo kanaa addaan kutaani bahuuf mirgaa guutuu qabduu. Kanaan waaliqabate taajaajille hospitaala isiinraa hafuu tokkoole hin jiraatuu. Qoraannoo kanaa ilaalchise gaaffii kamuu gaafaatani ibsaa gahaa argaachuu mirgaa guutuu qabduu. Bu ‘aa qoraannoo labooraatorii kaaffalti malee argaachuufilee mirgaa ni qabduu. Haa ta ‘uu malee oddeeffaannoon isiini nuuf keennitaan hammaa rakkoo hir ‘iisuu ykn dhabaamsisuuf waan nuu gaargaarruf gaaffiiwwaan gafaatamtaanif deebii sirrii akkaa nuuf deebistaan kabaajaadhan isiini gafaanna.

Gaaffii yoon qabaadhee ykn ammoo yoo raakkoon naa muddatee maal gochuun qabaa?

Qoraannoo kanaa ilaalchisee ykn qoraannoo kanaan waaliqabate rakkoon tasaa isiini mudaate yokaan gaaffiin yoo jiraate teessoo armaan gaadi faayyaadama.

Muhaammad Hashim mobayila +251 -917-981-006 Email: mohedhajo2014@gmail,com

Dr. Aster Tsagaaye mobayila +251_911-696-085 Email: tsegayeaster@yahoo.com

ANNEX IV: CONSENT FORM (ENGLISH VERSION)

Informed consent (study participants)

Name of main researcher: Mohammed Hashim, MLS; AAU. Advisors/Co-investigators: Aster Tsegaye (MSc, PhD), Mogos Hordofa (MSc)

Name of institute: AAU and AHRI

Funded by: AHRI and AAU

Reviewed by: DREC (AAU), AAREC and NRERC

RESEARCH TITLE: Establishment of hematological parameters reference intervals for apparently healthy Geriatrics in Asella town, South East Ethiopia.

Name:_____Age:__sex___kebele_Address_____phone__Serial number

If you agree that to take part, please read this form and sign the consent sheets at the end.

I have read, or it was read to me, the information sheet concerning this study and I understand what will be required of me if I take part in the study.

1. I am aware of the possible risk and benefits of this study.
2. I know that being in this study is voluntary.

I understand that at any time I may withdraw from this study without giving a reason and without affecting my normal care.

3. My questions concerning this study have been answered
4. I know that there is no special payment for being participating in the study
5. I agree to take part in this study.

Name:_____Signature:_____Date: _____

ANNEX V: CONCENT FORM (AMHARIC VERSION)

መለያ ቁጥር …….

ጥናቱን በሚያካሂዱት ሰዎች ስለ ጥናቱ በቂ መረጃ ተሰጥቶኛል፡፡ የዚህ ጥናት አላማም የደም ህዋሳት ሪፈረንስ ቫልዩ ማወቅነው፡፡ ከከኔ የሚወሰደዉ የደም የሰገራ፣ የሽንት፣ ናሙና ላይ ምንም አይነት የጤና ጉዳት የማያስከትል መሆኑን ተረድቻለሁ፡፡እንዲሁም በጥናቱ ለመሳተፍ ፍቃደኛ ካልሆንኩ በጥናቱ ለመሳተፍ እንደማልገደድ ነገር ግንበዚህ ጥናት በመሳተፌ ለሳይንሳዊ እዉቀት ጠቃሚ መረጃ ማበርከትና ወደፊት በዚህዙ ሪያለሚሰሩ ስራዎች መሰረትየ ሚሆን መረጃዎችን መስጠት እንደምችል ተረድቻለሁ፡፡በዚህ ጥናት ተሳታፊ በመሆን የሚከፈልምን ምክፍያ አለ መኖሩ ተረድቼ ጥናቱ ላይ ለመሳተፍ የተስማማሁ መሆኔን በፊርማዬ አረጋግጣለሁ፡፡

የተሳታፊ ፊርማ_____ ቀን

የጥናት አድራጊ ፊርማ_____ቀን

ANNEX VI: CONSENT FORM IN AFAAN OROMOO VERSION

Maqaa namaa qoraannoo ademsisuu Muhammad Hashim, MLS; AAU.

