ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Determination of Hematological Parameters Reference Interval for Apparently Healthy Population aged 15 to 60 years in Addis Ababa, Ethiopia

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A research thesis submitted to the Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University, in partial fulfillment of Master of Science Degree in Clinical Laboratory Sciences (Hematology and Immunohematology).

July, 2021

Addis Ababa, Ethiopia

Addis Ababa University

School of Graduate Studies

This is to certify that the thesis prepared by Endalkachew Befekadu, entitled:

"Determination of Hematological Parameters Reference Interval for Apparently Healthy Population aged 15 to 60 years in Addis Ababa, Ethiopia'' 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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Acknowledgment

First of all, I would like to acknowledge Addis Ababa University College of Health Sciences Department of Medical Laboratory Sciences for providing me with knowledge during my stay in the School and for financial support. My heartfelt gratitude also goes to Amanuel mental Specialized Hospital for sponsoring of my graduate study and providing me with monthly salary during my stay in graduate school. Again I am extremely grateful to health professionals and staff of the health centers and the participants for their cooperation and hospitability.

My deepest and heartfelt gratitude forwarded to my advisor, Dr. Aster Tsegaye for her unreserved scientific guidance, topic selection, constructive comments, hospitability, friendly approach, encouragement and support. My sincere thanks also go to my advisor Zemenu Tamir for the scientific guidance and support during this study. The study team for the RI study staffs and MSc students are gratefully acknowledged for the great team work. Federal Ministry of Health, Ethiopian Public Health Institute, Addis Ababa Health Bureau, Jammed Health Center, the Central Statistics Agency, and all the health centers and woreda offices which facilitate this study are gratefully acknowledged. Ministry of Innovation and Technology is also gratefully acknowledged for financially supporting this study and study participants for their kind collaboration. My sincere thanks also go to Sysmex Europe GmbH, Germany for generously providing the sysmex 5 part diff reagents. Finally it is my pleasure to thank all individuals who have in one or another way contributed to the thesis to be in this form. My special thanks go to my beloved family who has been on my side at all times.

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Abbreviations

AAU	Addis Ababa University
ANC	Antenatal care
CBC	Complete Blood Count
CLSI	Clinical Laboratory Standards Institute
EDTA	Ethylene Di amine tetra acetic acid
HB	Hemoglobin
HBS	Hepatitis B virus
HCT	Hematocrit
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IFCC	International Federation for Clinical Chemistry and Laboratory Medicine
MCH	Mean cell hemoglobin
MCHC	Mean cell hemoglobin concentration
MCV	Mean cell volume
MCV	Mean corpuscular volumes
MOH	Ministry of health
MPV	Mean platelet volume
NCCLS	National Committee for Clinical Laboratory Standards
PCT	Platlatecrit
PDW	Platelet distribution width
PLT	Platelet
PPS	Probability Proportional to Size
QC	Quality control
RBC	Red blood cells
RDW	Red cell distribution width
SPSS	Statistical Package for the Social Sciences
UK	United Kingdom
WBC	White blood cell
WHO	World health organization

Abstract

Background: Complete blood count (CBC) reference intervals were essential for effectively diagnosing diseases, measuring drug toxicity or side effects, disease staging and monitoring of response to treatment, therapeutic management decision, or other physiological assessment in the clinical laboratory and assessing overall health. They may also be used in clinical trials as a guide to set inclusion and exclusion criteria. Factors such as genetics, dietary patterns, gender, age, ethnic origin, altitude, pregnancy, and geographical factors and geochemical and environmental pathogens were known to influence hematological reference intervals (RIs). Hence, there is a need to determine locally relevant hematological reference intervals.

Objectives: To determine hematological parameters reference intervals for apparently healthy population aged 15 to 60 years in Addis Ababa.

Methods: A cross- sectional community based study consisting 790 males and females (pregnant and non-pregnant) at household level was conducted from January to May 2019 in Addis Ababa, Ethiopia.. A complete blood count (CBC) was performed using Sysmex XT1800i automated hematology analyzer. The non-parametric test as per the CLSI guide was used to determine the 2.5th and 97.5th percentiles. SPSS-IBM version 24 statistical software was used for data entry and analysis. Differences among groups were tested and level of significanc was set at P value less than 0.05.

Result: Males comprise 262, and 346 non-pregnant females and 182 pregnant women were included. The 2.5^{th} and 97.5^{th} RIs determined were somehow inconsistent with the RI currently in use. RBC count, Hgb, HCT and MCHC were significantly higher in males than females while median value for MCV, MCH, RDW-CV and RDW-SD values were higher in females than males. Non-pregnant females had significantly higher median PLT count and PCT than males and pregnant women. Pregnant women had significantly higher median PDW, MPV, P-LCR than their non-pregnant counterparts and males. A decrease in RBC parameters and increase in WBC count was observed with increasing trimester.

Conclusion: As differences were noted with the company derived RIs and other population groups, the current RI needs to be in use in Addis Ababa.

Key words: *Reference Interval, Hematological parameters, Complete blood count, Ethiopia*

1. Introduction

1.1. Background

Complete blood count (CBC) reference intervals (RIs) are essential for effectively diagnosing diseases, screening of blood donors, make a medical diagnosis, drug toxicity or side effects, disease staging and monitoring of response to treatment, therapeutic management decision, or other physiological assessment in the clinical laboratory and assessing overall health (1–4). They may also be used in clinical trials as a guide to set inclusion and exclusion criteria (5).

In the last decade, a small number of studies have been conducted in Africa demonstrating differences in normal values compared to those established in industrialized nations (6,7). Studies conducted in Nigeria also reported significant differences in normal laboratory ranges compared with those of other African countries and industrialized world (8,9). Such variations among populations have been supported by studies from other African countries including Ethiopia (10-15). The differences noted among the different populations could be due to factors such as genetics, dietary patterns, gender, age, ethnic origin, altitude, pregnancy, and geographical factors as well as geochemical and environmental pathogens were known to influence hematological and immunologic indices (15-17).

Especially altitude and pathogens have been reported to affect the reference values of the hematological parameters, suggesting that the development of reference values for the African population is beneficial for quality health care. However, reference values being used in most laboratories in African countries have been obtained from the literature, reagent inserts accompanying the reagent kits or instrument manuals derived from other populations; use of these reference intervals may lead to unnecessary inclusion and exclusion criteria as well as the basis of safety monitoring for trial participants. Locally appropriate reference intervals are essential for planning and executing trials in a safe, efficient and ethical manner (5,11).

Establishing locally appropriate reference intervals is also recommended by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (18). Furthermore, the biological reference intervals should be reviewed periodically and whenever there is any change in laboratory technology as per the requirement of ISO 15189:2012 (19). Nevertheless such recommendations and requirements are followed by few laboratories since it is challenging to identify appropriate reference population, time consuming and expensive.

1.2. Statement of The Problem

Hematological Reference intervals are very important laboratory tools used to make a medical diagnosis, monitoring of treatment and selection of participants for clinical trials (1,2,5,11). There is a need to have accurate and appropriate locally-derived population-specific hematological reference ranges for the interpretation of the normalcy of results. Unfortunately, the reference ranges of hematological indices used in many African countries including our country Ethiopia are obtained from the literature, reagent inserts accompanying the reagent kits or an instrument manual which is derived from populations of industrialized countries (15). These laboratory parameters might be influenced by differences in genetic, environmental, dietary and social factors (15-17).

Studies have been conducted in the last decade in sub-Saharan Africa demonstrated the existence of significant inter-city/regional variation in multiple hematological parameters for infants, children and adult populations (9-14, 20-23).

Using reference values derived from another population might lead to a wrong interpretation, which may influence the outcome. For instance, parameters in areas where infectious diseases and parasitic infestations were prevalent, and those living in high altitudes, were likely to be significantly different from those living in other areas (24,25).For example, African populations were reported to have lower hemoglobin (HB), red blood cells (RBCs), hematocrit (HCT), mean corpuscular volumes (MCV), platelets and neutrophils, and higher monocyte and eosinophil levels than their western counterparts (10). In contrast, the hemoglobin and hematocrit levels in Ethiopians were reportedly high most likely due to the fact that highlands (altitude, .2.000 m), where the major food, *injera*, has a very high iron content (15,21,26). Thus, there is a need to establish locally relevant reference intervals.

On the other hand, pregnancy is another factor affecting the levels of hematological parameters mostly as a result of physiological dilution and increased demand by the growing fetus (26, 27). This implies a separate reference interval is needed for pregnant women.

The Clinical and Laboratory Standards Institute (CLSI) and the International Federation for Clinical Chemistry (IFCC) recommend that each laboratory establishes its own reference values (17,18).

A small number of publications address reference values in Ethiopia, but these were restricted geographically to selected areas of Ethiopia and none was determined for Addis Ababa.

Hence this study tried to address this gap by determining reference interval for adult men, non-pregnant and pregnant women following the CLSI guide.

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1.3. Significance of The Study

Despite the recommendation for each laboratory to determine its own reference interval, in all clinical settings of Addis Ababa they are using hematological reference range provideed by the instrument manufacturers. Hence, the findings of this study have significance to the patients as their laboratory results could be interpreted against values detrmined locally. Physicians could better manage their patients with confidence. The finding will also be helpful to aoid unnecessary review or repeat of testing or wastage due to abnormal result flagging by automated analysers reducing the burden on the laboratory personnel side so that they can focus on providing quality results. Policy makers can use the findings in the revision of treatment gudelines. Other researchers can use the findings as reference and in selection of participants in clinical trials.

2. Literature Review

2.1 The Need for Reference Interval and Selection Of Reference Population

The medical laboratory plays an indespensible role in the health care system and it is estimated that more than 70% of medical decisions depend on laboratory test results (28,29). The results are meaningful when they are interpreted against a reference interval which is detrmined for a particular age, sex and locality (16-18). Moreover, the limited clinical trials in Africa are also reportedly challenged by the lack of appropriate reference intervals to screen individulas to participate in the studies (5). For example, studies conducted in Africa showed that there is significant hematological parameters difference between the continents of Africa from industrialized or Caucasians population values. The hematological indices in all age groups were on most occasions far lower comparing with those of other western industrialized countries. Most notably in hemoglobin, packed cell volume, platelets, total white blood cell count, and neutrophil values (7,10-13, 30,31).

Genetical factors have been shown to contribute to all blood cell measures, accounting for between 61%–96% of variance. In almost all studies, the ethnic and sex differences were significant, with Caucasians values being higher than those of Africans and Afro-Caribbean (8,9,14). These lower values for areas in sub-Saharan Africa have been attributed to factors such as poor nutritional status, genetic red blood cell disorders (such as sickle cell trait) or parasitic infections including schistosomiasis or malaria (8,9,14). On the otherhand, established values from Ethiopia are in some cases inconsistent with these reports especially with regards to RBC parameters as these values are high (15,21,22).

One of the challenges in referenc intrvals determination is selection of the reference population. There are different methods of selection; in the the *a priori* selection criterion, which population to select and how to partition them is decided in advance while in the *posteriori* selection criterion, first collecting a relevant number of subjects, analyse their data and decide thereafter which of them to be kept in the reference population and how to partition them (32). Then the reference interval is determined by calculating the 2.5^{th} and 97.5^{th} percentile using the non-parametric test. It is also recommended that reference limits should always be presented together with their 90% confidence intervals (CIs) (17,18,32).

2.2. Reference Interval Studies

Several studies revealed the need for locally appropriate reference intervals. Accordingly, a study in France reported that they defined full blood count (FBC) normal values for healthy adults, in a population of 33,258 subjects, 19,612 men and 13,646 women. The respective mean, 2.5th and 97.5th percentile values for men and women were as follows: hemoglobin (Hb) 150 g/L (134–167 g/L) versus 134 (117–150); MCV 87.3 fL (80.2–95.0) versus 87.5 (78.4–95.3); mean corpuscular hemoglobin (MCH) 30.0 pg (27.2–32.8) versus 29.7 (26.1–32.5); mean cell hemoglobin concentration (MCHC) 343 g/L (324–363) versus 338 (319–358); platelet count 269×10^9 /L (171– 397) versus 394×109 /L (186–440) which is significantly higher than those in men while the RBC parameters were significantly lower in women. The mean value of leucocytes was almost consistent betwenn the two sexes; they were 6.6×10^9/L (4.1–10.8) versus 6.6×10^9/L (3.9–10.9) in men and women, respectively (p=0.130). The respective values for me and women for neutrophils were 3.6×10^9/L (1.8–6.8) versus 3.7×10^9/L (1.7–7.1); eosinophils 0.21×109 /L (0.05–0.56) versus 0.19×10^9/L (0.04–0.53); lymphocytes 2.3×10^9/L (1.3–3.8) versus 2.2×109/L (1.3–3.6); monocytes 0.43×109/L (0.23–0.74) versus 0.38×10^9/L (0.20–0.65) and basophils which are identical in men and women: 0.04×109/L (0.00–0.09) (33).

In a study from China, a total of 4,642 healthy individuals (2,136 males and 2,506 females) were recruited from six clinical centers in China. They noted differences between centers where one center had median and mean platelet counts lower than those from other centers. RBC, Hb and Hct values were higher in males than in females at all ages. Other CBC parameters showed no significant instrument-, region-, age-, or sex-dependent difference. Thalassemia carriers were found to affect the lower or upper limit of different RBC profiles (4).

In a comprehensive haematological indices reference intervals study for healthy Omani population age and gender specific values were detrmined and compared in a total of 2202 healthy individuals aged 18 to 69 years from January 2012 to April 2017. RBC, Hb, Hct, platelet levels of the healthy donors were significantly different between males and females at all ages ($p < 0.05$), with males having higher mean values of RBC, Hb and Hct than females. Other complete blood count parameters showed no significant differences between genders, age groups, instruments, or blood groups. The authors concluded that a lower hemoglobin

limit for the normal reference interval in males and females were found as compared to the RIs used in Oman (34).

Several studies from Africa also demonstrated that the RIs currently in use in the respective countries show variations from the values used in routine clinical practice. For instance, a study conducted in Gambia and Tanzania showed that the values of the hematological parameters were lower than those form Caucasians of the same age group, a finding consistent with other African studies (35,36).

Clinical laboratory reference values in adults in Kisumu County, Western Kenya was detrmined by recruiting 299 participants aged 18-35 years. Hemoglobin range (2.5th—97.5th percentiles) was 12.0–17.9 g/dL and 9.5–15.3 g/dL in men and women respectively. The MCV range was 59-95fL, WBC 3.7–9.2×10^3/μL, and platelet 154–401×10^3/μL for both sexes (37).

In some studies platelet counts differ significantly for instance study conducted in Gambia, Kenya, Togo, and Nigeria showed that Platelet counts were significantly higher among young adult females compared to the males in the same age group and also differed between adolescent and young adult males (6,9,10,13).

On the other hand, the total WBC and absolute neutrophil count were significantly lower in the black population than in all of other groups. Mechanisms by which black population have lower values of neutrophils is steal not clear (13). But higher eosinophil counts were shown in the Africa than of Caucasians. The high eosinophilia is most likely a result of the high prevalence of parasitemia, since Africa is endemic for schistosomiasis, helminthic infections and perennial malaria (9-11).

Cross-sectional study was conducted in 2015 in Asmara (Eritrea) on 600 volunteers ages ranging between 18 and 49 years. The city is located at an altitude of 2230 m above sea level. The results were WBC (x10^9 /L) 3.4-9.0; Lym 22–59.9 % versus 22.3–58.2%, granulocyte 31.7–73.6 % versus 33.5–70.5 %; Platelet (x10^9/L) 128.4–318.4 both sexes; RBC (x10^{12} /L) 4.2–6.07 and 4.0–5.7 for males and females, respectively. There was a gender-based difference in the RIs for specific RBC parameters including RBC count, Hgb, Hct and RBC indices like MCH and MCHC (14).

Studies from Ethiopia also demonstrated the need for population specific reference intervals. Hematological reference intervals established from adult healthy population of Northwest

Ethiopia (Gondar and surrounding areas) were different from Caucasian and African counties. This is possibly because of the higher altitude and dietary factors in Ethiopia (15,38).

For example, the reference interval of RBC, Hgb and Hct were found to be higher when compared to the study done in Kenya, Nigeria, Togo, and Ghana. , possibly this difference may be attributed to the higher altitude and dietary factors in Ethiopia. This reported result signifies the importance of altitude as a contributory factor to specific hematological indices (15,21,38).

Even between the localities hematological profiles show significant differences. Comparison of hematological results indicated that similarity could not be found based on geographical proximity, this may be due to difference geographical differences, environment, diet, and ethnic background in altitude, method and instrument used for analysis (15,21,39).

Hematological profiles also differ based on age and sex difference. In this regard, studies in Gambian infants, Kenya, Gilgelgibe Ethiopia and Gambian young children showed that Hemoglobin, total white cell count (WBC), and platelet levels declined significantly with increasing age (21,39,20). Whereas most of the white cell counts subsets except monocytes did not vary with age. Specially studies done on Kenya and Gilgelgibe Ethiopia showed that differences in the hematological indices among males by age, with the young adults having higher levels of HB, HCT, RBC, and PLT as compared to adolescents. This difference could be attributed to higher levels of androgen hormones among the older as compared to the younger males (10,39).

In addition to the gender differences for selected hematological parameters reference intervals, women during pregnancy have a different profile. Many physiological changes which could have been pathologic in non-pregnant women are characteristic features of normal pregnancy. During pregnancy, the total blood volume increases by about 1.5 liters, mainly to supply the demands of the new vascular bed and to compensate for blood loss occurring at delivery. As a result RBC parametes decrease. In pregnant woemen WBC is increased, while the platelet count decreases during pregnancy, particularly in the third trimester resulting in what is referred as gestational thrombocytopenia (40).

During pregnancy Total WBC was however significantly higher in pregnant women than their non-pregnant counterparts and platelet and the RBC indexes among pregnant women is

in the reverse (38). This has been confirmed by a recent study from the Eastern part of Ethiopia which demonstrated that pregnant women had lower values for most of red cell parameters than non-pregnant women. Pregnant women, in the contrary had higher WBC parameters than their non-pregnant counterparts (41). But the changes seen during pregnancy come to normal after 1 months of delivery; thus, it may not be possible, even, to have one standard reference between two localities in the same county even when countries share similar characteristics or geographical conditions.

Taken together, these findings underscore the need for establishing local reference intervals specific to the population under study for routine clinical practice.

3. Objectives

3.1. General Objective

- To determine local relevant hematological reference intervals for apparently healthy population in Addis Ababa, Ethiopia.

3.2. Specific Objectives

- To determine sex specific hematological reference interval.
- To determine hematological reference internal for pregnant women

4. Methods and Materials

4.1 Study Area

This study was conducted in Addis Ababa the capital city of Ethiopia which is the largest city in the country and a seat of the African Union. Addis Ababa has a population of 3,384,569 according to the 2007 census and population count as of 2017 was growing closer to 4 million. The city lies between 2200 and 2500 meters above sea level and lies at the foot of the 3000 meters elevated entoto mountains. Addis Ababa covers about 540 km2 of which 18.2 kms were rural and has a higher population of female residents than males. The city has three layers of Government: City Government at the top, 10 Sub City Administrations in the middle, and 99 Kebele/woreda Administrations at the bottom. At time of this study there were ten subcities (11 currently). This study was carried out in four of the 10 sub-cities (Figure 1) selected based on Probability Proportional to Size (PPS) with a support from the Ethiopian statistical agency.