Goorsa qorannoo kanaa (Advisors):

Aster Tsegaye (MSc, PhD)

Mogos Hordofa (MSc,)

Maqaa qamaa qoraanno gaaggeessu (Name of institute): AAU and AHRI Qamaa bajaata qoraanoo kana rammadee (Funded by): AHRI and AAU

Qamaa qoraannoo kana hordoffuu (Reviewed by): DREC (AAU), AAREC and NRERC

Mataa duree qoraannoo kana: Giddu galeessummaa baayina dhiiga hemaatoloojjii fi kilnikaal keemistriinamaa fayyaa umriin isaa 60 fi isa ol magaaala Asallaa bu ‘uurreessuu.

Maqaa:_____Umrii:_____Salaa:_Gandaa:_____ Address_____phone_

_____tartibaa lakk:

Qoraannoo kanaa irraatti akkaa hirmaattan yoo fedhii qabattaan barreeffamaa armaan gadii dubisuun unkaa waali galtee qophaa ‘ee kanaa irraati mallaatteessa.

1 Oddeeffannoo dhimaa qoraannoo kanaa ibsuu duubisee ykn naaf duubiffammee qoraannoo kanaa irraattii yoo hirmaatee/ttee maalituu akka irraa baarbachisuu hubaadheen jiraa.

2 Bu ‘aasi ta ‘ee miidhaa qoraannoo kanaa hubaadheen jira.

3 Qoraannoo kanaarrattii hirmaachuun fedhiidhaan akkaa ta ‘ee hubaadheen jira.

4 Yeroon barbaadaameti qoraannoo kanaa keessaa bahuu yoo barbaadaan Sabaabaa tokkoo malee bahuu akkaa dandaa ‘aan hubaadherra.

5 Qoraannoo kanaa ilaalchisee gaaffiin qabuu kamiyuu naaf deebi ‘ee jiraa

6 Kaafaaltiin qoraannoo kanaarraati hirmaachuuf namaa kafaalamu kamuu akkaa hin jiree naan beekaa

Qoraannoo kanaarrati akka hirmaatu/ttuuf heyyaamaama ta ‘eerraa.

maqaa:_____mallaattoo:___ Guyyaa: _____

Qoraannoo kanaarraatti akka hirmaataanif heyaammama waan taatanif galaattoommaa.

ANNEXVII: QUESTIONNAIRES IN ENGLISH VERSION

Questionnaires to be filled by health professionals Part I. General information

Code Number_____Region_____Zone__ Woreda_____/ city /_sub city _____Kebele_____

Part II. Personal information

1. Age (in years)
2. Place of birth_____
3. For how long (years) did you live in the birth place?
4. How long do you live in this specific area? (If different from the birth place)__year

No.	Questions	Responses
	Part III. SOCIO-DEMOGRAPHIC INFORMATION	
5.	Educational status	1 Illiterate 2 Read and write 3 Primary (1-8) 4 Secondary (9-12) 5 College diploma/degree and above
6.	Occupation	1 Student 2 House wife 3 Government employees 4 Private employees 5 Farmer 6 Others (specify)

7	Marital status	1. Single 2. Married 3. Divorced 4. Widowed 5. Not applicable (children)

8	Religion	1. Orthodox Christian 2. Muslim 3. Protestant 4. Catholic 5. Others (Specify)
9	Ethnicity	If mixed, specify
10	Monthely in come (in birrcollected from salary, rent, and other income)	Birr_____
11.	Presence of domestic animals	1. Yes 2. No
	Part IV. Clinical information	
12	Did you take any type of drug for any illness for the last three months?	1. Yes 2. No
13	If yes to Q12, what type of drug? (more than one answer possible)	1 Anti-protozoa 2 Anti-helminthic 3 Anti-allergies 4 Birth control pills 5 Anti-bacterial 6 Anti-TB 7 Other (specify

	History of common diseases	
14	History of diabetes	1. Yes 2. No
15	History of Hypertension	1. Yes 2. No
16	History of Hospital Admission for the last 1 year	1. Yes 2. No
17	History of Surgical procedure for the last three years?	1. Yes 2. No
18	History of chronic gastritis	1. Yes 2. No
19	History of Malaria for the last 6 months	1. Yes 2. No
20	History of TB for the last two years	1. Yes 2. No
21.	History of Cancer	1. Yes 2. No
22.	History of Cardiac illness	1. Yes 2. No
23.	History of Bleeding disorders	1. Yes 2. No
24.	History of allergy	1. Yes 2. No
25	History of Wheezing	1. Yes 2. No

	Part V. Life style/Habit Continued…	
26	Do you have Fasting habit?	1. Yes 2. No
27	If Yes, how is your fasting habit?	1 Eating vegetable food only 2 Complete abstinence from food

		then eating all kinds of food 3 Complete abstinence from food then eating vegetable food only
28	Did you eat undercooked/raw meat?	1. Yes 2. No
29	Do you have the habit of physical Exercise?	1. Yes 2. No
30	If yes, how many times do you do the exercise per week?	
31	Any sexual contact	1. Yes 2. No 3. Notapplicable (children)
32.	If yes to Q31, condom use`	1. Yes 2. No
	Part VI. Anthropometric measurement	
33.	Height (in cm)	_____
34	Weight (in kg)	_____
35.	MUAC (in cm)	_____
36	Blood pressure (mm Hg)	_____
37	Temprature (Degree centgrade)	_____

❖ We thank you for your cooperation!