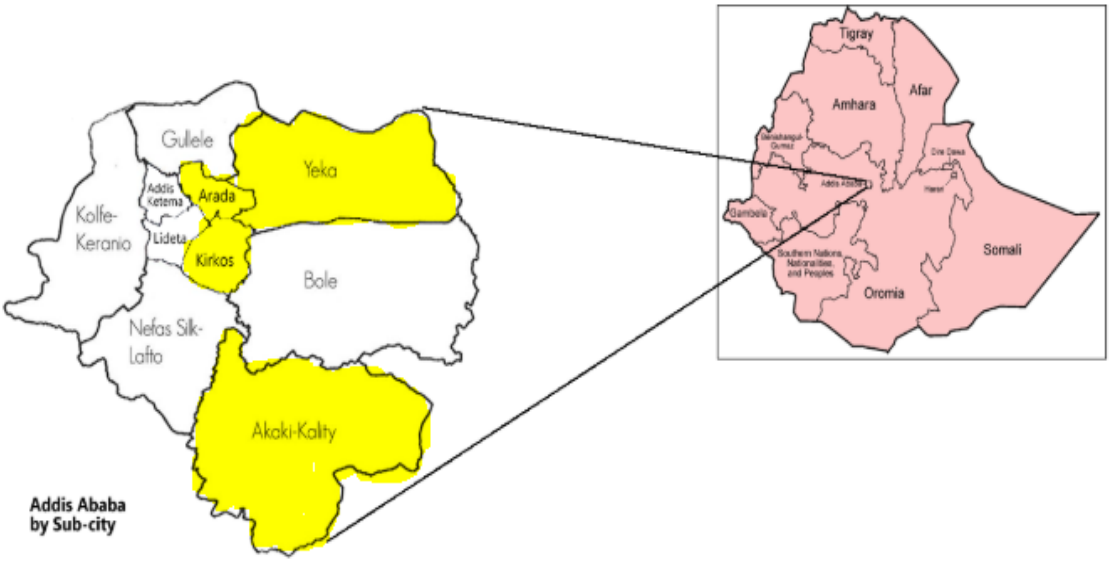

Figure 1. Map of Study Sites In Addis Ababa, Ethiopia

4.2. Study Design and Period

A cross-sectional study design was implemented from January to May 2019 to determine the hematological reference interval for the people who live in the city of Addis Ababa. Samples were measured on the selected four sub-cities (Arada, Kirkos, Akaki and Yeka sub-cities) and Kebeles/woredas inside them.

4.3. Population

4.3.1. Source Population

The source populations for this study were voluntary Residents in the city of Addis Ababa, of both sexes with age of 15 years and above; that is, 15 to 60 years for adult groups of both sexes and 15-45 years for pregnant groups.

4.3.2. Study Population

The study populations were people with age of 15 years and above that live in the four selected kifle ketemas of Addis Ababa, who meet the eligibility criteria.

4.4. Inclusion and Exclusion Criteria

4.4.1. Inclusion Criteria

Individuals who were beyond the age of 15 years and individuals who met the Clinical Laboratory Standard Institute (CLSI) (17) inclusion and exclusion criteria as well as individuals who lived at least for 5 years in the study were included in the study.

4.4.2. Exclusion Criteria

- Individuals with chronic illnesses like diabetes mellitus, chronic renal insufficiency, hypertension, ischemic heart disease, anemia, thyroid, liver diseases, cancer of any type
- Individuals taking pharmacologically active substances: all prescription drugs, and have habit of smoking and alcohol consumption
- seropositive Individuals for HIV, syphilis, Hepatitis B and C , malaria
- Individuals who donated blood within the previous 3 months
- Individuals who received blood transfusion within the previous 1 year
- Individuals who had undergone surgery in the recent past

4.5. Study Variables

4.5.1. Dependent Variables

- Age and sex specific reference intervals for Hematological Parameters (including WBC, differential white cell count, RBC, Hgb, HCT, MCV, MCH, MCHC, RDW, MPV, PCT, PDW, Platelet count)

4.5.2. Independent Variables

- Sex
- Pregnancy status

4.6. Sample Size Determination and Sampling Technique

4.6.1. Sample Size Determination

According to the National Committee for Clinical Laboratory Standards (NCCLS), International Federation of Clinical Chemistry (IFCC) and Clinical Laboratory Standards Institute (CLSI) Guideline recommendations, a minimum size of 120 observations from each category is needed, by non-parametric means for each partition (e.g. sex, age range) with a power of 90% (17). In the current proposed study, the maximum partition needed will be for hemoglobin determinations as follows based on WHO 2011 (42) which recommends the following age partitions: 5-11 years; 12-14 years; Non-pregnant women 15 years and above, pregnant women 15 years and Men 15 years and above and older age group (>60 years). In the current study, however, three age and sex partition groups per site were needed; that is, 15 years and above males, females non-pregnant and pregnant (3 x 120=360).

According to previous studies in other African countries, about 30% of apparently healthy population (5).do not qualifies for reference interval determination for various reasons when tested for the common viral infections and syphilis. Considering a 30% exclusion from data analysis, to reach the CLSI recommended total sample size of 360 for the reference interval determination, a minimum of 468 individuals will be enrolled (i.e., 30 % x 468=108 to be excluded during data analysis; 468-108=360); thus giving a total minimum sample size of 468.

Thus, since this study was part of a large community based study for reference interval determination, all the 790 volunteering participants were enrolled. The study participants were selected using systematic random sampling by considering woreda as a sampling frame

for each town and then households the final selection units. All individuals in the household fulliling the eligibility criteria and willing to participate were included.

4.6.2. Sampling Technique

Probability Proportional to Size (PPS) sampling method was implemented, where the size depends on the number of households of Woredas in a city. Accordingly, all the woredas in the city were considered to be the participants of the study. Since Addis Ababa is very large city, four sub-cities were selected based on PPS, namely Arada, Kirkos, Akaki and Yeka sub-cities; thus all woreda's under the selected sub cities were included. To recruit 790 participants, the number of households was determined by dividing the total household in the selected city (sub-cities for A.A) by the estimated number of individuals per household which is 4 for urban. Individuals in every K^{th} household (see Table below) were approached at their households through health extension workers. Once volunteering participants fulfilling the eligibility criteria were identified by the health extension workers, they were invited to go to nearby health facilities for interview using structured questionnaire and to facilitate biological sample collection. With regard to pregnant women, consecutive pregnant women with normal pregnancy who attended at different health facilities of the four selected subcities for ANC follow up were included in this study. Letter has been written to the respective Health Bureaus by the Federal Ministry of Health.

Table1. Selected sites with household information

Selected Sites	No. Households	Individuals per household	No. Household to be included in the study*	K^{th}
Akaki	47021	3.8	55	861
Kirkos	54398	4.0	52	1049
Arada	49564	4.1	50	995
Yeka	90195	3.8	109	829

Note: Source for total population and number of households is from CSA 2007;

*total number of household to be sampled was computed from the total sample size needed for the larger community based referral interval study (i.e. 1030) by the estimated individuals per household for each study site

4.7. Measurement and Data Collection

The study aim, risks, benefits of study participation and right to withdraw from the study at any time was explained. From those consenting participants, demographic information and a brief medical history were collected. Then Blood specimen was collected for hematological count, and screening for major diseases (HIV, HBV, HCV, syphilis and hemoparasites) was done. Laboratory results were given to participants through the health extension workers. HIV testing was done following the national guideline. The data collection procedure for the larger community based RIs study out of which the specific partitions used for the current study is summarized in Figue 2.

4.7.1. Demographic and Clinical Data

Socio -demographic and clinical data was collected using structured questionnaire; the questionnaire was first prepared in English and then translated in to Amharic, as the study subjects were believed to speak Amharic despite their difference in educational level and ethnicity. The data collection tool had 6 parts; part I was about general information on address; part II was personal information; part III socio-demographic characteristics; part IV clinical information; part V Nutritional habit and life style; and part VI is Anthropometric measurement (detail was annexed).

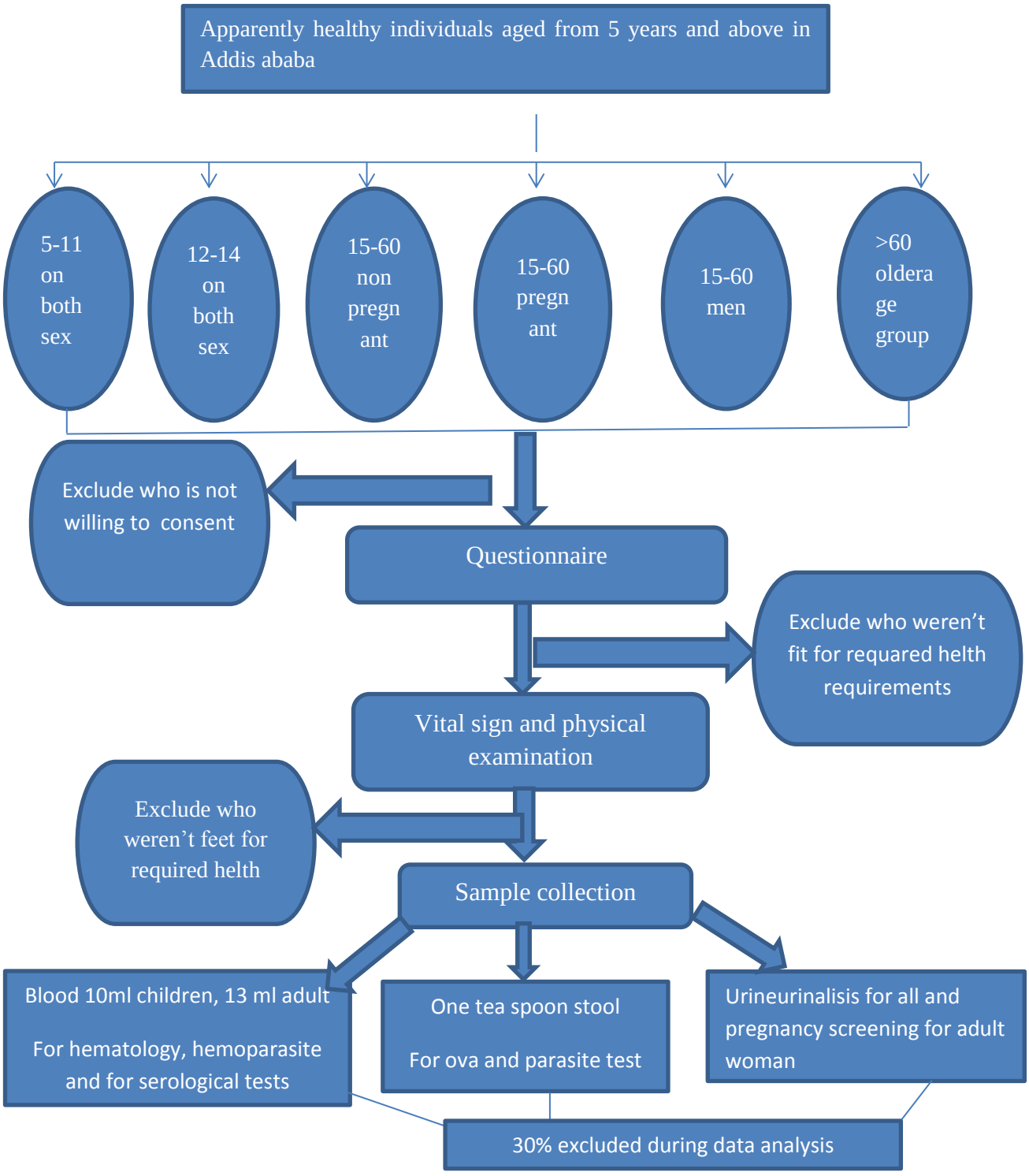

Figure2. Data Collection Procedure

4.7.2. Sample Collection for Laboratory Analysis

After completion of the interview, all respondents who were selected for hematological tests were given early morning appointment. Whole Blood sample of about 13 ml was collected from the participants in the morning (8:00am to 11:00 noon) to avoid diurnal variation. Venous blood was drawn from each subject using vacutainer system and stored in vacutainer tube containing ethylene di amine tetra acetic acid (EDTA) after cleaning the cubital area by 70% alcohol. Subsequently the blood was mixed with anticoagulant and transported to the hematology laboratory immediately. The blood samples were stain and fixed on the same day.

Thin and thick blood films was made by the push-Edge technique and stained for the identification of hemoparasites. Adequate quality control measures were taken on each test procedure to ensure the reliability of the results.

Whole blood was used for hematological analysis and hemoparasites identification while serum samples for screening HIV, HBV, HCV, and syphilis. Part of the whole blood was used for ABO and Rh typing following standard operating procedures.

Stool samples were collected for parasitological analysis and urine for Urinalysis and determining pregnancy status. Leak proof clean containers were used to collect urine and stool samples.

All samples were labeled with unique identification number (Site name plus 0001 to 1030). Hematological analyses were performed according to the keeping time for each test and maximum within 8 hours in the reference laboratory from each site. Direct and concentration stool analysis were performed on site in the respective health facilities where participants were invited to (MOH letter is sent to all Health Bureaus). Serum and left over plasmas were collected and stored at $-20^{O}C$ in the respective Reference laboratory and transported in cold chain using cold boxes to the the Ethioian Public Health Institute and the National Blood Bank for batch analysis of the clinical chemistry parameters and serological tests, respectively. All results entered into SPSS and hard copies for cross checking were sent to the supervisor of this study and the PI of the larger reference interval project at the Department of Medical Laboratory Sciences, AAU.

4.7.3. Hematological Analysis

A complete blood count (CBC) and differential was performed on the blood sample using an automated hematological analyzer sysmex XT1800i which is a quantitative, automated

hematology analyzer and 5 part leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories uses two independent measurement methods; they are: • Electrical impedance method is used for determining WBC, RBC, and PLT count. As the cells pass through the aperture of the van Behrens transducer, a change in electrical resistance occurs generating an equivalent voltage pulse. The number of pulses sensed during each cycle corresponds to the number of WBC, RBC and PLT counted. The amplitude of each pulse is essentially proportional to the cell volume.

• Modified met hemoglobin method for determining HGB through photometric measurement. After the WBCs have been counted and sized, the remainder of the lysed dilutions transferred to the hemoglobin (HGB) flow cell assembly. In the flow cell, the machine measures the ability of the dilution to absorb light at a wavelength of 540nm. The absorbed light is proportional to the concentration of hemoglobin.

The analyzer is used for the quantitative determination of the following 26 parameters and 2 histograms (RBC, PLT) of blood samples. White Blood Cell or leukocyte (WBC) (10^9/L), Neutrophil NEUT#, Neutrophil NEUT %, Lymphocyte LYMPH#, Lymphocyte LYPH%, Monocyte MONO#, Monocyte MONO%, Eosinophil EO#, Eosinophil EO%, Basophile BASO#, Basophil BASO%, RBC, Hgb, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT and P-LCR).

Red Blood Cell or erythrocyte (RBC) (10^{12}/L), Hemoglobin Concentration (HGB) (g/dl), Mean Corpuscular (erythrocyte) Volume MCV (fl), Mean Cell (erythrocyte) Hemoglobin MCH (pg),, Mean Cell (erythrocyte) Hemoglobin Concentration MCHC (g/dl), Red Blood Cell (erythrocyte) Distribution Width Coefficient of Variation RDW-CV, Red Blood Cell (erythrocyte) Distribution Width Standard Deviation RDW-SD, Hematocrit HCT (%), Platelet PLT(10^9/L),, Mean Platelet Volume MPV, Platelet Distribution Width PDW, Plateletcrit PCT.

4.7.4 Serological Analysis

Blood was tested for Hepatitis B surface antigen, Hepatitis C antibody, HIV antibodies and syphilis sero status using enzyme immunoassay. All enrolled subjects provided urine samples for urinalysis. Samples were transported and tested within 4 hours after collection. Urine pregnancy tests for HCG were performed on all women 15-60 years.

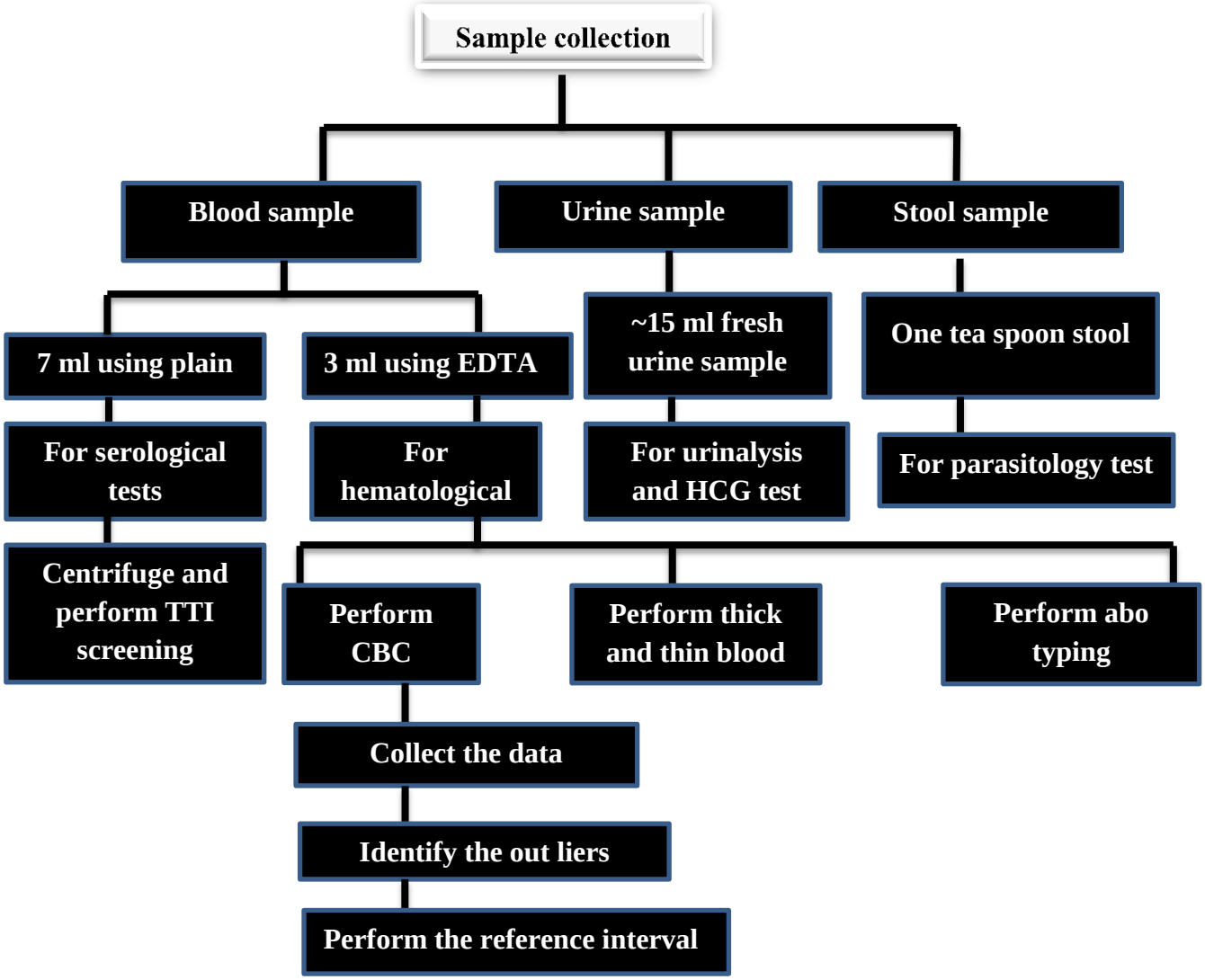

Figure3. Flow Chart of Sample Process

4.8. Data Quality Assurance

Data were collected by trained health extension workers and the investigating team. Healthcare practitioners should have sufficient experience and training according to local research governance procedures to take written informed consent and perform the procedure.

Preanalytic:

At the preanalytic phase proper blood and other biological sample containers were used and blood was collected by experienced phlebotomist. Same four digit codes with woreda prefix were used to label all biological samples and the questionnaire. The procedure and timing of blood sample collection were standardized to minimize the pre analytical variables.

Analytic:

Blood samples were collected and processed the same day. Samples were visually inspected for clotting or lysis and discarded if any was observed. The quality and accuracy of the technique and the machine was assessed by using three levels quality control (low, Normal, High). Hematological analysis was performed in an accredited laboratory following standard operating procedures.

According to Clinical and Laboratory Standards Institute (CLSI) before collecting samples for final analysis, the performance of the automated hematology analyzers was evaluated. After calibration by a field service representative, the imprecision, carry over, and linearity of the analyzers is evaluated according to the International Council for Standardization in Hematology (ICSH) guidelines. Fresh K2EDTA anticoagulant specimens were taken and tested within 8 hours after sample collection.

The commercial control samples at three different levels (high, medium, and low) are measured before and after every analytical run. In addition all safety precautions were implemented to minimize error and to meet the standard of CLSI protocol

Post-Analytic:

The print out from hematology analyser and other results were properly document. Hard copies were kept at the Department of Medical Laboratory Sciences and a copy sent to the respective health facilities' health extension workers.

4.9. Data Analysis and Interpretation

Data was cleaned, edited and checked for completeness of the whole data and organized and put in to the SPSS Version 24 Statistical software for analyses to manage and as well as to interprete the results. Descriptive statistics was used to determine frequency, median, mean, 2.5^{th} and 97.5^{th} percentiles with their 90% confifence interval. Outliers were excluded using the MedCalc software. Mann-Whitney U test to compare median and Analysis of Variable (ANOVA) to compare mean between groups were were also used. Group specific reference interval was determined using a non-parametric test as recommended by CLSI. Significance difference was declared when P value is less than 0.05.

4.10. Ethical Considerations

The study was carriedout after obtaining ethical clearance from the department of Medical Laboratry Sciences of Addis Ababa University Ethical Committee. The larger community based study was also approved by College of Health Science Institutional Review Board. Before enrolling any of the eligible study participants, the purpose and the benefit of the study was discussed with each study participants and parents or guardians for those aged less than 18 years old to obtain consent and assent for participation.. Informed consent of the respondent was obtained first. The right of the respondents to refuse to answers for few or all questions and the right to refuse the sample taking procedure was respected. The interview was conducted in a way that it was not compromising their privacy and confidentiality of information. Names were linked only to give participants back their laboratory test results; otherwise hard copies were locked in the superviser office at Department of Medical Laboratory Sciences.

4.11. Communication of Results

The study outcome will be disseminated to the Federal Ministry of Health and Addis Ababa Health Bureau to be used for the adult population of Addis Ababa. The thesis will be publicly defended and manuscript will be submitted to reputable journals. The data will be dessiminated to the medical and scientific community through presentation on conferences.

4.12. Operational Definition

Reference Interval: The interval between, and including two reference values defined by a specific percentage (usually 95%) for hematologic parameters of healthy individuals.

Hematological Parameters: in this study refers to the complete blood count which embrace the twenty four parameters result value of an individual (WBC,NEUT, LYMPH, MONO, EO, BASO, NEUT%, LYMPH%, MONO%, EO%, BASO%, RBC, Hgb, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT and P-LCR)

Pregnancy: The state of carrying a developing embryo or fetus within female body, which is confirmed by urine HCG positive result.

Adult: A human being with the age 18-60 years old for both genders. Married pregnant women between the age of 15 and 18 were also included in this category.

Apparently Healthy: Study subjects who fulfilled the inclusion criteria for health related assessments designed for this study.

5. Result

5.1. Sociodemographic Characteristics

A total of 790 individuals, from ages 15 to 60 years for both sexes and 15-45 years for pregnant groups were included in this study. Males comprise 262, and 346 were non-pregnant females while 182 were pregnant women; The mean ± SD age of study participants was male 26.03±10.22 years, Females 30.57±12.22, years and pregnant women were 26.67±4.44 years. There was significant age differences between male and female with p value of ($p<0.000$), between pregnant and non-pregnant women with p value of ($P<0.000$). Of the participants, 47.8% were married 32.7% were Government employee, 38.2% were in secondary school, 30.6 attain diploma and above while 4.1 were illiterate. Of the total 182 pregnant women, 42(26.8%); 50(31.8%); and 65(41.4%) were first (1-12 weeks of gestation); second (13-27 weeks of gestation); and third trimester (28-40 weeks of gestation), respectively. Table 2 summarises socio-demographic characteristics of the study participants.

Table 2. Socio demographic characteristics of study participants, Addis Ababa, Ethiopia from January-May, 2019.

Variable	Frequency	Percent
Sex		
Male	262	33.2
Female	528	66.8
Marital States		
Single	212	26.8
Married	378	47.8
Divorced	18	2.3
Widowed	20	2.5
Not applicable (students)	160	20.3
Residence		
rural	1	0.1
urban	785	99.4
Religion		
Orthodox Christian	669	84.7
Muslim	47	5.9
Protestant	65	8.2
Catholic	1	0.1
Others (Specify)	5	0.6
Educational States		
Illiterate	32	4.1
Read and write	16	2.0
Primary (1-8)	196	24.8
Secondary (9-12)	302	38.2
College diploma/degree and above	242	30.6
Occupation		
Student	194	24.6
House wife	162	20.5
Government employee	258	32.7
Private employee	158	20.0
Farmer	1	0.1

5.2 Anthropometric Data of Study Participants

Weight was measured using a digital weighing scale and the mean ± SD height of study subjects were 159.86±8.64 centimeters ranging between 121.7-184.1 centimeters and the body weight was 58.52±12.14kg with a range of 21.4-97.5kg. The body mass index (BMI) showed mean ± SD value of 22.91±4.6Kg/m^2 varying between 8.75-41.63Kg/m^2. The anthropometric data of each study partition is illustrated in table 3.

Table 3: Mean ± SD and median values of anthropometric data of study participants of Addis Ababa population, Addis Ababa, Ethiopia from January-May, 2019

Variable	Category		Mean ± SD(range)	Median	
Age (year)	Male		34.19±10.09(18-65)	32	
	Female		32.36±9.98(18-61)	31	
	Pregnant		26.2±5.1(16-45)	26.05	
Height (cm)	Male		172.34±7.44(155-186)	172	
	Female		166.07±7.06(148-186)	166	
	Pregnant		165.1±6.5(150-181)	166.0	
Weight (kg)	Male		68.68±8.04(50-91)	69	
	Female		63.53±7.08(45-84)	166.0	
	Pregnant		66.6±6.5(46-89)	66.0	
BMI (kg/m2)	Male		23.07±1.7(18.7-29.8)	22.9	
	Female		23.07±2.12±(18.5-29.3)	22.6	
	Pregnant		24.39±2.3(18.9-29.8)	24.5	
Bp (mmhg)	SBP	male	116.86±7.12(99-161)	118	
		female	116.3 ±7.25(101-142)	116	
		Pregnant	119.1±12.17(87-156)	118.0	
	DBP	male	80.1±7.8(70-128)	79	
		female	78.7±6.17(70-97)	78	
		Pregnant	79.95±7.53(63-101)	79.0	
MUAC	Male		85.28±8.2(68-101)	86	
	Female		87.45±8.39(72-102)	90	
	Pregnant		93.39±7.7(72-115)	93.0	

5.3. Life Style and Nutritional Habit

In this study 152(19.4%), 8(1%), 1(0.1%) participants are ‘‘occasional’’ alcohol, *khat*, and cigarettes users on which they used it only during holiday and special ceremony. In addition, 36(4.6%), 4(0.5), 1(0.1%) were alcohol, khat and cigarettes users 2 to 3 times per week. Table 4 shows dietary style of study participants.

Table 4: The dietary style of study participants of Addis Ababa population, Addis Ababa, Ethiopia from January-May, 2019

Dietary type	**Diatry frequency**				
	Once/day	> Once/day	2-3times/week	Occasionally	Never
Eating of Roots and Tuber (Potato, sweet potato, Enset, Cassava)	54(6.9)	20(2.5)	335(42.6)	352(44.8)	24(3.1)
Eating of Legumes (Beans, peas, chicken pea, etc.)	150(19.1)	318(40.5)	132(16.8)	169(21.5)	15(1.9)
Eating of Cereals (Corn, Teff, Wheat, sorghum, etc.)	264(33.6)	423(53.8)	57(7.3)	41(5.2)	
Eating of Vegetables (Tomato, cabbage, etc.)	163(20.8)	54(6.9)	296(37.7)	254(32.4)	17(2.2)
Eating of Fruits (Orange, banana, etc.)	58(7.4)	19(2.4)	224(28.7)	459(58.8)	20(2.6)
Eating of Meat (including poultry, fish, etc.)	25(3.2)	12(1.5)	140(17.9)	558(71.4)	45(5.8)
Eating of Milk and Milk products (Butter, yoghurt, cheese, etc.)	59(7.5)	21(2.7)	147(18.8)	453(57.9)	100(12.8)
Eating of Egg	63(8.1)	14(1.8)	189(24.2)	467(59.9)	46(5.9)
Drinking of Tea and/or coffee	475(60.8)	167(21.4)	68(8.7)	43(5.5)	27(3.5)
consume/use of Alcohol	7(0.9)	2(0.3)	36(4.6)	152(19.4)	587(74.9)
consume/use of *khat*			4(.5)	8(1.0)	771(98.5)
consume/use of Cigarettes	2(0.3)		1(0.1)	1(0.1)	780(99.5)

5.4. Distribution of ABO Blood group and Rh phenotype

The most prevalent blood group was blood group O+(31.01%) followed by A+ (29.75%), B+ (26.71%), but the least was blood group AB (6.33%). Regarding Rh (D) positivity,93.8% were Rh positive while 6.2% were Rh negative (Figure 4).

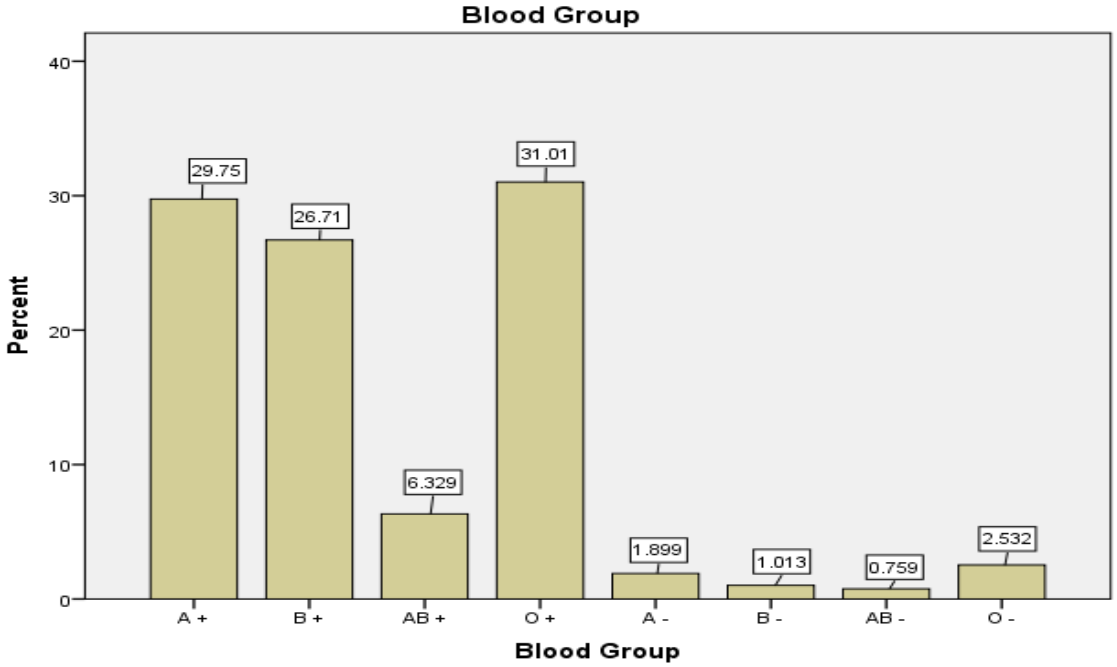

Figure 1. Distribution of ABO and Rh blood phenotypes of study participants of Addis Ababa population, Addis Ababa, Ethiopia from January-May, 2019

5.5. Reference Intervals of Hematologic Parameters

The 95% (2.5^{th}-97.5^{th} limits) reference intervals for hematologic parameter for three partitioned study participants were illustrated in tables 5-7. Sample size for each parameter is indicated since after excluding non eligible participants based on screening tests and remival of outliers, sample sizes vary as shown in the tables.

5.5.1. White Blood Cells Parameters Reference Interval

Table 5 shows significant difference based on gender as well as between pregnant and non-pregnant women for most of white blood cell parameters.

Table 5: Median and 95% RI values of white blood cells parameters of males, females and pregnant women of Addis Ababa population, Ethiopia from January-May, 2019

Parameter	Category	N	Median	RI (2.5th-97.5th)	90% CI		P-VALUE	
					LLC	ULC	M & F	NP & P
WBC(x103/µl)	Male	245	5.8	3-9.91	2.71-3.35	9.2-10.48	P = 0.7616[b]	P < 0.0001[b*]
	Female	330	5.95	3-10.1	2.79-3.24	9.69-10.64		
	Pregnant	185	7.7	4-12.9	3.57-4.56	12.46-13.61		
Neut#(x103/µl)	Male	217	2.92	0.9-6.08	0.62-1.1	5.67-6.54	P = 0.6520[b]	P < 0.0001[b*]
	Female	317	2.98	0.83-6.31	0.77-1.08	5.73-6.55		
	Pregnant	144	5.05	1.9-9.9	1.3-2.5	9-11		
Neut %	Male	222	50.2	24.68-73.43	22.3-27	71-75.81	P = 0.1281[a]	P < 0.0001[b*]
	Female	326	51.45	27.47-73.8	25.6-29.33	71.93-75.66		
	Pregnant	140	66.85	45.7-80.9	43.1-50.3	78.9-83.9		
Lymph#(x103/µl)	Male	233	2.08	1.2-3.5	0.99-1.32	3.3-3.55	P = 0.9104[b]	P < 0.0001[a*]
	Female	315	2.15	1.19-3.13	1.11-1.26	3.05-3.21		
	Pregnant	183	1.79	0.85-2.7	0.75-0.95	2.6-2.8		
Lymph %	Male	238	37.25	16.23-59.45	14.19-18.27	57.42-61.49	P = 0.9633[b]	P < 0.0001[b*]
	Female	324	37.35	20.51-61.27	15-22.6	57.6-63		
	Pregnant	179	22.8	10.18-36.2	8.76-11.59	34.78-37.62		
Baso# (x103/µl)	Male	217	0.02	0.0-0.065	0.0-0.0	0.06-0.08	P = 0.4683[b]	P = 0.9787[b]
	Female	300	0.02	0-0.06	0.0-0.0	0.06-0.07		
	Pregnant	184	0.02	0.01-0.06	0-0.01	0.04-0.06		
Baso %	Male	230	0.5	0.0-1.5	0.0-0.1	1.2-1.5	P = 0.3363[b]	P < 0.0001[b*]
	Female	309	0.5	0.1-1.2	0.1-0.1	1.1-1.2		
	Pregnant	182	0.3	0.1-0.64	0-0.1	0.6-0.7		
EO# (x103/µl)	Male	199	0.14	0.0-0.51	0.0-0.01	0.49-0.56	P < 0.0001[b*]	P < 0.0001[b*]
	Female	279	0.1	0-0.3	0-0.01	0.27-0.3		
	Pregnant	144	0.09	0.016-0.3	0.0-0.03	0.29-0.34		
EO %	Male	196	2.4	0.3-7.7	0.2-0.5	7.2-8.5	P = 0.1183[b]	P = 0.1504[b]
	Female	294	1.8	0.33-6.3	0.2-0.4	6-6.8		
	Pregnant	132	1.1	0.23-3.36	0.0-0.4	2.9-3.5		
MONO# (x103/µl)	Male	231	0.48	0.24-0.8	0.19-0.29	0.75-0.85	P < 0.0001[b*]	P < 0.0001[b*]
	Female	319	0.4	0.2-0.71	0.19-0.2	0.66-0.74		
	Pregnant	180	0.55	0.25-0.87	0.22-0.28	0.84-0.91		
MONO %	Male	229	7.9	4.8-12.6	3.9-5	11.7-13.5	P = 0.012[b*]	P = 0.0146[b*]
	Female	315	6.9	3.89-10.9	3.4-4.4	10.3-11.1		
	Pregnant	181	7.1	4.0-11.5	2.7-4.6	10.8-11.9		

LLC, Lower Limit Confidence interval; ULC, Upper Limit Confidence interval; M, Male; F, Female; NP, Non-Pregnant; P, Pregnant

[a] independent-Samples Mann-Whitney U Test **[b]** independent sample t-test

***** *p values* < 0.05: statistically significant different

5.5.2. Red Cells Parameters Reference Interval

RBC count, Hgb, HCT and MCHC were significantly higher in males than females while median value for MCV, MCH, RDW-CV and RDW-SD values were higher in females than males (Table 6).

Table 6: Median and 95% RI values of red blood cells parameters of males, females and pregnant women of Addis Ababa population, Ethiopia from January-May, 2019

Parameter	Category	N	Median	RI (2.5th-97.5th)	90% CI		P-VALUE	
					LLC	ULC	M & F	NP & P
Hgb (gm/dl)	Male	251	16.8	14.24-19.11	14.01-14.46	18.89-19.34	P < 0.0001[a*]	P < 0.0001[a*]
	Female	327	14.8	13.08-16.58	12.94-13.22	16.44-16.72		
	Pregnant	184	13.8	11.68-15.73	11.46-11.9	15.51-15.94		
RBC# (x106/µl)	Male	250	5.53	4.77-6.24	4.7-4.83	6.17-6.31	P < 0.0001[a*]	P < 0.0001[a*]
	Female	333	4.84	4.2-5.51	4.15-4.25	5.46-5.56		
	Pregnant	182	4.38	3.63-5.17	3.54-3.7	5.09-5.26		
HCT (%)	Male	251	47.3	41.6-52.87	41.08-42.11	52.35-53.39	P < 0.0001[a*]	P < 0.0001[a*]
	Female	330	43.2	38.11-48.53	37.71-38.53	48.11-48.95		
	Pregnant	183	39.6	33.89-44.85	33.3-34.48	44.26-45.44		
MCV (fl)	Male	243	85.9	78.74-93	78-79.41	92.35-93.69	P < 0.0001[a*]	P = 0.1619[b]
	Female	318	89.4	81.22-97.03	80.58-81.87	96.39-97.68		
	Pregnant	182	89.35	79.88-99.58	77.5-82.7	98.6-100.6		
MCH (pg)	Male	247	30.5	27.45-33.4	27.17-27.72	33.13-33.68	P = 0.3777[a]	P < 0.0001[a*]
	Female	311	30.6	28.01-33.21	27.8-28.23	33-33.43		
	Pregnant	180	31.3	28.2-34.34	27.86-28.53	34.01-34.68		
MCHC (gm/dl)	Male	250	35.3	33.12-37.5	32.92-33.33	37.3-37.7	P < 0.0001[b*]	P < 0.0001[b*]
	Female	324	34.2	32.41-35.7	32.2-32.6	35.6-35.9		
	Pregnant	184	34.75	33.3-36.43	33.1-33.4	36.2-37		
RDW-CV	Male	241	13.2	12.21-14.7	12.1-12.4	14.4-14.8	P = 0.0088[b*]	P = 0.0398[b]
	Female	320	13.4	12.2-15	12-12.5	14.9-15.2		
	Pregnant	177	13.6	11.93-15.24	11.75-12.1	15.06-15.43		
RDW-SD	Male	249	41.1	36.56-45.94	36.13-36.99	45.51-46.38	P < 0.0001[b*]	P = 0.0048[b*]
	Female	328	42.65	37.29-48.6	36.3-38.1	48.2-49.8		
	Pregnant	181	43	37.25-51.89	34.9-38.3	50.3-52.5		

LLC, Lower Limit Confidence interval; ULC, Upper Limit Confidence interval; M, Male; F, Female; NP, Non-Pregnant; P, Pregnant

[a] independent-Samples Mann-Whitney U Test **[b]** independent sample t-test ***** *p values* < 0.05: statistically significant different

5.5.3. Platelet Parameters Reference Interval

As displayed in Table 7, non-pregnant females had significantly higher median PLT count and PCT than males and pregnant women. In contrast, pregnant women had significantly higher median PDW, MPV, P-LCR than their non-pregnant counterparts and males.