Interview Date:_____ Interviewer ‘s Name_____Signature

ANNEX VIII: QUESTIONNAIRE IN AMHARIC VERSION

በጤና ባለሞያዎች የሚሞላ ቃለ መጠይቅ

መመሪያ:

በቅድሚያ ይህንን ቃለመጠይቅ ለመሙላት ለሰጡን ጊዜ ና ትብብር አድናቆቴን እገልፃለሁ፡፡ የዚህ ቃለመጠይቅ አላማ በላቦራቶሪ ውስጥ የጥራት መመርመሪያ ንጥረ ነገር እና የጤና ማሰውደም ውስጥ የሚገኙ የሄማቶሎጂ ና የክሊኒካል ኬሚሰትሪ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል እድሜአቸው 60 ዓመት ና ካዚያ በላይ ለሆኑ ኢትዬጵያውያን ለመስራት መረጃ ለመሰብሰብ ነው፡፡የዚህ ጥናት ሃሳቡን ያመጡት የጥናቱ ዋና ተመራማሪ በአዲስ አበባ ዩኒቨርስቲ የህክምና ላቦራቶሪ ትምህርት ክፍል ተባባሪ ፕሮፌሰር የሆኑት ዶ/ር አስቴር ፀጋዬ ሲሆኑ የኢትዮጵያ ህክምና ላቦራቶሪ ማህበር ያስተዳድረዋል፡፡የጥናቱን ወጪ የሸፈነው የፌደራል ሳይንስና ቴክኖሎጂ ሚኒስቴር ነው፡፡ስለሆነም የእርስዎ ቅን ትክክለኛ መልስ በሰዓቱ መስጠት የዚህን ጥናት ስኬት ይወስናል፡፡

አስራ አምስት የሚሆኑ ተቋማት ማለትም ዩኒቨርስቲዎች፣ሪጅናል ላቦራቶሪዎች፣እና ብሄራዊ የደም ባንክ አገልግሎት ጥናቱን ለመደገፍ ዝግጁነታቸውን ገልፀዋል፡፡ ስለሆነም ይህንን ቃለ መጠይቅ ሃቀኝነትና ሃላፊነት በተሞላው መንገድ እንዲሞሉ በትህትና እጠይቃለሁ፡፡

አመሰግናለሁ!!!

ክፍል 1. አጠቃላይ መረጃ

ኮድ____ክልል___ዞን

ወረዳ___ከተማ/ክፍለ ከተማ_____ቀበሌ

ክፍል 2. የግል መረጃ

1. እድሜ
2. ጾታ_____
3. የትውልድ ቦታ_____
4. በትውልድ ቦታዎ ለምን ያህል ጊዜ ኖረዋል? _____
5. አሁን ያሉበት ቦታ ለምን ያህል ጊዜ ኖረዋል? (ከትውልድ ቦታዎ የተለየ ከሆነ)_ዓመት----------

ቁጥር.	ጥያቄ	ምላሽ
	ክፍል 3. ማህበራዊ ናኢኮኖሚያዊ መረጃ	
6.	የትምህርትደረጃ	1. ያልተማሩ 2. ማበብና መፃፍ 3. አንደኛ ደረጃ (1-8) 4. ሁለተኛ ደረጃ (9-12) 5. ኮሌጅ ዲፕሎማ/ዲግሪ እናከዚያ በላይ
7	ሥራ	1. ተማሪ 2. የቤትእመቤት 3. የመንግስት ሠራተኛ 4. የግል ተቀጣሪ 5. ገበሬ 6. ሌላ ካለ ይግለፁ
8	የጋብቻሁኔታ	1. ያላገቡ 2. ያገቡ 3. የተፋቱ 4. ባል/ሚስት የሞተባቸው 5. አይመለከታቸውም (ህፃናት)
9	ሃይማኖት	1. ኦርቶዶክስ ክርስቲያን 2. ሙስሊም 3. ፕሮቴስታንት 4. ካቶሊክ 5. ሌላካለይግለፁ
10	ብሄረሰብ	ድብልቅ ከሆኑ ይግለፁ
11	ወራዊ ገቢ (በብር ከደሞዝ፣ኪራይ፣እናሌሎች ገቢዎች)	ብር----------
12	የቤት እንስሳት መኖር	1. አለ 2. የለም

	ክፍል 4. የጤና መረጃ		
13	ባለፉት ሶስት ወራት ለማንኛውም ዓይነት ህመም ማንኛውንም ዓይነት መድሃኒት ወስደኃል?	1. አዎን	2. የለም
14	ለተራ ቁጥር 13 መልስዎ ወስጃለሁ ከሆነ የትኛውን ዓይነት መድሃኒት ነው የወሰዱት? (ከአንድ በላይ መልስ ይቻላል)	1. 2. 3. 4. 5. 6. 7.	ፀረ-ፕሮቶዞአ ፀረ-ሄልሚንትስ ፀረ-አለርጂ የወሊድ መከላከያ ኪኒን ፀረ-ባክቴሪያ ፀረ-ቲቢ ሌላካለይግለፁ
	የሚከተሉት የህመም ዓይነቶች አሞዎት ያውቃል?		
15	የስኳር ህመም?	1. አዎን	2. የለም
16	የደም ግፊት ከፍ ማለት?	1. አዎን	2. የለም
17	ባለፈው 1 ዓመት ሆስፒታል ተኝተው ያውቃሉ?	1. አዎን	2. የለም
18	ባለፉት 3 ዓመታት የቀዶ ህክምና ተደርጎል ዎያውቃል?	1. አዎን	2. የለም
19	የቆየ የጨጓራ ህመም አለብዎት?	1. አዎን	2. የለም
20.	ባፉት 6 ወራት የወባ ህመም ኢጋጥሞዎት ያውቃል?	1. አዎን	2. የለም
21	ባለፉት 2 ዓመታት የቲቢ ህመም ኖሮዎት ያውቃል?	1. አዎን	2. የለም
22	ካንሰር ህመም	1. አዎን	2. የለም
23	የልብ ህመም	1. አዎን	2. የለም
24	የመድማት ችግር/ህመም	1. አዎን	2. የለም
25	አለርጂ (የሰውነት መቆጣት)	1. አዎን	2. የለም
26	የመተንፈስ ችግር (ሲተነፍሱ ሲርሲር የሚል ድምፅ)	1. አዎን	2. የለም
	ከክፍል 5 የቀጠለ. የህይወትአመራርናልምዶች		
27	የመፆም ልምድ አለዎት?	1. አዎን	2. የለም
28	መልስዎ አዎን ከሆነ፣የመፆም ልምድዎ እንዴት ነው?	1.አትክልቶችን ብቻ መመገብ	
		2. በአጠቃላይከምግብመታቀብከዚያምያገኙ	

	ትን መመገብ
	3. በአጠቃላይ ከምግብ መታቀብ ከዚያም አትክ
	ልቶችን መመገብ

29	በደንብ ያልበሰለ ወይም ጥሬ ሥጋ ይመገባሉ?	1.	አዎን	2. የለም
30	የሰውነት እንቅስቃሴ የማድረግ ልምድ አለዎት?	1.	አዎን	2. የለም
31	መልስዎ አለኝ ከሆነ በሳምንት ለምን ያህል ጊዜ ይንቀሳቀሳሉ?			
32	የግብረ ሥጋ ግኑኝነት አድርገው ያውቃሉ	1.	አዎን	2. የለም 3. አይመለከትም (ለህፃናት)
33	ለተ/ቁ 32 መልስዎ አዎን ከሆነ፣ኮንዶም ይጠቀማሉ? `	1.	አዎን	2. የለም
	ክፍል 6. ክብደት፣ቁመት፣የክንድና የደም ግፊት ልኬት			
34	ቁመት	ሴንቲሜትር		
35	ክብደት	ኪሎግራም		
36	የክንድ መሃለኛው ክፍል ዙሪያው (MUAC)	ሴንቲሜትር		
37.	የደምግፊት	(mm Hg)		
38	የሙቀት ልኬት መለኪያ	(በዲግሪ ሴንቲግሬድ)		