Table 7: Median and 95% RI values of Platelet parameters of males, females and pregnant women of Addis Ababa population, Addis Ababa, Ethiopia from January to May, 2019

Parameter	Category	N	Median	RI (2.5th-97.5th)	90% CI		P-VALUE	
					LLC	ULC	M & F	NP & P
Platelet (x103/µl)	Male	244	259	149-376	138-160	366-387	P < 0.0001[b*]	P < 0.0001[b*]
	Female	331	286	176-414	151-194	406-425		
	Pregnant	181	232	116-342	104-128	330-355		
P.LCR	Male	209	29.4	17-41.56	15.81-18.28	40.33-42.8	P = 0.4886[a]	P < 0.0001[a*]
	Female	278	29.7	16.79-43.2	15.63-17.94	42.04-44.35		
	Pregnant	181	32.5	18.66-47.0	17.12-20.19	45.51-48.58		
MPV (fl)	Male	238	10.4	7.9-12.1	7.8-8.3	11.9-12.3	P = 0.2152[b]	P = 0.1446[b]
	Female	320	10.5	8.33-12.56	8.16-8.5	12.39-12.74		
	Pregnant	181	10.9	9.3-13.3	9-9.5	12.8-13.4		
PDW	Male	206	12.5	9-16	8.7-9.41	15.73-16.44	P = 0.6024[b]	P = 0.1433[b]
	Female	270	12.25	9.5-16.62	9.4-9.7	16-17.1		
	Pregnant	176	13.1	10.2-18.3	9.5-10.5	17.2-19.2		
PCT	Male	208	0.27	0.17-0.39	0.16-0.19	0.37-0.42	P < 0.0001[b*]	P = 0.2232[a]
	Female	279	0.31	0.21-0.43	0.21-0.22	0.42-0.46		
	Pregnant	179	0.26	0.15-0.35	0.13-0.16	0.34-0.4		

LLC, Lower Limit Confidence interval; ULC, Upper Limit Confidence interval; M, Male; F, Female; NP, Non-Pregnant; P, Pregnant

[a] independent-Samples Mann-Whitney U Test **[b]** independent sample t-test

***** *p values* < 0.05: statistically significant different

5.6. Comparison of Hematologic Parameters Between Pregnant And Non-Pregnant Women

Comparison of pregnant and non-pregnant women for hematologic parameters indicated significantly higher mean value for RBC, HCT, Hgb, HCT, Lymph# Lymph% and PLT# and in non-pregnant as compared to the pregnant women. Whereas, significantly higher mean value was observed for WBC, MCH, MCHC, RDW-SD, P.LCR, NEU#, NEU%, MONO# MONO% and EO# in pregnant women than the non-pregnant (Table 5-7).

5.7. Comparison of Hematological Parameters of Pregnant Women Based On Trimesters

The mean ± SD gestational age of pregnant women was 23.07±10.40 weeks ranged from 4-48 weeks and the mean ±SD number of family size was 1.78±1.09 ranged 1-8. In this study, an increased trend in the value of hematologic parameter as the gestational age progressed from the 1st to 2nd and then to 3rd trimester for: MCV, MCH, RDW-CV, MONO%, MONO#, NEUT#, NEUT%, BASO#, and EO#. However, a decreased trend for RBC count,HGB, HCT, MCHC,PLT, LYPH%, LYMPH# and PCT as the gestational age decreased from the 1st to 2nd and then to 3rd trimester was observed. Gestational-based reference interval of pregnant women for the hematological parameters at were shown in Table 8

Table 8: Median and 95% RI of hematological values over the three trimesters of pregnant women of Addis Ababa, Ethiopia of from January-May, 2019

Parameter	Trimester-1			Trimester-2			Trimester-3			p-value		
	N	Median	RI (2.5th-97.5th)	N	Median	RI (2.5th-97.5th)	N	Median	RI (2.5th-97.5th)	1st & 2nd	1st & 3rd	2nd & 3rd
WBC(x103/µl)	49	7.13	3.77-10.37	55	7.84	3.47-12.95	80	8.19	4.04-13.25	0.030[b*]	0.046[b*]	0.924[b]
Neut#(x103/µl)	41	4.17	1.07-7.64	40	5.35	1.46-9.59	63	5.75	1.51-9.88	0.025[a*]	0.003[a*]	0.911[a]
Neut %	40	61.4	40.13-82.48	37	68.1	57.21-79.04	61	68.9	53.18-82.71	0.017[a]	0.002[a*]	0.925[a]
Lymph#(x103/µl)	48	1.88	0.83-2.84	54	1.68	0.9-2.65	80	1.79	0.83-2.65	0.041[b*]	0.025[b*]	0.601[b]
Lymph %	46	26	12.51-39.89	54	21.6	10.23-34.50	80	22	9.29-35.22	0.009[a*]	0.000[a*]	0.736[a]
Baso# (x103/µl)	50	0.02	0.01-0.06	54	0.02	0.01-0.04	75	0.02	0.0-0.03	0.897[b]	0.008[b*]	0.019[b*]
Baso %	49	0.30	0.1-0.7	54	0.30	0.1-0.7	75	0.2	0.1-0.4	0.388[b]	0.007[b*]	0.148[b]
EO# (x103/µl)	41	0.07	0.0-0.18	35	0.08	0.02-0.27	57	0.06	0.0-0.31	0.919[b]	0.690[b]	0.711[b]
EO %	37	1.00	0.0-3.50	37	1.20	0.3-4.3	59	1.1	0.1-4.0	0.578[b]	0.738[b]	0.902[b]
MONO# (x103/µl)	49	0.55	0.18-0.91	54	0.53	0.25-0.85	79	0.59	0.27-0.9	0.798a	0.379a	0.782a
MONO %	48	7.20	3.20-12.38	55	6.90	3.69-10.32	79	7.2	4.13-10.55	0.097[a]	0.321[a]	0.683[a]
Hgb(gm/dl)	49	14.6	12.49-16.17	56	13.8	12-15.39	78	13.3	11.36-15.21	0.003[a*]	0.000[a*]	0.189[a]
RBC# (x106/µl)	47	4.73	4.03-5.42	55	4.36	3.74-4.98	79	4.26	3.55-4.97	0.000[a*]	0.000[a*]	0.244[a]
HCT (%)	49	40.8	35.29-46.27	56	39.7	34.50-44.33	79	38.8	33.03-44.10	0.017[a*]	0.000[a*]	0.326[a]
MCV (fl)	44	86.9	80.22-94.28	55	90.7	81.69-99.59	80	90.7	82-99.51	0.003[a*]	0.000[a*]	0.892[a]
MCH (pg)	45	31.2	28.31-33.34	53	31.5	28.57-34.32	80	31.5	27.99-34.70	0.164[a]	0.117[a]	1.000[a]
MCHC	49	35.4	33.50-	55	34.7	33.37-	80	34.5	32.99-	0.006[a*]	0.000[a*]	0.598[a]

(gm/dl)			36.94			35.91			36.08			
RDW-CV	45	13.3	11.73-14.89	55	13.9	12.44-15.48	76	13.4	11.85-15.12	0.985[a]	0.677[a]	0.773[a]
RDW- SD	47	41.9	35.63-47.71	56	45.4	38.29-52.09	72	42.7	37.54-47.97	0.006[a*]	0.225[a]	0.188[a]
PLT(x103/µl)	48	250	153-356	56	244	128-349	78	204	93.90-316	0.458[a]	0.001[a*]	0.032[a*]
P.LCR	48	31.7	18.03-45.28	54	30.6	19.67-43.61	79	33.7	18.93-49.86	1.000[a]	0.063[a]	0.051[a]
MPV(fl)	48	10.8	8.98-12.75	54	10.7	9.27-12.39	80	11.1	9.1-13.38	0.975[a]	0.093[a]	0.044[a*]
PDW	47	12.6	9.30-16.63	53	12.4	10.13-17.02	79	13.8	9.12-19.21	0.812[b]	0.018[b*]	0.012[b*]
PCT	48	0.28	0.17-0.38	54	0.27	0.16-0.35	77	0.23	0.13-0.35	0.103[b]	0.000[b*]	0.004[b*]

[a] One-way analysis of variance (ANOVA); [b] Kruskall-Wallis; ***p values** < 0.05: statistically significant different

5.8. Comparison Of Hematological Parameter RI With Currently Practiced And African Studies

Comparison of this finding with currently practiced values revealed an out of range in the RIs for WBC, 22.8% in males and 14.2% in females; RBC count, 7.6% in males and 17.1% in females; HGB 27.4% in males and 17.4% in females; HCT, 8.3% in males and 27.8% in females; plt count, 13.1% in male and 16.9% in female were indicated.

Comparison of this study reference interval with studies conducted from different geographic location in Africa indicated higher RBC, Hgb and PLT (RBC=4.77-6.24; HGB=14.24-19.11; PLT=149-376) in this study for the lower and upper limit than from the study conducted in Asmera(RBC=4.2–6.07; HBG=12.6–17.8; PLT=128.4–318.4),Ghana(RBC=3.79–5.96, HGB=11.3–16.4; PLT=88–352) and Kenya(RBC=4.3–6.5; HBG=11.4–16.9; PLT=102–307) in males. In addition, RBC, HGB, HCT and PLT (RBC=4.2-5.51; HGB=13.08-16.58; HCT=38.11-48.53; PLT=176-414) were higher in this study for the lower limit compared to research conducted in Asmera (RBC=4–5.7; HBG=12.5–17.6; HCT=37.9–52; PLT=145.4–351.6), Ghana(RBC=3.09–5.30; HBG=8.8–14.4; HCT=26.4–45.0; PLT=89–403) and Kenya RBC=3.4–5.7; HGB=8.0–14.2; HCT=23.2–44.3; PLT=88–439) whereas lower in WBC (3-10.1) of lower limit for female than Asmera=3.3–8.9; Ghana=3.4–9.3; Keniya=3.3–9.7 as shown in Table 9. Overall, the WBC count refrence interval is consistently low in the African studies both in the lower and upper limits.

Table 9: Comparison of adult hematological reference values obtained from currently practiced RI in Addis Ababa and African studies with this study of study participants of Addis Ababa, Ethiopia of from January-May, 2019

Parameter	Sex	This study		Currently the labs using	% Out of range	African studies		
						Asmera(14)	Ghana(7)	Kenya(10)
		N	RI	RI		RI	RI	RI
RBC (×1012/L)	Male	250	4.77-6.24	4.63-6.08	7.6%(19/250)	4.2–6.07	3.79–5.96	4.3–6.5
	Female	333	4.2-5.51	3.93-5.22	17.1%(57/333)	4–5.7	3.09–5.30	3.4–5.7
HGB (g/L)	Male	251	14.24-19.11	13.7-17.5	27.4%(69/251)	12.6–17.8	11.3–16.4	11.4–16.9
	Female	327	13.08-16.58	11.2-15.7	17.4%(57/327)	12.5–17.6	8.8–14.4	8.0–14.2
HCT (L/L)	Male	251	41.6-52.87	40.1-51.0	8.3%(21/251)	40.5–55	33.2–50.5	32.6–51.5
	Female	330	38.11-48.53	34.1-44.9	27.8%(92/330)	37.9–52	26.4–45.0	23.2–44.3
MCV (fL)	Male	243	78.74-93	79.0-92.2	7.4%(18/243)	85.7–100	70–98	55–98
	Female	318	81.22-97.03	79.4-94.8	15.0%(48/318)	85.5–100	73–96	60–94
MCH (pg)	Male	247	27.45-33.4	25.7-32.2	10.9%(27/247)	28–33	22.7–33.5	
	Female	311	28.01-33.21	25.6-32.2	15.4%(48/311)	26.5–32.6	22.3–33.6	
MCHC (g/L)	Male	250	33.12-37.5	32.3-36.5	15.6%(39/250)	30.4–33.7	30.6–36.0	
	Female	324	32.41-35.7	32.2-35.5	9.5%(31/324)	30–33.7	30.4–36.5	
WBC (×109/L)	Male	245	3-9.9.1	4.23-9.07	22.8%(56/245)	3.7–9.3	3.5–9.2	2.5–7.4
	Female	330	3-10.1	3.98-10.04	14.2%(47/330)	3.3–8.9	3.4–9.3	3.3–9.7
NEUT (%)	Male	222	24.68-73.43	34.0-67.9	18.9%(42/222)			
	Female	326	27.47-73.8	34.0-71.1	11.3%(37/326)			
LYM (%)	Male	238	16.23-59.45	21.8-53.1	14.7%(35/238)	39.0–41.3	24.0–57.2	
	Female	324	20.51-61.27	19.3-51.7	12.6%(41/324)	37.1–39.1	26.9–58.3	
MONO (%)	Male	229	4.8-12.6	5.3-12.2	9.6%(22/229)	7.3–7.7	5.7–17.4	
	Female	315	3.89-10.9	4.7-12.5	9.5%(30/315)	7.2–7.7	5.0–14.4	
EO (%)	Male	196	0.3-7.7	0.8-7.0	11.2%(22/196)			
	Female	294	0.33-6.3	0.7-5.8	27.8%(82/294)			

BASO (%)	Male	230	0.0-1.5	0.2-1.2	10.8%(25/230)			
	Female	309	0.1-1.2	0.1-1.2	7.1%(22/309)			
NEUT	Male	217	0.9-6.08	1.78-5.38	29%(63/217)			0.8–3.9
(×109/L)	Female	317	0.83-6.31	1.56-6.13	21.4%(68/317)			1.3–3.8
LYM	Male	233	1.2-3.5	1.32-3.57	3.8%(9/233)		1.2–5.2	1.0–3.5
(×109/L)	Female	315	1.19-3.13	1.18-3.74	5.3%(17/315)		1.2–4.4	1.3–3.8
MONO	Male	231	0.24-0.8	0.04-0.54	30.7%(71/231)		0.2–1.4	0.2–0.9
(×109/L)	Female	319	0.2-0.71	0.24-0.36	21.9%(70/319)		0.2–0.9	0.3–0.8
EO	Male	199	0.0-0.51	0.04-0.54	10%(20/199)			0.1–1.7
(×109/L)	Female	279	0-0.3	0.04-0.36	28.3%(79/279)			0.1–1.3
BASO	Male	217	0.0-0.065	0.01-0.08	16.5%(36/217)			0.01–0.19
(×109/L)	Female	300	0-0.06	0.01-0.08	22.6%(68/300)			0–0.20
PLT	Male	244	149-376	163-337	13.1%(33/244)	128.4–318.4	88–352	102–307
(×109/L)	Female	331	176-414	182-369	16.9%(56/331)	145.4–351.6	89–403	88–439
MPV	Male	238	7.9-12.1	9.4-12.4	15.5%(37/238)			
	Female	320	8.33-12.56	9.4-12.3	23.4%(75/320)			
RDW-CV	Male	241	12.21-14.7	11.6-14.4	4.14%(10/241)	12.3–15.5	11.5–16.7	
	Female	320	12.2-15	11.7-14.4	14.6%(47/320)	12.3–17	11.4–16.8	
RDW-SD	Male	249	36.56-45.94	35.1-43.9	14.4%(36/249)			
	Female	328	37.29-48.6	36.4-46.3	18.9%(62/328)			
PDW	Male	206	9-16				12–23.4	
	Female	270	9.5-16.62				12.6–22.9	
PCT	Male	208	0.17-0.39					
	Female	279	0.21-0.43					

6. Discussion

This study aimed to establish hematologic reference interval for selected parameters of Addis Ababa population after collecting and analyzing of whole blood from apparently healthy adult individuals of both sexes and pregnant women. A statistically significant difference ($p<0.05$) was noted for most of hematologic parameters based on gender as well between pregnant and non-pregnant women. Pregnant women hematologic RI based on trimester has showed significant difference ($p<0.05$) in some hematological parameters.

A study conducted in Gambia and Tanzania showed that the values of the hematological parameters were lower than those form western population of the same age group, a finding consistent with other African studies (35,36). Where as in the current study the results of RBC parameters were somehow higher than that of done in China (4), Oman (34) and Kuwait (25) as also demonstrated in the other studies from Ethiopia (15,21); this may be due to difference in altitude, method and instrument used.

The RBC, Hgb and Hct were also found to be higher when compared to the study done in Kenya (10), Nigeria (8), Togo (13), and Ghana (7). The current result is somehow consistent with the research done in Northwest Ethiopia (Gondar and surrounding areas) (21). This is possibly because of the higher altitude and dietary factors in Ethiopia where the major food, *injera*, has a very high iron content (15,21,26). Besides, the physiological adaptation to the high altitude in Addis Ababa might have also contributed to the high RBC parameters observed in the current study (43). Studies indicated high altitude has an effect on blood count parameters especially it favors for higher red cell parameters values. In order to compensate for the low partial pressure of oxygen at high altitude, the human body undergoes a number of physiological changes. A vital component in this process is the increase in the concentration of circulating hemoglobin. The role of Hypoxia Inducible Factor-1 (HIF-1) alpha, erythropoietin and red blood cells in this acclimatization process, together with the fall in plasma volume that increases the concentration of hemoglobin in the early stages of hypoxic exposure affect the levels of RBC parameters (43).

Genetic factors have been suggested to contribute to differences in blood parameters. However, studies conducted in Africa showed that there is significant hematological parameters difference between the continents of Africa population indicating racial differences might not be the major contributor for the observed differences among population groups (44,45). Other factors such as poor nutritional status, genetic red blood cell disorders (such as sickle cell trait) or parasitic infections including schistosomiasis or malaria have

been attributed to the low level of RBC parameters observed in other African countries unlike the current study (9-12).

The platelet counts in the current study were significantly higher among adult females compared to the males which is consistent with that of research done for instance in Kenya (10), Togo (13), Nigeria (8) and Oman (34) which showed that platelet counts were significantly higher among females compared to males. The possible explanation for gender difference in platelet count is not well understood. It is suggested that platelets and their medullar progenitors, megakaryocytes, express estrogen receptors (ER) that may partly explain a sensitivity to hormonal changes. As indicated in one review paper published in 2019, making a clear picture of the impact of estrogens on platelet production and functions *in vivo* is difficult and the authors suggested that further studies are needed (46).