- ስለ ትብብርዎ እናመሰግናለን!
- ቃለመጠይቅ የተደረገበት ቀን:_____ ቃለመጠይቁን ያካሄደው ስም_____ፊርማ

ANNEX IX: QUESTIONARY IN AFAAN OROMOO VERSION

Gaaffii fi deebii Ogeessa Fayyaatiin Guutamu

Qajeelfama: Kaayyoon gaaffii kana Laabooratoorii keessati qulqulinaa wantoota sakata ‘aamu fi dhiiga ijoollee f a y y a a b u l e s s a ta ‘ee tokko keessati kan argamu kilinikaal Hemaattoloojjii fi keemistirii ilaalchisee hanga argama isaa giddu-galessan jirata magaala Assalaa umurii waggaa 60 fi isaa olii ta ‘aanif hojjaachuuf data funaanuu dha. Yaad - rimeen qorannoo kana kan burqisiisan yunivaaristii Finfinneetti gosaa barnoota medical laboratorii tti gargaraa poroffesera kan t a ‘aan Dr. Aster Tsaagayee ta ‘uu ibsaa gaaffilee kana itti gaafatamummaa fi amanamumman a k k a guuttaniif kabajaan isin gaafanna.

Galatooma!!!

Ku**taa 1ffa. OdeeffannooWaliigalaa**

Lakkofsaa Koodi

Ganda

Lakkofsa bilbila

Kutaa 2ffa. OdeeffannooDhuunfaa

1. Umurii (Waggaadhaan) _____
2. Saala _____
3. Iddoo dhaloota keessaan_____
4. Turtii Iddoo dhaloota keessan jiraataan (waggadhan) _____
5. Turtii iddoo ammaa jiraatani (yoo iddoo dhalootan alaa jiraatan ta ‘ee) _____

	Kutaa3ffaa. HalaaOdeeffannooummaata	
6	Haala barnoota	1 kan hin baranne 2 Duubisuu fi baareessu 3 Sadaarka tokkoffaa (1-8) 4 Sadaarka Lammaaffaa (9-12) 5 Kolleejjii dipilooma/Digirii fi sana olii
7.	Haala hojii	1 Baraataa 2 Mana keessaa 3 Mootummaa 4 Dhuunfaa 5 Kaan biro
8.	Haalaa fudhaa fi heruuma	1 Hin funne/hin heruumne 2 Fudhee/ heruume 3 Hiikee 4 Kaadhimaame 5 Hin genyee (daa 'imaa)
9.	Ammaantaa keessaan	1 kiristaana ortoodoksii 2 Muusilimaa 3 Porotestaanti 4 Katoolikii 5 kan biro
10.	Saabbummaa	makkaa yoo ta 'ee ibsi
11.	Gaalii ji 'aati argaatani	Qaarshii_____
12.	Beeylaada manaa qabduu?	1. eyyeen / 2. lakkii

	Kutaa 4ffaa. Haala odeeffannoofayyummaa/Kilinikaal	
13.	Ji‘oota saddeen darbaanif qorichii fudhate jira.	1. eyyeen 2. lakkii
14	Deebiin Gaaffii 13 eyyeen yoo ta‘ee qorichaa gosaa kamittii?(Deebiin tokkoo olii ni dandaa‘ama)	1 Antiyii-pirotozuwwaa 2 Antiyii-helmeentikii 3 Antiyii-allaarjiiki 4 Qorsaa Quusaana maattii 5 Antiyii baacteriyyaa 6 Antiyii-TB 7 Kan biro
	Haala dhukkubaa waaligala	
15	Dhukkuubaa suukaraa qabdaa	1. Eyyeen 2. lakkii
16	Dhukkuubaa dhiibbaa dhigaa qabdaa	1. Eyyeen 2. lakkii
17	Waggaa tokkoo keessaa hospitaala ciistee jirtaa	1. Eyyeen 2. lakkii
18	Waggaa saddeen keessaa qamaa baqaafattee jirta	1. Eyyeen 2. lakkii
19	Dhukkuubaa garaachaa qabda	1. Eyyeen 2. lakkii
20	Ji‘aa jahaan darbee keessaa buusaa dhukkubsatee	1. Eyyeen 2. lakkii
21	Waggaa lamaan keessaa daraamyoo sombaan qabaamtee jirtaa	1. Eyyeen 2. lakkii
22	Kaanseerii dhukkubsattee bektaa	1. Eyyeen 2. lakkii
23	Dhukkuubaa onnee dhukkuubsatee	1.Eyyeen 2. lakkii

24	Dhukkuubaa dhiguu dhukkuubsatee	1.Eyyeen 2. lakkii
25	Dhukkuubaa Allaarjiikkii dhukkuubsate	1.Eyyeen 2. lakkii
26	Dhukkuubaa sirnaa hargaansuu dhukkuubsate	1.Eyyeen 2. lakkii

	Kutaa 5ffaa. Haalajireenyaa /barmaata itti fufaa…	
27	Barmaata soommuu ni qabdaa?	1.Eyyee2. lakkii
28	Eyyeen yoo ta ‘ee soomma akkami?	1 Nyaata kuduraafi fudura qofa nyachuu 2 Nyaata irraa turuun sana bodaa gosaa nyaata hunda nyachuu. 3 Nyaata hundaa irraa turuun sana booda kuduraafi fudura qofa nyaachuu.
29	Foonii dheedhii nyaata?	1. Eyyee 2. Lakkii
30	Jaajjabinaa qamaa ni hojataa?	1. Eyyee 2. Lakkii
31	Eyyeen yoo ta ‘ee torbaanit si ‘aa meqaa hojaata	_____
32	Hariiroo waal qunaamti salaa qabda?	1.eyyee 2. lakkii3.hingafatamu (da ‘iimaani)
33	Eyyeen yoo ta ‘ee kondoomii fayyadamtaa?	1.eyyee 2. lakkii
	Kutaa 6ffaalakkoftuulfaatina, dheerina, fi dhiibbadhiigaa	
34	Dheerina (Seentimeetiriin)	(cm)
35	Ulfaatina qaama (Kiiloogiramaan)	(kg)
36.	Maawakii	(cm)

	(Seentimeeteriin)	
37	Dhiibbadhiiga (miilimeetirmeerkurin)	(mm Hg)
38	Hoo’ina qaamaa (digrii seentigireedii)	Digrii seentigireedii

Waan hirmaattaanif guddaa galaatooma!

Guuyyaa gaafataamani:

Maqaa namaa gaafatee_____Maallaattoo___

ANNEX XI: STANDARDS OPERATING PROCEDURES (SOPS)

URINE REAGENT STRIP PROCEDURE

1. Dip the test – strip in the urine specimen. Remove the test-strip immediately and let the excess urine drain off on a paper towel, or tap the edge of the strip.
2. Read the color change
3. Report the result according to the color chart provided by manufacturer.
4. Always read the test strip in good white light and ignore color developing on the test area after the period specified as the reading time of the test.
5. Be careful not to wet the reagent strip excessively. So that the acid buffer from the protein area runs into the pH area, causing an orange discoloration.

Urine Microscopy procedure

1. Mix the urine specimen
2. Transfer about 10 ml of urine into a labeled centrifuge tube.
3. Centrifuge the specimen at a medium speed (from 1500 – 2000 rpm) for 3-5 minutes
4. Discard the supernatant by quick inversion of the tube.
5. Re suspend the sediment that is at the bottom of the tube, by tapping the tube by your fingers
6. Take the sediment by Pasteur pipette from the tube and transfer a drop into the clean and dry slide.
7. Apply cover slide on the urine sediment that is on the slide.
8. Put on the microscope and look under 10x objective of the microscope.
9. Then after looking through the low power objective, change the objective in to 40x objective.
10. Then report what you get under low power and high-power objective on the laboratory request form of the patient.

Procedure for stool examination using wet mount preparation

1. Instruct the participant how to collect the stool in the labeled, clean, and dry leak proof container.
2. Receive the sample and check with participant Id and observe the appearance of the stool and record it.
3. Place a drop of fresh physiological saline on one end of a slide and a drop of iodine on the other end.
4. Using a wire loop or piece of stick, mix a small amount of specimen, about 2 mg, (matchstick head amount) with the saline and a similar amount with the iodine.
5. Make smooth thin preparations.
6. Cover each preparation with a 22x22 cover glass.
7. Examine systematically the entire saline preparation for larvae, ciliates, helminthes eggs, cysts, and oocysts. Use the 10x objective with the condenser iris closed sufficiently to give good contrast.
8. Use the 40x objective to assist in the detection and identification of eggs, cysts, and oocysts.
9. Always examine several microscope fields with this objective before reporting No parasites found_.
10. Use the iodine preparation to assist in the identification of cysts
11. Report the presence of larvae, ciliates, helminthes eggs, cysts, and oocysts