The distributions of the RBC parameters (median hemoglobin, hematocrit, and RBC) MCH, MCHC were statistically significantly different by gender, women having lower values than men. However, one previous study from north-western Ethiopia reported high Hct in women (18). The significant difference between male and female is a well established phenomenon. Biological and physiological factors such as the influence of the hormone androgen on erythropoiesis and also menstrual blood loss in females are among the contributing factors (47).

In this study the total WBC and absolute neutrophil count were lower, a finding consistently reported in the African studies (7, 10, 14), compared to the company provided reference intervals. As well higher eosinophil counts were shown in our study when compared to the other studies from western population. The high eosinophilia is most likely a result of the high prevalence of intestinal parasites, since Africa is endemic for schistosomiasis, helminthic infections and perennial malaria (7,10,14,30). However, in the current study intestinal parasites positive individuals as determined by both direct and concentration methods were excluded and malaria from thin and thick smear were confirmed to be negative; plus during interview any medication for intestinal parasites in the previous months is checked as exclusion criteria.

In the current study, the platelet counts is somehow higher compared to values of platelet compared to other African studies as well of research done in Ethiopia where lower platelet counts have been reported for example from Kenya (10), Ghana (7), Asmara (14) and previous study from Akaki, central Ethiopia (15). But the etiology of low platelet count is not well know though dietary, environmental and genetic factors have been proposed (7,15).

But No gender-specific differences were observed for WBC and WBC subset values as these parameters were not significantly different between men and women which is consistent with research done in other African countries (7,8,13,14). However, a study conducted in Uganda showed statistically significant sex-related difference for WBC counts (11).

Finally, this study pregnant and non-pregnant women for hematologic parameters and found significantly higher mean value for RBC, HCT, Hgb, HCT, Lymph# Lymph% and PLT count in non-pregnant as compared to the pregnant women. Whereas, significantly higher mean value was observed for WBC, MCH, MCHC, RDW-SD, P.LCR, NEU#, NEU%, MONO# MONO% and EO# in pregnant women than the non-pregnant. Total WBC and WBC subsets in the current study were significantly higher in pregnant women than their non-pregnant counterparts and platelet and the RBC indexes among pregnant women are in the reverse. This finding is consistent with other studies in pregnant women mostly as a result of physiological dilution, increased demand by the growing fetus and the increased in WBC count is thought to be secondary to bone marrow granulopoiesis (26, 27,48).

In our study an increased trend in the value of hematologic parameter as the gestational age progressed from the 1st to 2nd and then to 3rd trimester was observed for MCV, MCH, RDW-CV, MONO%, MONO#, NEUT#, NEUT%, BASO#, and EO#. However, a decreased trend for RBC count, HGB, HCT, MCHC,PLT, LYPH%, LYMPH# and PCT as the gestational age decreased from the 1st to 2nd and then to 3rd trimester was observed. The WBC count also significantly increased from the first to third trimester attributed to pregnancy related stress. The change of hematological parameters by trimester is consistent with previous studies (26,41,48).

7. Strength and Limitation

7.1. Strength

The strengths of this study include the use of the same instruments with identical operational settings to obtain CBC results. This study allowed data collection from a more representative demographic population in the community as per the advice of the statistical agency. Moreover; this study includes adequate sample size for reference interval determination and adhered to follow strict study protocol.

7.2. Limitation

Antibody testing was employed to screen TTI's, which may be limited to screen early acquired infection.

8. Conclusion and Recommendation

8.1. Conclusion

There is extensive variation in hematological reference values between genders for almost all hematologic parameter, hence this suggest for the importance of utilizing the gender specific reference interval.

This research has also investigated that a trend of increasing or decreasing of hematologic parameters among pregnant women; thus, it is important to understand changes in hematologic parameter based on their gestational age. Hence it is vital to use trimester specific RI to monitor changes during pregnancy and help to avoid pregnancy related hematologic complication.

The red cells parameters are slightly lower than studies conducted in Ethiopia emphasizing the need for locally specific RIs. The reference interval of platelet count is well comparable except with an earlier study in Ethiopia, while the WBC count is consistent with other studies within Ethiopia and other African countries which in all cases areconsistently low compared to company provided values.

The RI obtained from this study different from the clinical practice currently utilized by most laboratories.

8.2. Recommendation

The present study tried to give a baseline reference interval for hematological parameters for the population of Addis Ababa, which helps for better management, diagnosis and monitoring of hematologic parameters for adults of both genders and pregnant women. More research is needed to better understand the variation across geriatric age groups and paediatrics by conducting similar study for hematologic reference interval for these age group**s**. The findings of this study also have a number of important implications for hematologic disorder management and suggested to be utilized by all health facilities of Addis Ababa.

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Annex

Annex I. Information sheet for children aged 15-17 years

Project Title: Establishment of hematological Reference Intervals for Addis Ababa

Project PI: ENDALKACHEW BEFEKADU

Sponsor: PI AMANUEL MENTAL SPECIALIZED HOSPITAL; Financed by Ministry of Science and Technology

Introduction:

Hello! My name is _____ and I am conducting a study to develop Hematological Reference Intervals For Addis Ababa aged ≥ 15years from various sub cities in the city.

Purpose of the research:

The health laboratory plays an indispensable role in the health cwere system. It supports diagnosis (to rule in or rule out a diagnosis), monitoring of response to treatment, epidemiological surveillance, prevention as well as Research (to understand the pathophysiology of a particular disease process). Especially there is lack of local reference interval for indigenous population and local. Therefore, the purpose of this proposed study is to develop Hematological and Reference Intervals for Addis Ababa aged ≥ 15years in various sub city's in Addis.

You have been chosen for this study as well your guardian/family has been asked and gave consent for your participation in the study. Therefore, I invite you to take part in this study and contribute to the establishment of indigenous reference values Which is needed for providing quality laboratory service. Thus, result from this study is anticipated to improve the health status of the children at large in Addis Ababa.

Procedures:

After agreeing that you can take part, I will visit your school on a certain day and ask you/your pwerents some questions which will take up to 15 minutes. Your height, height and vital signs will be measured. You will be asked to provide urine and fresh stool on a particular container that I provide. I will also collect 10 ml venous blood (about 1 table spoon) from you by sterile-disposable vacutainer tube and needle (7ml in plane tube and 3 ml in tube containing EDTA). I will conduct laboratory examination to determine different hematological, serological and parasitological parameters.

Confidentiality:

The information obtained during the study will remain confidential. Disclosure of any of the data to third parties other than those allowed in the Informed Consent form will not be permitted. The results of the research study may be published, but participants' names or identities will not be revealed. To maintain confidentiality, the investigator will keep records in locked cabinets in a locked room at the office and the results of the tests will be coded to prevent identification of the volunteers. Access to data entered into computerized files will be permitted only for authorized personnel darectly involved with the study and will be password protected. Individual-specific information may be provided to responsible local medical personnel only with your permission. Urine, stool and blood collected will not be used for other purposes. The leftover samples will be stored at the Department of Medical Laboratory Sciences of AAU in a secure place for additional tests as needed. Finally, all the biological wastes, after analysis will be safely disposed in an environmentally friendly manner.

Risks and Discomfort:

There will be minimal discomfort in giving urine and stool samples. However, there might be some minimal risk and discomfort when I take venous blood. Nevertheless, I will try to minimize the discomfort as much as possible, as the blood samples will be taken by experienced laboratory professionals.

Safety:

The venous blood sample will be collected using sterile vacutainer tube/syringe and needle by experienced health professional after disinfecting the site of picture by 70% ethanol. Moreover, leftover stool, urine and blood sample (that is not stored) will be discarded following the guideline of bio-safety.

Benefits:

By participating in the study, you will darectly benefit by being investigated for any pathogenic organisms and other clinical and hematological abnormalities. Establishing the reference interval and developing hematological reference interval will be used in the future to improve the general health status of the city.

Incentives:

Any positive finding in your stool/urine/blood will be taken cwere of by referring you to the nearby health institution; you will get all the laboratory investigation results for free. However, I

will not pay you for taking part in this study as Well as your treatment costs. But, I will thank you for your participation.

Right to refuse or withdraw:

I assure you that our best cwere will be taken if you agree to take part in the study. You should also know that you were free to withdraw from the study at any time and that you will not be discriminated in any form of service like health.

Whom to contact:

If you have any questions, you may ask the person whom you were giving your urine, stool and blood or the principal investigator (PI) of the study or the investigators/focal persons using the following addresses:

1. Endalkachew Befekadu, Lead PI: AAU 09 13 95 02 50

IRB address: Addis Ababa University, College of Health Science +251 -11-896-13 96

Code No._____

Annex II. Assent form for children aged 15-17 years

I have read the information above, or it has been read to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. I voluntarily assent that I would participate in this study provided my pwerents/guardians give their consent.

To give my stool ☐

To give my urine ☐

To collect my blood ☐ and be a participant in this study and understand that I have the right to withdraw from the study at any time ☐.

Print name of participant, date and signature or thumb impression of participant

_____ ____ /____ /____ (dd/mm/yy)

_____

If illiterate;

Print name of independent literate witness, date and signature of witness (if possible, this person should be selected by the participant and should have no connection to the research team)

_____ ____/____/_____ (dd/mm/yy) _____

Phone number (pwerents/guardians)_____

Print name of researcher, date and signature of researcher

_____ _____/____/_____ (dd/mm/yy) _____

Annex III: Information sheet for adults (≥18 years)

Project Title: Hematological reference interval for Addis Ababa

Project PI: Endalkachew Befekadu

Sponsor: PI=Amanuel mental specialized hospital; Financed by Ministry of Science and Technology

Introduction:

Hello! My name is _____ and I am conducting a study to develop Hematological Reference Intervals For Ethiopians aged ≥ 15years from various localities in the city.

Purpose of the research:

The health laboratory plays an indispensable role in the health care system. It supports diagnosis (to rule in or rule out a diagnosis), monitoring of response to treatment, epidemiological surveillance, prevention as Well as Research (to understand the pathophysiology of a particular disease process). Especially there is lack of local reference interval for indigenous population and local quality control materials. Therefore, the purpose of this proposed study is to develop Hematological Reference Intervals for Ethiopians aged ≥ 15years in various sub cities in the city. You have been chosen for this study. Therefore, I invite you to take part in this study and contribute to the establishment of indigenous reference values providing quality laboratory service. Thus, result from this study is anticipated to improve the health status of the adult population at large in city.

Procedures:

After agreeing that you can take part, I will ask you some questions which will take up to 15 minutes. Your weight, height and vital signs will be measured. You will be asked to provide urine and fresh stool on a particular container I provide. I will also collect 13 ml venous blood (about 1 table spoon) from you by sterile-disposable vacutainer tube and needle (9ml in plane tube and 4 ml in tube containing EDTA). I will conduct laboratory examination to determine different hematological, serological, parasitological and clinical chemistry parameters.

Confidentiality:

The information obtained during the study will remain confidential. Disclosure of any of the data to third parties other than those allowed in the Informed Consent form will not be permitted. The results of the research study may be published, but participants' names or identities will not be

revealed. To maintain confidentiality, the investigator will keep records in locked cabinets in a locked room at the office and the results of the tests will be coded to prevent identification of the volunteers. Access to data entered into computerized files will be permitted only for authorized personnel darectly involved with the study and will be password protected. Individual-specific information may be provided to responsible local medical personnel only with your permission. Urine, stool and blood collected will not be used for other purposes. The leftover samples will be stored at the Department of Medical Laboratory Sciences of AAU in a secure place for additional tests as needed. Finally, all the biological wastes, after analysis will be safely disposed in an environmentally friendly manner.

Risks and Discomfort:

There will be minimal discomfort in giving urine and stool samples. However, there might be some minimal risk and discomfort when I take venous blood. Nevertheless, I will try to minimize the discomfort as much as possible, as the blood samples will be taken by experienced laboratory professionals.

Safety:

The venous blood sample will be collected using sterile vacutainer tube/syringe and needle by experienced health professional after disinfecting the site of picture by 70% ethanol. Moreover, leftover stool, urine and blood sample (that is not stored) will be discarded following the guideline of bio-safety.

Benefits:

By participating in the study, you will darectly benefit by being investigated for any pathogenic organisms and other clinical and hematological abnormalities. Establishing the reference interval and developing the in-house quality control materials will be used in the future to improve the general health status of Ethiopians.

Incentives:

Any positive finding in your stool/urine/blood will be taken cwere of by referring you to the nearby health institution; you will get all the laboratory investigation results for free. However, I will not pay you for taking part in this study as Well as your treatment costs. But, I will thank you for your participation.

Right to refuse or withdraw:

I assure you that our best cwere will be taken if you agree to take part in the study. You should also know that you were free to withdraw from the study at any time and that you will not be discriminated in any form of service like health.

Whom to contact:

If you have any questions, you may ask the person whom you were giving your urine, stool and blood or the principal investigator (PI) of the study or the investigators/focal persons using the following addresses:

1. Endalkachew Befekadu, Lead PI: AAU/ 09 13 95 02 50

IRB address:

Addis Ababa University, College of Health Science +251 -11-896-13 96

Code No._____

Annex IV. Consent form for adults (≥18 years)

I have read the information above, or it has been read to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. I voluntarily consent that I would participate in this study.

To give my stool ☐

To give my urine ☐

To collect my blood ☐ and be a participant in this study and understand that I have the right to withdraw from the study at any time ☐.

Print name of participant, date and signature or thumb impression of participant

_____ ____ /____ /____ (dd/mm/yy) _____

If Illiterate;

Print name of independent literate witness, date and signature of witness (if possible, this person should be selected by the participant and should have no connection to the research team)

_____ ____/____/_____ (dd/mm/yy) _____

Phone number_____

Print name of researcher, date and signature of researcher

_____ _____/____/_____ (dd/mm/yy) _____

Annex V: Information sheet for Pwerents/guardians

Project Title: Establishment of hematological reference interval for Addis Ababa

Project PI: Endalkachew Befekadu

Organization: Ethiopian Medical Laboratory Association (EMLA), Universities, Regional Laboratories and National Blood Bank, Addis Ababa, Ethiopia

Sponsor: PI=Amanuel mental specialized hospital; Finance by Ministry of Science and Technology

Introduction:

Hello! My name is _____ and I am working with a study to develop Hematological Reference Intervals For Ethiopians aged ≥ 15years from various localities in the city.

Purpose of the research:

The health laboratory plays an indispensable role in the health cwere system. It supports diagnosis (to rule in or rule out a diagnosis), monitoring of response to treatment, epidemiological surveillance, prevention as Well as Research (to understand the pathophysiology of a particular disease process). Especially there is lack of local reference interval for indigenous population and local quality control materials. Therefore, the purpose of this proposed study is to develop Hematological Reference Intervals for Ethiopians aged ≥ 15years in various sub cities in the city.

Your child has been chosen for this study. Therefore, I invite you and your child to take part in this study and contribute to the establishment of indigenous reference values were needed for providing quality laboratory service. Thus, result from this study is anticipated to improve the health status of children at large in the city.

Procedures:

After agreeing that your child can take part, I will ask you some questions which will take up to 15 minutes. Your child's weight, height and vital signs will be measured. Your child will be asked to provide urine and fresh stool on a particular container I provide. I will also collect 10 ml venous blood (about 1 table spoon) from your child by sterile-disposable vacutainer tube and needle (7ml in plane tube and 3 ml in tube containing EDTA). I will conduct laboratory

examination to determine different hematological, serological, parasitological and clinical chemistry parameters.

Confidentiality:

The information obtained during the study will remain confidential. Disclosure of any of the data to third parties other than those allowed in the Informed Consent form will not be permitted. The results of the research study may be published, but participants' names or identities will not be revealed. To maintain confidentiality, the investigator will keep records in locked cabinets in a locked room at the office and the results of the tests will be coded to prevent identification of the volunteers. Access to data entered into computerized files will be permitted only for authorized personnel darectly involved with the study and will be password protected. Individual-specific information may be provided to responsible local medical personnel only with your permission. Urine, stool and blood collected will not be used for other purposes. The leftover samples will be stored at the Department of Medical Laboratory Sciences of AAU in a secure place for additional tests as needed. Finally, all the biological wastes, after analysis will be safely disposed in an environmentally friendly manner.

Risks and Discomfort:

There will be minimal discomfort in giving urine and stool samples. However, there might be some minimal risk and discomfort when I take venous blood. Nevertheless, I will try to minimize the discomfort as much as possible, as the blood samples will be taken by experienced laboratory professionals.

Safety:

The venous blood sample will be collected using sterile vacutainer tube/syringe and needle by experienced health professional after disinfecting the site of picture by 70% ethanol. Moreover, leftover stool, urine and blood sample (that is not stored) will be discarded following the guideline of bio-safety.

Benefits:

By participating in the study, your child will directly benefit by being investigated for any pathogenic organisms and other clinical and hematological abnormalities. Establishing the reference interval and developing the in-house quality control materials will be used in the future to improve the general health status of Ethiopians.

Incentives:

Any positive finding in your child's stool/urine/blood will be taken cwere of by referring him/her to the nearby health institution; you will get all the laboratory investigation results for free. However, I will not pay you/your child for taking part in this study as Well as for your child's treatment costs. But, I will thank you for your participation.

Right to refuse or withdraw:

I assure you that our best cwere will be taken if you agree to take part in the study. You should also know that you/your child were free to withdraw from the study at any time and that you/your child will not be discriminated in any form of service like health.

Whom to contact:

If you have any questions, you may ask the person whom you were giving information or the principal investigator (PI) of the study or the investigators/focal persons using the following addresses:

1. Endalkachew Befekadu, Lead PI: AAU/ 09 13 95 02 50

IRB address: Addis Ababa University, College of Health Science +251 -11-896-13 96

Code No._____

Annex VI. Consent form for pwerents/guardians

I have read the information above, or it has been read to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. I voluntarily consent that my child participates in this study (provided he/she gives assent for children 15-17 years).

To give his/her stool ☐

To give his/her urine ☐

To collect her/his blood ☐ and be a participant in this study and understand that I have the right to withdraw my child from the study at any time ☐.

Print name of participant, date and signature or thumb impression of participant

_____ ____ /____ /____ (dd/mm/yy) _____

If Illiterate;

Print name of independent literate witness, date and signature of witness (if possible, this person should be selected by the participant and should have no connection to the research team)

_____ ____/____/_____ (dd/mm/yy) _____

Print name of researcher, date and signature of researcher

_____ _____/____/_____ (dd/mm/yy) _____

Annex VII: Information sheet for children 15—17 years (15—17 ዓመት ለሆኑ ህፃናት መረጃ)

የ ፕሮጀክቱ ርዕስ፡ “እድሜአቸው አምስት ዓመትና ከዚያ በላይ ለሆኑ ኢትዬጵያውያን የጠፍ ማ ሰው ደም ወስጥ የሚ ኙ የ ክሊኒ ካል ላቦራቶሪ ምር መራዎች ማጠን ሪፈረንስ ኢንተርቫል ማ ራት “፡ በበርካታ ሜ ከላት የሚ ራ ጥናት “

የ ፕሮጀክቱ ዋና ተመራማሪ: እንዳልካቸው በፍቃዱ (ኤም.ኤስ.ሲበአዲስ አበባ ዩኒቨርስቲ የ ህክምና ላቦራቶሪ ትምህርት ክፍል ተባባሪ ፕሮፌሰር)

ተባባሪ ተመራማሪዎች የ ስምዝርዝር ተያይዟል

ተቋማት፡ የ ኢትዮጵያ ህክምና ላቦራቶሪ ማህበር፣ ዩኒቨርስቲዎች፣ ሪጅናል ላቦራቶሪዎች፣ እና ብሄራዊ የ ደም ባንክ አገ ልግሎትየ ኢትዮጵያ ህክምና ላቦራቶሪ ማህበር፣

ስፖንሰር (ወጪውን የ ሸፈነ ው)፡ ሳይንስና ቴክኖሎጂ ሚ ስቴርነ ው፡ ፡ የ ፒአዩን ደምዘ የ ሸፈነ ውአ ሙኤል ሆስፒታልነ ው፡ ፡

መግቢያ:

ጤ ይስጥልኝ! ስሜ _____ ነ ው፡ ፡ በላቦራቶሪ ወስጥ የ ጥራት መሞ ሜሪያ ንጥረ ነ ገ ር እና የ ጠፍ ማ ሰውደም ወስጥ የ ሚ ኙ የ ሄማቶሎጂ ምር መራዎች ማጠን ሪፈረንስ ኢንተርቫል እድሜአቸውአምስት ዓመትና ከዚያ በላይ ለሆኑ ኢትዮጵያውያን ለማ ራት በአዲስ አበባ የ ተለያዩ ክፍለ ከተማዎች ጥናት እያካሄድኩኝ ነ ው፡ ፡

የ ምርምር ጥናቱ አላማ:

የ ህክምና ላቦራቶሪ በጠፍ ው አገ ልግሎት ወስጥ ከፍተኛ ሚ ና ይጫወታል፡ ፡ ምር መራን ለሚ ጋገ ጥ፣ ህመማን ለመድሃ ኒ ቶች ምላሽ ማ ጠቃቸውን ከትትል ለሚድረግ፣ የ በሽታዎችን ስርጭት ለማጥና ት፣ በሽታ ለማ ላከል እና ስለበሽታዎች ምን ጭምርምር ለሚድረግ አስተዋፅ ዎ ያደር ጋል፡ ፡ በተለይም በከተማዎችን የ ጠፍ ማ ሰውየ ላቦራቶሪ ወጤ ማመዳደሪያ ሪፈረንስ ኢንተርቫል የ ለም፡ ፡ ስለሆነ ምየ ዚህ ጥናት ዓላማበአገ ር የ ጠፍ ማ ሰውየ ሄማቶሎጂ ወጤ ማወዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸው አምስትና ከዚያ በላይ ለሆኑ በተለያየ በአዲስ አበባ ለሚኖሩ ኢትዮጵያውያን መሥራት ነ ው፡ ፡

አንተም/አንቺም በዚህ ጥናት እንድትሳተፍ/ፊ እየ ጋበዝኩኝ ወላጆችሽ/ወላጆችህ ፈቃዳቸውን ገ ልፀ ዋል፡ ፡ ፡ ስለዚህ በዚህ ጥናት በማ ተፍ በአገ ራችን በላቦራቶሪ ወስጥ የ ሚሚ ት የ ጥራት መሞ ሜሪያ እና የ ጠፍ ማ ሰው

የክሊኒካል ላቦራቶሪ ወጤት ማመዳደሪያ ሪፈረንስ ኢንተርቫል ለማስራት አስተዋፅዎ እንድታደርግ/ጊ ተጋብዘሃል/ሻል፡፡ ጥራት ያለውየላቦራቶሪ አገልግሎት ለማጠት አስፈላጊ ናቸው፡ ስለዚህ የዚህ ጥናት ወጤት በከተማውወስጥ የአዋቂ ሰዎች ጠፍን ለማሻሻል ይረዳል፡፡

የ ጥናቱ አካሄድ:

በጥናቱ ለማሳተፍ ከተስማማህ/ሽ 15 ደቂቃ የሚወስድ ጥያቄ ጠይቅሃለወ/ሻለው፡ ከብደት፣ ቁመት፣ የ ከንድ እና የ ደም ግፊት ልኬት ይወሰዳል፡፡ ሽንትና አይነ ምድር በ ምሳጠው እቃ እንድትሰጠኝ/ጯኝ እጠይቃለው፡፡፣ በተጨማሪም 10 ሚሊ ሊትር (አንድ የ ሾርባ ማንኪያ የ ሚሆን) በንፁህ ቫኩቴይነ ር ብልቃጥ እና ሞርፌ እቀዳለው (7ሚሊ ሊትር በ ባዶ ቲዩብ፣ 3 ሚሊ ሊትር ደምእንዳይረጋ የ ሚያደርግ ንጥረ ነ ገ ር ፣ ኢዲቲኤ፣ ባለበት ቲዩብ)፡፡ የ ሄማቶሎጂ፣ ሴሮሎጂ፣ ፓራሲቶሎጂ ምርመራዎችን አካሂዳለው፡፡

ሚስጥር ስለማጠበቅ:

በዚህ ጥናት የ ሚሰበሰብ መረጃ በ ሚስጥር ይጠበቃል፡፡ መረጃ በዚህ የ ስምምነ ት ቅፅ ከተፈቀደው ወጪ ለሶስተኛ ወገን ተላልፎ አይሰጥም፡ የዚህ ጥናት ወጤት ሊታተም ይችላል ነ ገ ር ግን የ ጥናቱ ተሳታፊዎች ስምና ማንኛውም መለያ አይገለፅም፡ ሚስጥራዊነ ቱን ለማጠበቅ የዚህ ጥናት መረጃዎችን በተቆለፈ ክፍል በተቆለፈ ካቢኔት ወስጥ ይቀመጣል፣ የ ፈቃደኛ ተሳታፊዎችን ማንነ ትን ላለማሳወቅ ወጤቶችም በ ኮድ ይቀመጣሉ፡፡ በ ኮምፒዩተር ወስጥ ለተቀማጡ ፋይሎች ለጥናቱ ተመራማሪዎች ብቻ የ ሚፈቀዱና በ ሚስጥር ቁልፍ የ ሚጠበቁ ይሆናል፡፡ የ ተሳታፊ ወጤት ለህክምና ባለሞያ ሊተላለፍ የ ሚችለውበተሳታፊውፈቃድ ብቻ ነ ው፡ የ ተሰበሰበው ሽንት፣ ዓይነ ምድርና ደም ለሌላ አገልግሎት አይወልም፡ የ ሚጠርፉት ናሙናዎች በአዲስ አበባ ዩኒቨርስቲ ህክምና ላቦራቶሪ ትምህርት ክፍል ደህና ቦታ ተቀምጠውለተጨማሪ ምርመራዎች እንደ አስፈላጊታቸውጥቅም ላይ ይወላሉ፡፡ በ ሜጨረሻም ተሰርቶባቸው የ ተራረፉ የ ሚዱፉ ናሙናዎች አካባቢን በ ሚይበክል መልኩ በጥንቃቄ ይወገዳሉ፡፡

ጥናቱ የ ሚያስከትላቸውየ ጠፍ ችግሮችና አለመመቸት:

ሽንትና ዓይነ ምድር በ ማጠት የ ሚደርስ ማንነ ኛ አለመመቸት ሊኖር ይችላል፡፡ ሆኖም ደም በ ሜቃዳበት ጊዜ ማንነ ኛ መጎዳትና የ ተወሰነ አለመመቸት ሊኖር ይችላል፡፡ ይሁን እንጂ በ ተቻለ ማጠን ልምድ ያለውየ ላቦራቶሪ ባለሞያ በ ማጠቀምአለመመቸቱን ለመቀነ ስ እንሞክራለን፡፡

ደህንነ ት:

የደምናማ በሚወሰድበት ጊዜ በንፅህ የደም መቅጃ በማጠቀም የሚቃዳውን ቦታ በ70% አልኮል በሚፅዳት ልምድ ባለውባለሞያ ይከናወናል፡፡ በተጨማሪም ጥቅም ላይ ከዋሉ በኋላ ለሚከቀመጥ የሚሆኑ የሚደፉ የዓይነ ምድር፣ ሽንት እና ደምትራፊዎች የላቦራቶሪ ደህንነት መመሪያ በማከተል ይወገዳሉ፡፡

ጥቅማጥቅሞች፡

በዚህ ጥናት በማተፍ ለበሽታ አምጪተህዋስያን፣ ደምና ሽንት ምርመራ በሚድረግ የጤንነት ሁኔታ ማወቅ ይቻላል፡፡ በአገር ወስጥ በላቦራቶሪ ወስጥ የሚሞረት የጥራት መሞርመሪያ እና የጠፋማሰውየሄማቶሎጂ ወጠት መመዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸውአምስትና ከዚያ በላይ ለሆኑ በተለያየ ክፍለ ከተማለሚኖሩ አዲስ አበቤዎች ማከራቱየአዲስ አበባ ነዋሪዎችን የጠፋ ሁኔታለማሻሻል ይረዳል፡፡

በጥናቱ ለማተፍ ማትጊያ:

ከዓይነ ምድር፣ ሽንት እና ደም ምርመራ ጠፋማ ያልሆነ ወጠት ከተገኘ በአቅራቢው ወደ ማኝ ጠፋ ተቋም ትላካለህ/ትላኪያለሽ፣ የላቦራቶሪ ወጠቆቹን በነፃ ታገኛለህ/ታገኚያለሽ፡፡ ይሁን እንጂ በዚህ ጥናት ለማተፍምሆነ ለመድሃኒት ክፍያ አይሰጥም፡፡ ስለተሳትፎህ/ህ ግን እናማሰግናለን፡፡

ያለማተፍ መበት:

በዚህ ጥናት ከተሳተፍክ/ሽ የቻልነወን ሁሉ እንክብካቤ እናደርጋለን፡፡ በሜኘውም ሰዓት ከጥናቱ መወጣት እንደሜቻልና ይህም በምታገኘወሰኚው አገልግሎት ላይ (ለምሳሌ የጠፋ አገልግሎት) ምንም አይነት ልዩነት አይደረግም፡፡

ጥያቄ ካለ ለማን ጋገር:

ምንም ዓይነት ጥያቄ ካለ የዓይነ ምድር፣ ሽንት እና የ ደምናማ የሰጠሽወን/የሰጠሽወን ሰውማጠየቅ ይቻላል ወይምየፕሮጀክቱ ዋና ተመራማሪን ወይምተባባሪዎችና በየተቋመየ ማኘ ተወካዮችን በማከተለውአድራሻ ማጠየቅ ይቻላል፡፡

1. እንዳልካችውበፍቃዱ፣ መሪ ተመራማሪ፣ አ.አ.ዩ 09 13 95 02 50

ኮድ._____

Annex VIII. Consent form for children 15-17 years 15—17 ዓመት ለሆኑ ህፃናት የ ስምምነ ት ቅፅ)

ከላይ የ ተገ ለፀ ውን መረ ጃ አን ብቤአለ ሁ /ወይም ተነ ቦልኛ ል፡ ፡ ጥያ ቄ ለማ ጠየ ቅ ዕድ ል ተሰ ጥቶኝ ጠይቄ በሚያ ረካ መል ኩ ተመ ልሶ ልኛ ል፡ ፡ ወላ ጆቼ እስ ከፈ ቀዱ ድረ ስ በዚህ ጥና ት ለመ ሳተ ፍ ተስ ማሙ ቻለ ሁ፡ ፡

የ ዓይነ ምድ ር ናመ ኛ ለመ ሳጠ ት ☐

የ ሽን ት ናመ ኛ ለመ ሳጠ ት ☐

ደም ለመ ቀዳ ት ☐ እና በዚህ ጥና ት ተሳ ታፊ ለመ ሆን ፣ በማ ንኛ ውም ሰዓ ት ከጥና ቱ ለመ ውጣ ት መበ ት እን ዳለ ኝም ተረ ድቻ ለሁ ☐.

የ ተሳ ታፊ ስም፡ ቀን እና ፊር ማ(ወይ ምአ ሻራ) ከዚህ በታ ች ይፃ ፉ

_____ ____ /____ /____ (ቀን /ወር /ዓመ ተ ምህ ረት)

ያ ልተ ሙ ከሆ ኑ ;

የ ተሙ ገ ለልተ ኛ እማ ኝ ሰው ስም፡ ቀንና ፊር ማ (ከተ ቻለ ይህ ሰው በተሳ ታፊ ውቢ ሚጥ ና ከተ ሙሚ ሪ አባ ላት ግኑ ኝነ ት የ ሌለ ውቢ ሆን)

_____ ____/____/_____ (dd/mm/yy) _____

ስልክ ቁጥር (የ ወላ ጅ ወይም አሳ ዳጊ)_____

የ ተሙ ሚሪ ውስ ም፡ ቀንና ፊር ማ

_____ _____/____/_____ (dd/mm/yy) _____

Annex IX: Information sheet for adults (≥18 years old) (18 ዓመትና ከዚያ በላይ ለሆኑ አዋቂዎች መረጃ)

የ ፕሮጀክቱ ርዕስ፡ ‘‘እድሜቸውአምስት ዓመትና ከዚያ በላይ ለሆኑ ኢትዬጵያወያን የ ጠፍማ ሰውደም ወስጥ የ ሚ ኙየ ክሊኒ ካል ላቦራቶሪ ምርመራዎች ማጠን ሪፈረንስ ኢንተርቫል ማስራት ‘‘፡ በበርካታ ሜዕከላት የ ሚሰራ ጥናት ‘‘

የ ፕሮጀክቱ ዋና ተመራማሪ: እንዳልካቸውበፍቃዱ (ኤም. ኤስ. ሲ)

ስፖንሰር (ወጪውን የ ሸፈነ ው)፡ አማኑኤል ሆስፒታል

መግቢያ:

ጤና ይስጥልኝ! ስሜ_____ነው፡ ፡ በላቦራቶሪ ወስጥ የ ጠፍማ ሰውደም ወስጥ የ ሚ ኙየ ሄማቶሎጂ ምርመራዎች ማጠን ሪፈረንስ ኢንተርቫል እድሜቸውአምስት ዓመትና ከዚያ በላይ ለሆኑ ኢትዮጵያወያን ለማስራት በአገራችን የ ተለያዩ ክልሎች ጥናት እያካሄድኩኝ ነው፡ ፡

የ ምርምር ጥናቱ አላማ:

የ ህክምና ላቦራቶሪ በጠፍው አገልግሎት ወስጥ ከፍተኛ ሚና ይጫወታል፡ ፡ ምርመራን ለማረጋገጥ፣ ህመማን ለመድሃኒቶች ምላሽ ማስጠታቸውን ከትትል ለሚድረግ፣ የ በሽታዎችን ስርጭት ለማጥናት፣ በሽታ ለማስላከል እና ስለበሽታዎች ምንጭምርምር ለሚድረግ አስተዋፅዎ ያደርጋል፡ ፡ በተለይም በከተማቸን የ ጠፍማ ሰውየ ላቦራቶሪ ወጤት ማመዳደሪያ ሪፈረንስ ኢንተርቫል የ ለም፡ ፡ ስለሆነ ም የ ዚህ ጥናት ዓላማ በከተማቸን የ ጠፍማ ሰው የ ሄማቶሎጂ ወጤት ማወዳደሪያ ሪፈረንስ ኢንተርቫል እድሜቸውአምስትና ከዚያ በላይ ለሆኑ በተለያየ ክፍለ ከተማለሚኖሩ ኢትዮጵያወያን መሥራት ነው፡ ፡

እርስዎም ለዚህ ጥናት ተመርጠዋል፡ ፡ ስለዚህ በዚህ ጥናት እንዲሳተፉና በከተማቸን በላቦራቶሪ ወስጥ የ ሚመረት የ ጠፍማ ሰውየ ሄማቶሎጂ ወጤት ማመዳደሪያ ሪፈረንስ ኢንተርቫል ለማስራት አስተዋፅዎ እንዲያደርጉ ተጋብዘዋል፡ ፡ ሁለቱም ጥራት ያለውየ ላቦራቶሪ አገልግሎት ለማጠት አስፈላጊ ናቸው፡ ፡ ስለዚህ የ ዚህ ጥናት ወጤት በከተማውወስጥ የ አዋቂ ሰዎች ጠን ለማሻሻል ይረዳል፡ ፡

የ ጥናቱ አካሄድ:

በጥናቱ ለመሳተፍ ከተስማሙ15 ደቂቃ የሚወስድ ጥያቄ እጠይቅዎታል፡፡ ከብደት፣ ቁመት፣ የክንድ እና የደም ግፊት ልኬት ይወሰዳል፡፡ ሽንትና አይነ ምድር በምሳጡአቃእንድትሰጠኝ እጠይቃለው፡፡፣ በተጨማሪም 13 ሚሊ ሊትር (አንድ የሾርባ ማንኪያ የሚሆን) በንፁህ ቫኩቴይነር ብልቃጥ እና ሞርፌ እቀዳለው (9ሚሊ ሊትር በባዶ ቲዩብ፣ 4 ሚሊ ሊትር ደም እንዳይረጋ የሚያደርግ ንጥረ ነገር ፣ኢዲቲኤ፣ ባለበት ቲዩብ)፡፡ የሄማቶሎጂ፣ ሴሮሎጂ፣ ፓራሲቶሎጂ ምርመራዎችን እካሂዳለው፡፡

ሚስጥር ስለመጠበቅ:

በዚህ ጥናት የሚሰበሰብ መረጃ በሙሉ በሚስጥር ይጠበቃል፡፡ መረጃ በዚህ የስምምነት ቅፅ ከተፈቀደው ወጪ ለሶስተኛ ወገን ተላልፎ አይሰጥም፡፡ የዚህ ጥናት ውጤት ሊታተም ይችላል ነገር ግን የጥናቱ ተሳታፊዎች ስምና ማንኛውም መለያ አይገለፅም፡፡ ሚስጥራዊነቱን ለመጠበቅ የዚህ ጥናት መረጃዎችን በተቆለፈ ክፍል በተቆለፈ ካቢኔት ወስጥ ይቀመጣል፣ የፈቃደኛ ተሳታፊዎችን ማንነትን ላለማሳወቅ ወጤቶችም በኮድ ይቀመጣሉ፡፡ በኮምፒዩተር ወስጥ ለተቀመጡ ፋይሎች ለጥናቱ ተመራማሪዎች ብቻ የሚፈቀዱና በሚስጥር ቁልፍ የሚጠበቁ ይሆናል፡፡ የተሳታፊ ወጤት ለህክምና ባለሞያ ሊተላለፍ የሚችለውበተሳታፊውፈቃድ ብቻ ነው፡፡ የተሰበሰበው ሽንት፣ ዓይነ ምድርና ደም ለሌላ አገልግሎት አይወልም፡፡ የሚጠርፉት ናሙናዎች በአዲስ አበባ ዩኒቨርስቲ ህክምና ላቦራቶሪ ትምህርት ክፍል ደህና ቦታ ተቀምጠውለተጨማሪ ምርመራዎች እንደ አስፈላጊታቸውጥቅም ላይ ይውላሉ፡፡ በሜጨረሻም ተሰርቶባቸው የተራረፉ የሚፉ ናሙናዎች አካባቢን በሚይበክል መልኩ በጥንቃቄ ይወገዳሉ፡፡

ጥናቱ የሚያስከትላቸውየጤና ችግሮችና አለመመቸት:

ሽንትና ዓይነ ምድር በመሳጡት የሚደርስ ማከኛ አለመመቸት ሊኖር ይችላል፡፡ ሆኖም ደም በሚቆዳበት ጊዜ ማከኛ መነዳትና የተወሰነ አለመመቸት ሊኖር ይችላል፡፡ ይሁን እንጂ በተቻለ ማጠን ልምድ ያለውየላቦራቶሪ ባለሞያ በማጠቃምአለመመቸቱን ለመቀነስ እንሞክራለን፡፡

ደህንነት:

የደም ናሙና በሚወሰድበት ጊዜ በንፁህ የደም መቅጃ በማጠቃምየሚቆዳወን ቦታ በ70% አልኮል በሚፀዳት ልምድ ባለውባለሞያ ይከናወናል፡፡ በተጨማሪም ጥቅምላይ ከዋሉ በኋላ ለሚቀመጥ የሚሆኑ የሚፉ የዓይነ ምድር፣ ሽንት እና ደምትራፊዎች የላቦራቶሪ ደህንነት መመሪያ በመከተል ይወገዳሉ፡፡

ጥቅማጥቅሞች፡

በዚህ ጥናት በመሳተፍ ለበሽታ አምጪተህዋስያን፣ ደምና ሽንት ምርመራ በሚድረግ የጤንነት ሁኔታ ማወቅ ይቻላል፡፡ በከተማው ወስጥ የጠፋማ ሰውየሄማቶሎጂ ወጤት ማመዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸው

አምስትና ከዚያ በላይ ለሆኑ በተለያየ ከፍለ ከተማ ለሚኖሩ አዲስ አበቤዎች ማህራቱ የከተማውን የጠፍ ሁኔታ ለማሻሻል ይረዳል፡ ፡

በጥናቱ ለመሳተፍ ማትጊያ:

ከዓይነ ምድር፣ ሽንት እና ደም ምርመራ ጠፍ ማያልሆነ ወጪ ከተገኝ በአቅራቢውወደ ሚገኝ ጠፍ ተቋም ይላካሉ፣ የላቦራቶሪ ውጤቶቹን በነፃ ያገኛሉ፡ ፡ ይሁን እንጂ በዚህ ጥናት ለመሳተፍም ሆነ ለመድሃኒት ክፍያ አይሰጥም፡ ፡ ስለተሳትፎዎ ግን እናመሰግናለን፡ ፡

ያለመሳተፍ መብት:

በዚህ ጥናት ከተሳተፉ የቻልነውን ሁሉ እንከብካቤ እናደርጋለን፡ ፡ በሞኘውም ሰዓት ከጥናቱ መውጣት እንደሚቻልና ይህም በሚያገኙት አገልግሎት ላይ (ለምሳሌ የጠፍ አገልግሎት) ምንም አይነት ልዩነት አይደረግም፡ ፡

ጥያቄ ካለ ለማን ጋገር:

ምንም ዓይነት ጥያቄ ካለ የዓይነ ምድር፣ ሽንት እና የ ደም ናሙና የሰጡን ሰው ማከየቅ ይቻላል ወይም የፕሮጀክቱ ዋና ተመራማሪን ወይም ተባባሪዎችና በየተቋሙየሚገኙ ተወካዮችን በሚከተለው አድራሻ ማከየቅ ይቻላል፡ ፡

1. እንዳልካቸውበፍቃዱ፣ ሜሪ ተመራማሪ፣ አ.አ.ዩ 09 13 95 02 50

ኮድ._____

Annex X. Consent form for adults (≥18 years)(18 ዓመት እና ከዚያ በላይ ለሆኑ አዋቂዎች የ ስ ምምነ ት ቅፅ)

ከላይ የ ተገ ለፀ ውን መረ ጃ አን ብቤአለ ሁ /ወይም ተነ ቦ ልኛ ል፡ ፡ ጥያ ቄ ለ ማ ጠየ ቅ ዕ ድል ተሰ ጥቶ ኝ ጠይ ቄ በ ሚያ ረ ካ መ ልኩ ተ መ ል ሶ ል ኛ ል፡ ፡ በ ዚህ ጥና ት ለ መ ሳ ተ ፍ በ ፈ ቃ ደ ኝነ ት ተ ስ ማ ም ቻ ለ ሁ፡ ፡

የ ዓ ይነ ምድ ር ና መ ኛ ለ መ ሳ ጠት ☐

የ ሽ ን ት ና መ ኛ ለ መ ሳ ጠት ☐

ደ ም ለ መ ቀ ዳ ት ☐ እ ና በ ዚህ ጥና ት ተ ሳ ታ ፊ ለ መ ሆ ን ፣ በ ማ ን ኛ ው ም ሰ ዓ ት ከ ጥና ቱ ለ መ ው ጣ ት መ ብ ት እ ን ዳ ለ ኝ ም ተ ረ ድ ቻ ለ ሁ ☐.

የ ተ ሳ ታ ፊ ስ ም፣ ቀ ን እ ና ፊ ር ማ (ወ ይ ም አ ሻ ራ) ከ ዚህ በ ታ ች ይ ፃ ፉ

_____ ____ /____ /____ (ቀ ን /ወ ር /ዓ መ ተ ም ህ ረ ት)

ያ ል ተ ማ ሩ ከ ሆ ኑ ;

የ ተ ማ ሩ ገ ለ ል ተ ኛ እ ማ ኝ ስ ው ስ ም፣ ቀ ን ና ፊ ር ማ (ከ ተ ቻ ለ ይ ህ ስ ው በ ተ ሳ ታ ፊ ው ቢ ሚ ጥ ና ከ ተ መ ራ ሚ አ ባ ላ ት ግ ኑ ኝ ነ ት የ ሌ ለ ው ቢ ሆ ን)

_____ ____/____/_____ (dd/mm/yy) _____

ስ ል ክ ቁ ጥ ር _____

የ ተ መ ራ ሚ ው ስ ም፣ ቀ ን ና ፊ ር ማ

_____ _____/____/_____ (dd/mm/yy) _____

Annex XI: Information sheet for Pwerents/guardians (ለወላጆች/አሳዳጊዎች መረጃ)

የ ፕሮጀክቱ ርዕስ፡ “እድሜአቸው አምስት ዓመትና ከዚያ በላይ ለሆኑ ኢትዬጵያወያን የ ጠፍ ማ ሰው ደም ወስጥ የ ሚ ኙ የ ክሊኒ ካል ላቦራቶሪ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል መሻራት ፡ በበርካታ ሜዕከላት የ ሚሰራ ጥናት “

የ ፕሮጀክቱ ዋና ተመራማሪ : እንዳልካቸውበፍቃዱ (ኤም. ኤስ .ሲ)

ስፖንሰር (ወጪውን የ ሸፈነ ው)፡ አማኑኤል ሆስፒታል

መግቢያ :

ጤና ይስጥልኝ! ስሜ_____ ነው፡ ፡ በላቦራቶሪ ወስጥ የ ጠፍ ማ ሰውደም ወስጥ የ ሚ ኙ የ ሄማቶሎጂ ምርመራዎች መጠን ሪፈረንስ ኢንተርቫል እድሜአቸውአምስት ዓመትና ከዚያ በላይ ለሆኑ አዲስ አበባ ነዋሪዎች ለመሻራት በከተማቹን የ ተለያዩ ክፍለ ከተሞች ጥናት እያካሄድኩኝ ነው፡ ፡

የ ምርምር ጥናቱ አላማ:

የ ህክምና ላቦራቶሪ በጠፍው አገልግሎት ወስጥ ከፍተኛ ሚና ይጫወታል፡ ፡ ምርመራን ለማረጋገጥ፣ ህመማን ለመድሃኒቶች ምላሽ መከታተቸውን ከትትል ለሚድረግ፣ የ በሽታዎችን ስርጭት ለማጥናት፣ በሽታ ለመከላከል እና ስለበሽታዎች ምንጭምርምር ለሚድረግ አስተዋፅዎ ያደርጋል፡ ፡ በተለይም በከተማቹን የ ጠፍ ማ ሰውየ ላቦራቶሪ ወጤት መመዳደሪያ ሪፈረንስ ኢንተርቫል የ ለም፡ ፡ ስለሆነ ምየ ዚህ ጥናት ዓላማበከተማቹን ወስጥ በላቦራቶሪ ወስጥ የ ጠፍ ማ ሰውየ ሄማቶሎጂ ወጤት መመዳደሪያ ሪፈረንስ ኢንተርቫል እድሜአቸውአምስትና ከዚያ በላይ ለሆኑ በተለያየ ክልል ለሚኖሩ ኢትዮጵያወያን መሥራት ነው፡ ፡

ልጅዎ ለዚህ ጥናት ተመርጧል/ጣለች፡ ፡ ስለዚህ በዚህ ጥናት እንድትሳተፉና በከተማቹን በላቦራቶሪ ወስጥ የ ሚመረት የ ጠፍ ማ ሰውየ ሄማቶሎጂና የ ክሊኒ ካል ኬሚስትሪ ወጤት መመዳደሪያ ሪፈረንስ ኢንተርቫል ለመሻራት አስተዋፅዎ እንዲያደርጉ ተጋብዘኃል፡ ፡ ጥራት ያለው የ ላቦራቶሪ አገልግሎት ለመሻጠት አስፈላጊ ናቸው፡ ፡ ስለዚህ የ ዚህ ጥናት ወጤት በከተማውወስጥ የ ልጆችን ጤና ለማሻሻል ይረዳል፡ ፡

የ ጥናቱ አካሄድ:

በጥናቱ ልጅዎ እንዲሳተፍ ከተስማሙ15 ደቂቃ የሚወስድ ጥያቄ እጠይቅዎታው፡ ፡ የልጅዎ ክብደት፣ ቁመት፣ የክንድ እና የደም ግፊት ልኬት ይወሰዳል፡ ፡ ልጅዎ ሽንትና አይነ ምድር በምንሰጠው እቃ እንድትሰጠን/እንዲሰጠን እጠይቃለው፡ ፡ በተጨማሪም 10 ሚሊ ሊትር (አንድ የሾርባ ማንኪያ የሚሆን) በንፁህ ቫኩቴይነር ብልቃጥ እና ሞርፌ እቀዳለው(7ሚሊ ሊትር በባዶ ቲዩብ፣ 3 ሚሊ ሊትር ደም እንዳይረጋ የሚያደርግ ንጥረ ነገር ፣ኢዲቲኤ፣ ባለበት ቲዩብ)፡ ፡ የሄማቶሎጂ፣ ሴሮሎጂ፣ ፓራሲቶሎጂ እና የክሊኒካል ኬሚስትሪ ምርመራዎችን አካሂዳለው፡ ፡

ሚስጥር ስለማጠበቅ:

በዚህ ጥናት የሚሰበሰብ መረጃ በሚሉ በሚስጥር ይጠበቃል፡ ፡ መረጃ በዚህ የስምምነት ቅፅ ከተፈቀደው ወጪ ለሶስተኛ ወገን ተላልፎ አይሰጥም፡ ፡ የዚህ ጥናት ውጤት ሊታተም ይችላል ነገር ግን የጥናቱ ተሳታፊዎች ስምና ማንኛውም መለያ አይገለፅም፡ ፡ ሚስጥራዊነቱን ለማጠበቅ የዚህ ጥናት መረጃዎችን በተቆለፈ ክፍል በተቆለፈ ካቢኔት ወስጥ ያስቀምጣሉ፣ የፈቃደኛ ተሳታፊዎችን ማንነትን ላለማሳወቅ ወጤቶችም በኮድ ይቀመጣሉ፡ ፡ በኮምፒዩተር ወስጥ ለተቀማጡ ፋይሎች ለጥናቱ ተመራማሪዎች ብቻ የሚፈቀዱና በሚስጥር ቁልፍ የሚጠቁ ይሆናል፡ ፡ የተሳታፊ ወጤት ለህክምና ባለሞያ ሊተላለፍ የሚችለውበተሳታፊውፈቃድ ብቻ ነው፡ ፡ የተሰበሰበው ሽንት፣ ዓይነ ምድርና ደም ለሌላ አገልግሎት አይወልም፡ ፡ የሚጠፉት ናሙናዎች በአዲስ አበባ ዩኒቨርስቲ ህክምና ላቦራቶሪ ትምህርት ክፍል ደህና ቦታ ተቀምጠውለተጨማሪ ምርመራዎች እንደ አስፈላጊታቸውጥቅም ላይ ይውላሉ፡ ፡ በሚጨረሻም ተሰርቶባቸው የተራረፉ የሚፉ ናሙናዎች አካባቢን በሚይበክል መልኩ በጥንቃቄ ይወገዳሉ፡ ፡

ጥናቱ የሚያስከትላቸውየጠፉ ችግሮችና አለመመቸት:

ሽንትና ዓይነ ምድር በማጠት ማከኘ አለመመቸት ሊኖር ይችላል፡ ፡ ሆኖም ደም በሚቆዳበት ጊዜ ማከኘ መሳዳትና የተወሰነ አለመመቸት ሊኖር ይችላል፡ ፡ ይሁን እንጂ በተቻለ ማጠን ልምድ ያለውየላቦራቶሪ ባለሞያ በማጠቀምአለመመቸቱን ለመቀነስ እንሞክራለን፡ ፡

ደህንነት:

የደም ናሙና በሚወሰድበት ጊዜ በንፁህ የደም መቅጃ በማጠቀም የሚቆዳውን ቦታ በ70% አልኮል በሚፅዳት ልምድ ባለውባለሞያ ይከናወናል፡ ፡ በተጨማሪም ጥቅምላይ ከዋሉ በኋላ ለማስቀመጥ የሚይሆኑ የሚፉ የዓይነ ምድር፣ ሽንት እና ደምትራፊዎች የላቦራቶሪ ደህንነት መሚያ በማተል ይወገዳሉ፡ ፡

ጥቅማጥቅሞች፡

በዚህ ጥናት በመሳተፍ ለበሽታ አምጪተህዋስያን፣ ደምና ሽንት ምርመራ በሚድረግ የልጅዎን ጤንነት ሁኔታ ማወቅ ይቻላል፡፡ በከተማችን ወስጥ በላቦራቶሪ ወስጥ የሚሚት የጠፋሰውየሄማቶሎጂ ወጠጭ መመዳደሪያ ሪፈረንስ ኢንተርቫል እድሜቸው አምስትና ከዚያ በላይ ለሆኑ በተለያየ ክፍለ ከተማ ለሚኖሩ የከተማው ነዋሪዎች መሳራቱየከተማውን የጠፋ ሁኔታለማሻሻል ይረዳል፡፡

በጥናቱ ለመሳተፍ ማትጊያ:

ከዓይነ ምድር፣ ሽንት እና ደም ምርመራ ጠፋያልሆነ ወጠጭ ከልጅዎ ከተገኘ በአቅራቢውወደ ሚገኝ ጠፍ ተቋም ይላካሉ፣ የልጅዎን ላቦራቶሪ ወጠቆች በነፃ ያገኛሉ፡፡ ይሁን እንጂ በዚህ ጥናት ለመሳተፍም ሆነ ለመድሃኒት ክፍያ አይሰጥም፡፡ ስለተሳትፎዎ ግን እናመሰግናለን፡፡

ያለመሳተፍ መበት:

በዚህ ጥናት ከተሳተፉ የቻልነወን ሁሉ እንክብካቤ እናደርጋለን፡፡ በሞኘውም ሰዓት እርስዎም ሆነ ልጅዎ ከጥናቱ መውጣት እንደሚቻልና ይህም እርስዎም ሆኑ ልጅዎ በሚያገኙት አገልግሎት ላይ (ለምሳሌ የጠፍ አገልግሎት) ምንምአይነት ልዩነት አይደረግም፡፡

ጥያቄ ካለ ለማ ጋገር:

ምንም ዓይነት ጥያቄ ካለ የዓይነ ምድር፣ ሽንት እና የ ደም ናሙና የሰጠኩን ሰው ማጠየቅ ይቻላል ወይም የፕሮጀክቱ ዋና ተመራማሪን ወይም ተባባሪዎችና በየተቋሙየሚኙ ተወካዮችን በሚከተለው አድራሻ ማጠየቅ ይቻላል፡፡

1. እንዳልካቸውበፍቃዱመሪ ተመራማሪ፣ አ.አ.ዩ 09 13 95 02 50

Annex XII. Consent form for parents/guardians (ለወላጆች/አሳዳጊዎች የስምምነት ቅፅ)

ከላይ የተገለፀውን መረጃ አንብቤአለሁ /ወይምተነቦልኛል፡፡ ጥያቄ ለማቀርብ ዕድል ተሰጥቶኝ ጠይቄ በሚያረካ መልኩ ተመልሶልኛል፡፡ ልጄ እንዲሳተፍ/እንድትሳተፍ ተስማምቻለሁ፡፡ ከ 15-17 ዓመት በታች ለሆኑ ልጄ ከተስማማ/ማቹ በዚህ ጥናት እንድትሳተፍ/እንዲሳተፍ ፈቃደኝነቴን ገልጫለሁ፡፡

የ ዓይነ ምድር ናማ ለማጠት ☐

የ ሽንት ናማ ለማጠት ☐

ደምለመቀዳት ☐ እና በዚህ ጥናት ተሳታፊ ለመሆን፣ በማንኛውም ሰዓት ልጄን ከጥናቱ ለማስወጣት መብት እንዳለኝምተረድቻለሁ ☐.

የተሳታፊ ስም፣ ቀን እና ፊርማ(ወይምአሻራ) ከዚህ በታች ይፃፉ

_____ ____ /____ /____ (ቀን/ወር/ዓመተ ምህረት)

ያልተማሩ ከሆኑ;

የተማሩ ገለልተኛ እማኝ ሰውስም፣ ቀንና ፊርማ (ከተቻለ ይህ ሰውበተሳታፊውቢሚጥና ከተመራማሪ አባላት ግኑኝነት የሌለውቢሆን)

_____ ____/____/_____ (dd/mm/yy) _____

ስልክ ቁጥር _____

የተመራማሪውስም፣ ቀንና ፊርማ

_____ _____/____/_____ (dd/mm/yy) _____

Annex XIII. Questionnaare

Questionnaares 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. Sex _____
3. Place of Birth_____
4. For how long (years) did you live in the birth place?_____
5. How long do you live in this specific area? (If different from the birth place) _____years

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

		4. WidoId 5. Not applicable (children)
9.	Religion	1. Orthodox Christian 2. Muslim 3. Protestant 4. Catholic 5. Others (Specify) _____
10.	Ethnicity	_____If mixed, specify _____
11.	Residence	1. Rural 2. Urban
	Questions 7-12 were additional questions to Students	
12.	Father's Age	_____
13.	Mother's Age	_____
14.	Father's Educational Level	1. Welliterate 2. Read and write 3. Primary (1-8) 4. Secondary (9-12) 5. College diploma/degree and above
15.	Mother's Educational Level	_____
16.	Father's Occupation	
17.	Mother's Occupation	
18.	Monthly income (in birr collected from salary, rent, and other income)	_____Birr
19.	Family Size (Number of People)	_____
20.	Source of water	1. Pipe 2. Spring water 3. Well water 4. River 5. Other sources (specify)

21.	Type of house	1. Mud 2. Cement 3. Wood 4. Bricks 5. others/specify_____
22.	Presence of or contact with Pet animals (e.g. Cat, Dog)	1. Yes 2. No
23.	Presence of domestic animals	1. Yes 2. No
	Part IV. Clinical information	
	Questions 24-28 for female participant who were pregnant specify	
24.	Gestation _____(Ieks)	
25.	Parity _____	
26.	Iron supplementation:	1. Yes 2. No
27.	Folate supplementation	1. Yes 2. No
28.	Iron and folate combined supplementation	1. Yes 2. No
29.	Did you take any type of drug for any wellness for the last three month?	1. Yes 2. No
30.	If yes to Q29, what type of drug? (more than one answer possible)	1. Anti-protozoa 2. Anti-helminthic 3. Anti-allergy 4. Birth control pwells 5. Anti-bacterial 6. Anti-TB **7.** Other (specify) _____
	History of common diseases	
31.	History of diabetes	1. Yes 2. No
32.	History of Hypertension	1. Yes 2. No
33.	History of Blood transfusion for the last 1 year	1. Yes 2. No

34.	Any history of blood transfusion	1. Yes 2. No
35.	History of Hospital Admission for the last 1 year	1. Yes 2. No
36.	History of Surgical procedure for the last three years?	1. Yes 2. No
37.	History of chronic gastritis	1. Yes 2. No
38.	History of Malaria for the last 6 month	1. Yes 2. No
39.	History of TB for the last two years	1. Yes 2. No
40.	History of Cancer	1. Yes 2. No
41.	History of Cardiac wellness	1. Yes 2. No
42.	History of Bleeding disorders	1. Yes 2. No
43.	History of allergy	1. Yes 2. No
44.	History of Wheezing	1. Yes 2. No

Part V. Nutritional habit and your life style

How often do you eat the following food? (put a "√ " mark)							
No.	**Food type**	**A Once/day**	**B More than Once/ day**	**C 2-3 times/week**	**D Occasionally (e.g. holidays, special ceremonies)**	**E Never**	**Remarks**
45.	Roots and Tuber (Potato, sweet potato, Enset, Cassava)						
46.	Legumes (Beans, peas, chicken pea, etc.)						
47.	Cereals (Corn, Teff, Wheat, sorghum, etc.)						