Procedure of formal-ether concentration method

1. Using a rod or stick, emulsify an estimated 1 g (pea-size) of stool in about 4 ml of 10%formol water contained in a screw-cap bottle or tube.
2. Add a further 3–4 ml of 10% v/v formol water, cap the bottle, and mix well by shaking.
3. Sieve the emulsified stool, collecting the sieved suspension in a beaker.
4. Transfer the suspension to a conical (centrifuge) tube made of strong glass, co polymer.
5. Add 3–4 ml of diethyl ether or ethyl acetate.
6. Stopper the tube and mix for 1 minute.
7. With a tissue or piece of cloth wrapped around the top of the tube, loosen the stopper (considerable pressure will have built up inside the tube).
8. Centrifuge immediately at 750–1,000 g (approx. 3000 rpm) for 1 minute.
9. using a stick or the stem of a plastic bulb pipette, loosen the layer of fecal debris from the side of the tube
10. Invert the tube to discard the ether, fecal debris, and formol water. The sediment will remain.
11. Return the tube to its upright position and allow the fluid from the side of the tube to drain to the bottom.
12. Tap the bottom of the tube to re suspend and mix the sediment.
13. Transfer the sediment to a slide, and cover with a cover glass.
14. Examine the preparation microscopically using the 10x objective with the condenser iris closed sufficiently to give good contrast. Use the40x objective to examine small cysts and eggs.
15. To assist in the identification of cysts, run a small drop of iodine under the cover glass. Although the motility of Strongyloides larvae will not be seen, the non-motile larvae can be easily recognized.
16. If required, count the number of each species of egg in the entire preparation. This will give the approximate number pergram of stool.

TEST PROCEDURE, MATERIALS AND PRINCIPLE OF HIV TESTS

PRINCIPLE OF TEST

The chembio HIV ½ STAT-PAK employes a unique combination of a specific antibody binding protein,which is conjugated to colloidal gold dye particles,and HIV ½ antigens, which are bound to the membrane solid phase.the sample is applied to the sample (S) well followed by the addition of running buffer.The buffer facilitates the lateral flow of the released product and ptomotes the binding of antibodies to the antigens.If present,the antibodies bind to the gold conjugated antibody binding protein.in a reactive sample,the dye conjugated-immune complex migrate on the nitrocellulose membrane and is captured by the antigen immobilized in the TEST (T) area producing a pink /purple line.

MATERIALS PROVIDED

- 20 STAT-PAK individually pounched to test devices
- 1 HIV running buffer(3.5ml)
- 20 disposable 5µl sample loops
- 1 product insert
- Clock or timer

PROCEDURES

1 Remove the chemboi HIV ½ STAT-PAK test devices from its pouch and place it on a flat surface

2 Label the test devices with patient name or identification number.

3 Touch the 5µl sample loop provided to the specimen, allowing the opening of th loop to fill the liquid.

4 Holding the sample loop vertically, touch it to the sample pad in the centerof the SAMPLE(S) well of the devices to dispense 5µl of the sample (serum, plasma and whole blood)

5 Invert the running buffer bottle and hold it vertically over the sample well and add 3 drops of buffer slowlyin to sample well.

6 Read the test result 15 minutes after the addttion of the running buffer**.**

TEST PROCEDURE, MATERIALS AND PRINCIPLE OF HBSAG TESTS
PRINCIPLE OF TESTS

The HBsAg rapid test is a lateral flow chromatographic immunoassay based on the principle of the double antibody sandwich techniques.the membrane is precoated with anti-HBsAg antibodis on the test line region of the test.during testing ,hepatitis B surface antigen in the whole blood ,serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody.

MATERIALS PROVIDED

- The HBsAg test cassete containing anti-HBsAg antibody particles and anti-HBsAg antibody coated on the membrane.
- Disposable specimen dropper
- Package inserts
- Buffer
- Centrifuge for plasma and serum
- Clock or timer

TEST PROCEDURE

1 Remove the test device from the foil pouch and use it as soon as possible

2 Place the test device on a clean and level surface. And hold the the dropper vertically and transfer 3 drop of serum or plasma to the specimen well of the test devices.

3 Wait for the red line to appear.the result should be read at 15 minutes.

TEST PROCEDURE, MATERIALS AND PRINCIPLE OF HCV ANTIBODY TESTS

PRINCIPLE

Rapid HCV antibody test employes chromatographic lateral flow devices in a cassette format.Colloidal gold conjugated goat anti-human IGM and mouse anti-human IgGare dried and immobilized on the fiberglass strip.HCV antigen are immobilized at the test zone (T) and goat anti mouse IgG antibody are immobilized at control zone (C).When the sample is added,it migrates by capillary diffusion rehydrating the gold conjugated.if present in sample, HCV antibody will bind the gold conjugated anti-human IgG and/or IgM forming complexes.These complexes will continue to migrate along the strip until the Test zone(T) zone where they captured by the HCV antigen to form a visible red line.The unbound gold conjugate will continue to move and bind with goat anti-mouse IgG at the control zone (C) forming a visible red line. If no antibody in the sample, only a red line is appeared at the control zone, which indicates the validity of the test.

MATERIALS NEEDED

- Rapid HCV anit body test
- Sample buffer
- Instruction for use
- Centrifuge
- Clock or timer

TEST PROCEDURE

1 Allow the test strip and sample to reach room temperature

2 Open the pouch, take out the test strip and transfer pippet

3 Usimg the transfer pippet to draw up the sample, dispense one drop specimen to the sample pad and wait a few seconds until the sample is completely absorved by sample pad.

4 Add one drop sample buffer to the sample pad

5 Read sample result at 20 minutes.

TEST PROCEDURE, MATERIALS AND PRINCIPLE OF SYPHILIS ANTIBODY TESTS

PRINCIPLE

The syphilis rapid test is a lateral flow chromatographic immunoassay based on the principle of the double antigen sandwich techniques.in this test syphilis recombinant antigen is immobilized in the test line region of the strip in the test device. after the specimen is added to the specimen well of the device. It reacts with the syphilis recombinant antigen coated particles in the test. this mixture migrates chromatographically along the length of the test strip and interact with the immobilized syphilis antigen.if the specimen contain syphilis antibodies,a colored line will appear in the test line region indicating a positive result.If the specimen does not contain syphilis antibodies,a colored line will not appear in the test line region, indicating a negative result.to serve as procedure control, a colored line will always appear in the control line region,indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS NEEDED

- The syphilis Ab rapid test kits
- Specimen collection container
- Centrifuge for serum
- Disposable specimen dropper
- Clock or timer

TEST PROCEDURE

1 Remove the test device from the foil pouch and use it as soon as possible
2 Place the test device on a clean and level surface. And hold the the dropper vertically and transfer 3 drops of serum or plasma to the specimen well of the test devices.
3 Wait for the red line to appear.the result should be read at 15 minutes.

Principle of Hematological Assay

A complete blood count (CBC) and differential was performed on the blood sample, using Sysmex KX-21N, an automated 3-part differential hematology analyzer. The machine automatically dilutes whole-blood sample of 50 ml in the CBC/Differential mode, lyses and directly measures the WBC, RBC, HGB, HCT, and PLT, LYM #, MIXED #and NEUT #. The remaining parameters are calculated or derived, MCV, MCH, MCHC, MPV, RDW-CV and RDW-SD, and differential percentages LYM%, MIXED%, NEUT%. The KX-21N counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection.

Its principle was impedance principle which was based on the detection and measurement of changes in electrical resistance produced by a particle suspended in a conductive liquid as it is drawn through a small aperture. A blood sample is diluted in saline, which is a good conductor of electrical current. 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. The change in voltage generates a pulse. Each cell momentarily increases the electrical resistance between two electrodes. The amplitude and size of the pulse depends on the cell volume.

ANNEX XII: THE TABLE OF EXISTING REFERENCE INTERVAL

TABLE 5: EXISTING REFERENCE INTERVAL FOR HEMATOLOGICAL PARAMERE FOR BOTH SEXES.

Parameter	Existing reference Range for female N=117	Existing reference Range for male N =124
WBC	3.1-10.3	2.6-8.8
RBC	3.2-4.6	3.6-5.3
HGB	9.9-13.6	11.3-15.7
HCT	30.2-42.3	32.6-47.5
MCV	78.6-102.2	80.3-103.4
MCH	25.2-34.7	26-34.4
MCHC	31.3-35.4	31.8-36.3
PLT	128-434	134-377
LYM%	15-45.8	17.5-47.9
MIX%	1.3-25.9	1.9-24.6
NEU%	43.7-77.1	38.3-69
LYM NUMB	0.9-2.8	0.8-2.7
MIX NUMB	0.1-1.6	0.1-1.5
NEU NUMB	1.6-6.9	1.2-5.3
RDW-CV	10.6-15.7	10.8-14.9
RDW-SD	35.3-48.9	33.4-49.2
PDW	9.4-18.1	9.8-18.0
MPV	8.5-12.4	8.1-12.4
P-LCR	14.3-44	10.7-45.0

NOTE: The age range for female was 17-66 years with a mean age of 33.4.

. The age range for male was 17-72 years with a mean age of 42.2.

DECLARATION

I, the undersigned, declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

M.Sc. candidate: Mohammmed Hashim (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: Aster Tsegaye **(MSc, PhD)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Mogos Hordofa **(MSc)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.