48.	Vegetables (Tomato, cabbage, etc.)						
49.	Fruits (Orange, banana, etc.)						
50.	Meat (including poultry, fish, etc.)						
51.	Milk and Milk products (Butter, yoghurt, cheese, etc.)						
52.	Egg						
53.	Tea and/or coffee						
How frequent do you consume/use the following (put a √ mark)							
		Once/day (Regular)	More than once/day	2-3 times/week	Once a week	Occasionally (holiday, special ceremony)	Never
54.	Alcohol						
55.	*chat*						
56.	Cigwerettes						

	Part V. Life style/Habit Continued…	
57.	Do you have Fasting habit?	1. Yes 2. No
58.	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
59.	Did you eat undercooked/raw meat?	1. Yes 2. No
60.	Do you have the habit of physical Exercise?	1. Yes 2. No

61.	If yes, how many times do you do the exercise per week?	
62.	Any sexual contact	1. Yes 2. No 3, Not applicable (children)
63.	If yes to Q45, condom use`	1. Yes 2. No
	Part VI. Anthropometric measurement	
64.	Height (in cm)	_____
65.	Iight (in kg)	_____
66.	MUAC	_____in cm (wwell be interpreted later)
67.	Blood pressure (mm Hg)	_____

❖ I thank you for your cooperation!

Interview Date:_____

Interviewer's Name_____ Signature_____

Annex XIV: Questionnaare Amharic version (ቃለ ጥያቄ)

በጠፍ ባለሞያዎች የሚሞላ ቃለ ጥያቄ

መመሪያ፡

በቅድሚያ ይህንን ቃለ ጥያቄ ለመሞላት ለሰጠኔ ጊዜና ትብብር አድናቆቴን እገልፃለሁ፡፡ የዚህ ቃለ ጥያቄ አላማ "በላቦራቶሪ ወስጥ የጠፍ ማሰውደም ወስጥ የሚኙ የሄማቶሎጂ ምርመራዎች ጥበን ሪፈረንስ ኢንተርቫል እድሜ ቸውአምኳት ዓመትና ከዚያ በላይ ለሆኑ ኢትዬጵያወያን ለሚሰራት" ሚጃ ለሚሰብሰብ ነው፡፡ የዚህ ጥናት ሃሳቡን ያጣዙ የጥናቱ ዋና ተመራማሪ በአዲስ አበባ ዩኒቨርስቲ የህክምና ላቦራቶሪ ትምህርት ክፍል ተማሪ የሆኑት እንዳልካቸው በፍቃዱ ናቸው፡፡፡ ስለሆነ ም የእርስዎ ቅን ትክክለኛ ሜልስ በሰዓቱ ሚጠት የዚህን ጥናት ስኬት ይወስናል፡፡ ስለሆነ ም ይህንን ቃለ ጥያቄ ሃቀኝነትና ሃላፊነት በተሞላው መንገድ እንዲሞሉ በትህትና እጠይቃለሁ፡፡

አመሰግናለሁ!!!

ክፍል 1. አጠቃላይ ሚጃ

ኮድ_____ ክልል _____ ዞን_____

ወረዳ_____ ከተማ/ክፍለከተማ_____ቀበሌ _____

ክፍል 2. የግል ሚጃ

6. እድሜ_____
7. ጾታ_____
8. የትወልድ ቦታ_____
9. በትወልድ ቦታዎ ለምን ያህል ጊዜ ኖረዋል?_____
10. አሁን ያሉበት ቦታ ለምን ያህል ጊዜ ኖረዋል? (ከትወልድ ቦታዎ የተለየ ከሆነ) _____ዓመት

ቁጥር.	ጥያቄ	ምላሽ
	ክፍል 3. ማህበራዊና ኢኮኖሚያዊ መረጃ	
24.	የ ትምህርት ደረጃ	6. ያልተማሩ 7. ማንብና መፃፍ 8. አንደኛ ደረጃ (1-8) 9. ሁለተኛ ደረጃ (9-12) 10. ኮሌጅ ዲፕሎማ/ዲግሪ እና ከዚያ በላይ
25.	ሥራ	7. ተማሪ 8. የ ቤት እመቤት 9. የ መንግስት ሠራተኛ 10. የ ግል ተቀጣሪ 11. ገበሬ 12. ሌላ ካለ ይግለፁ _____
26.	የ ጋብቻ ሁኔታ	6. ያላገቡ 7. ያገቡ 8. የ ተፋቱ 9. ባል/ሚስት የ ሞተባቸው 10. አይመለከታቸውም (ህፃናት)
27.	ሃይማኖት	6. አርቶዶክስ ክርስቲያን 7. መስሊም 8. ፕሮቴስታንት 9. ካቶሊክ 10. ሌላ ካለ ይግለፁ _____
28.	ዘር	_____ድብልቅ ከሆኑ ይግለፁ
29.	መኖሪያ ቦታ	2. ገጠር 2. ከተማ

	ጥያቄ 7-12 ለተማሪዎች ተጨማሪ ጥያቄዎች	
30.	የአባት እድሜ	_____
31.	የእናት እድሜ	_____
32.	የአባት የትምህርት ደረጃ	6. ያልተማሩ 7. ማንበብና መጻፍ 8. አንደኛ ደረጃ (1-8) 9. ሁለተኛ ደረጃ (9-12) 10. ኮሌጅ ዲፕሎማ/ዲግሪ እና ከዚያ በላይ
33.	የእናት የትምህርት ደረጃ (ከተ/ቁ 14 ይምረጡ)	_____
34.	የአባት ሥራ	1. ተማሪ 2. የቤት እመቤት 3. የመንግስት ሠራተኛ 4. የግል ተቀጣሪ 5. ገበሬ 6. ሌላ ካለ ይግለፁ _____
35.	የእናት ሥራ (ከተ/ቁ 16 ይምረጡ)	_____
36.	ወሃዊ ገቢ (በብር ከደሞዝ፣ ኪራይ፣ እና ሌሎች ገቢዎች)	_____ብር
37.	የቤተሰብ ብዛት	_____
38.	የወሃ ምንጭ	6. ቧንቧ 7. የምንጭ 8. የጉድጓድ 9. የወንዝ 10. ሌላ ካለ ይግለፁ _____
39.	የቤት አይነት	2. ጭቃ 2. ሲሚንቶ

		3. እንጨት 4. ጡብ/ሽክላ 5. ሌላ ካለ ይግለፁ _____
40.	የቤት ወስጥ ለማዳ እንስሳ ማኖር ወይምንክኪ (ለምሳሌ ድመት፣ ውሻ)	2. አለ 2. የለም
41.	የቤት እንስሳት ማኖር	2. አለ 2. የለም
	ክፍል 4. የጡር ሚረጃ	
	ከ 24-28 ያሉት ጥያቄዎች ለነፍሰጡር ሴቶች ብቻነው	
45.	ከፀነሱስንት ጊዜዎነው?	_____(ሳምንት)
46.	ለስንተኛ ጊዜ ነውየፀነሱት?	_____
47.	ተጨማሪ ብረት ንጥረነገር	2. አዎን 2. የለም
48.	ተጨማሪ ፎሌት ንጥረነገር	2. አዎን 2. የለም
49.	ተጨማሪ የብረት ንጥረነገር ና ፎሌት	2. አዎን 2. የለም
50.	ባፉት ሶስት ወራ ለማንኛውምዓይነት ህመምማንኛውንም ዓይነት መድሃኒት ወስደኃል?	2. አዎን 2. የለም
51.	ለተራ ቁጥር 29 ሚልስዎ ወስጃለሁ ከሆነ የትኛውን ዓይነት መድሃኒት ነውወሰዱት? (ከአንድበላይ ሚልስ ይቻላል)	8. ፀረ-ፕሮቶዞአ 9. ፀረ-ሄልማንትስ 10. ፀረ-አለርጂ 11. የወሊድ መከላከያ ኪኒን 12. ፀረ-ባክቴሪያ 13. ፀረ-ቲቢ 14. ሌላ ካለ ይግለፁ _____
	የሚከተሉት የህመምዓይነቶች አሞዎት ያውቃል?	
52.	የስኳር ህመም?	2. አዎን 2. የለም

53.	የደምግፊት ከፍ ማለት?	1. አዎን 2. የለም
54.	ባለፈው1 ዓመት ደምተሰጥቶዎ ያወቃል?	1. አዎን 2. የለም
55.	ማንኛውምጊዜ ደምተሰጥቶዎ ያወቃል?	1. አዎን 2. የለም
56.	ባለፈው1 ዓመት ሆስፒታል ተኝተውያወቃሉ?	1. አዎን 2. የለም
57.	ባለፉት 3 ዓመታት የቀዶ ህክምና ተደርጎልዎ ያወቃል?	1. አዎን 2. የለም
58.	የቆየ የጨጓራ ህመምአለብዎት?	1. አዎን 2. የለም
59.	ባፉት 6 ወራት የወባ ህመምአጋጥሞዎት ያወቃል?	1. አዎን 2. የለም
60.	ባለፉት 2 ዓመታት የቲቢ ህመምኖሮዎት ያወቃል?	1. አዎን 2. የለም
61.	ካንሰር ህመም	1. አዎን 2. የለም
62.	የልብ ህመም	1. አዎን 2. የለም
63.	የመድማት ችግር/ህመም	1. አዎን 2. የለም
64.	አለርጂ (የ ሰ ወ ነ ት መቆጣት)	1. አዎን 2. የለም
65.	የ መ ኮ ን ፈ ስ ችግር (ሲተነ ፍሱ ሲር ሲር የ ሚል ድምፅ)	1. አዎን 2. የለም

ክፍል 5. የአመጋገብ እና የህይወት ልምድዎ

የሚከተሉትን የምግብ ዓይነ ቶች ምን ያህል ጊዜ ይመ ቧቸዋል ? (“√ “ ይህን ምልክት ያስቀምጡ)							
ተ/ቁ	**የ ምግብ ዓይነ ት**	**1** **በቀን አንድ ጊዜ**	**2** **በቀን ከአንድ ጊዜ በላይ**	**3** **በሳምንት ከ 2 እስከ 3 ጊዜ**	**4** **አልፎ አልፎ (ለ ምሳሌ፣ ለበዓል፣ ልዩ ዝግጅቶች ሲኖሩ)**	**5** **ተጠቅሜ አላ ወቅ ም**	**ማ ብራሪ ያ**
45.	ሥራ ሥር (ድንች፣ ስኳር ድንች፣ እንሰት፣ ካሳ ቫ ወዘ ተ)						
46.	አ ባ ዝር ት (Legumes፡						

	ባቄል፣ አተር፣ ሽንብራ ወዘተ)						
47.	ጥራጥሬ (በቆሎ፣ ጤፍ፣ ስንዴ፣ ማሽላ)						
48.	አትክልት (ቲማቲም፣ ጎመን፣ ወዘተ)						
49.	ፍራፍሬ (ብርትካን፣ ሙዝ፣ ወዘተ)						
50.	ሥጋ (የ ዶሮ፣ የ አሳን ጨምሮ)						
51.	ወተትና የ ወተት ተዋፅዎ (እርጎ፣ ቅቤ፣ አይብ፣ ወዘተ)						
52.	እንቁላል						
53.	ሻይ እና/ወይም ቡና						

የ ሚከተሉትን ምን ያህል ይበላሉ/ይጠቀሙ (√ ይህን ምልክት ያስቀምጡ)

		በቀን አንድ ጊዜ (ሀልጊዜ)	በቀን ከ1 ጊዜ በላይ	በሳምንት ከ 2 እስከ 3 ጊዜ	በሳምንት 1 ቀን	አልፎ አልፎ (ለምሳሌ፣ ለበዓል፣ ልዩ ዝግጅቶች ሲኖሩ)	ተጠቅሜ አላውቅም
54.	አልኮል						
55.	ጫት						
56.	ሲጋራ						

	ከ ክፍል 5 የ ቀጠለ. የ ህይወት አሟራርና ልምዶች	
57.	የ መ ፆ ም ልምድ አለዎት?	2. አዎን 2. የ ለ ም
58.	መ ልስ ዎ አዎን ከ ሆነ ፣ የ መ ፆ ም ልምድ ዎ እ ን ዴት ነ ው?	4. አ ትክልቶችን ብቻ መመ ገ ብ 5. በ አ ጠቃላ ይ ከ ምግ ብ መታቀ ብ ከ ዚያ ም ያ ገ ኙትን መመ ገ ብ 6. በ አ ጠቃላ ይ ከ ምግ ብ መታቀ ብ ከ ዚያ ም አ ትክልቶችን መመ ገ ብ
59.	በ ደ ን ብ ያ ልበ ሰ ለ ወ ይ ም ጥሬ ሥ ጋ ይመ ገ ባ ሉ?	2. አ ዎን 2. የ ለ ም
60.	የ ሰ ወ ነ ት እ ን ቅ ስ ቃሴ የ ሚ ድረ ግ ልምድ አለ ዎ ት?	2. አ ዎን 2. የ ለ ም
61.	መ ልስ ዎ አለ ኝ ከ ሆነ በ ሳ ምን ት ለ ምን ያ ህ ል ጊ ዜ ይ ን ቀሳ ቀሳ ሉ?	
62.	የ ግ ብረ ሥ ጋ ግ ኙ ኝ ነ ት አ ድር ገ ው ያ ወ ቃሉ	1. አ ዎን 2. የ ለ ም 3, አ ይ መ ላ ከ ት ም (ለ ህ ፃ ና ት)
63.	ለ ተ/ቁ 66 መ ልስ ዎ አዎን ከ ሆነ ፣ ኮ ን ዶ ም ይ ጠ ቀ ሚ ሉ?`	2. አ ዎን 2. የ ለ ም
	ክ ፍ ል 6. ክ ብ ደ ት፣ ቁ መ ት፣ የ ክ ን ድ ና የ ደ ም ግ ፊ ት ል ኬ ት	
64.	ቁ መ ት	_____ሴ ን ቲ ሜ ት ር
65.	ክ ብ ደ ት	_____ኪ ሎ ግ ራ ም
66.	የ ክ ን ድ መ ሃ ለ ኛ ው ክ ፍ ል ዙ ሪ ያ ው (MUAC)	_____ሴ ን ቲ ሜ ት ር
67.	የ ደ ም ግ ፊ ት (በ ሚ ሊ ሜ ት ር ሜ ር ኩ ሪ)	_____(mm Hg)

❖ ስ ለ ት ብ ብ ር ዎ እ ና መ ሰ ግ ና ለ ን !

ቃ ለ መ ጠ ይ ቅ የ ተ ደ ረ ገ በ ት ቀ ን :_____

ቃ ለ መ ጠ ይ ቁ ን ያ ካ ሄ ደ ው ስ ም_____ ፊ ር ማ_____

Standard Operating Procedure

Blood sampling and transportation

Purpose

This SOP describes the procedure for blood collection (venipuncture) from research participants.

Responsibility

It is the responsibility of the research personnel carrying out this procedure to ensure that all steps were completed both competently and safely.

ESSENTIAL EQUIPMENT

- 2 X 7.5 ml Purple top (Ethylene di amine tetra acetic acid (EDTA)) blood tubes
- 10 ml Syringe a green/blue needle or Vacutainer system with butterfly needle attachment
- Cotton Swab/Gauze
- Alcohol Swab
- Tourniquet
- Plastic gloves
- Royal Mail SAFEBOX for transport

Procedure

1. Explain the procedure clearly to participant giving time to ask any questions, ensuring the patient is comfortable about the procedure.
2. Obtain informed consent from the participant as per study protocol prior to blood taking.
3. Ensure all equipment is ready to hand in a tray next to the participant.
4. The research participant's arm wwell be hyperextended and positioned comfortably on the arm-rest of the venipuncture chair / couch as appropriate.
5. The tourniquet wwell be applied 3-4 inches above the selected puncture site and wwell not be left in position for longer than two minutes.
6. The research participant wwell be asked to make a fist without pumping the hand.

7. A vacuum collection system (for example Monovette) wwell be used for venipuncture where possible. Syringes and needles wwell be used in place of the vacuum collection system in special circumstances.
8. The puncture site wwell be cleansed using a Sterets pre-injection swab in a circular motion from the center to the periphery.
9. The cleansed site wwell be allowed to air dry prior to venipuncture.
10. The research participant's vein wwell be anchored and the needle wwell then be inserted through the skin, bevel edge uppermost, into the lumen of the vein.
11. The tourniquet wwell be released when the last collection tube to be drawn is fwelling.
12. Tubes containing anticoagulants must be properly mixed immediately after each is drawn by inverting the tube. See manufacturer instructions for number of inversions requared.
13. Clean dry gauze or cotton wool wwell be placed on the venipuncture site and the needle wwell be removed in a swift backward motion using a needle protector.
14. The research personnel wwell press down on the gauze/cotton wool once the needle has been drawn out of the vein applying adequate pressure to avoid formation of a hematoma.
15. The research participants arm wwell not be placed in a bent position at any time following venipuncture.
16. The research participants arm wwell be inspected to ensure bleeding has stopped and a Band-Aid strip wwell be applied.
17. The research personnel wwell ensure that the research participant has not experienced any adverse events from the venipuncture and wwell then assist them from the chair.
18. All contaminated materials/supplies wwell be disposed of in the designated containers.
19. All blood collection tubes wwell be labeled immediately following collection with the appropriate research study labels, for example a unique study identification number and /or bar code label. The time of collection wwell also be recorded in the study specific documentation and/or data management system.

20. The research personnel wwell arrange for the blood specimens to be transported to the research laboratory as applicable.

TIMING OF SAMPLE DELIVERY

1. Samples have immediately to be stored at -80°C until shipment. If a -80°C freezer is not available, storage at -20°C is acceptable.
2. Batches of c. 50 samples were collected and ready for shipment on dry ice, please alert the Study Co-coordinator (insert name) at the study center of their impending arrival so arrangements can be made to store the samples.

PERSONNEL

Appropriate staff to undertake venipuncture may include:

Research Nurse/ Practitioners

Clinical Research Fellows

Members of clinical staff trained to take blood, including doctors and nurses on the unit.

NO	Sample Lab code	Collection Date	Collection Time	Number of aliquots	Freezing Date	Shipment date	Centre	Isolation by	Signature
0001									
0002									
0003									
0004									
0005									
1029									
1030									

General Stool Examination (GSE)

Collection of samples

If a fecal sample is not properly collected and taken cwere of before examination, they wwell be of little or no value for accurate diagnosis. This is especially true if protozoa were present. Amoebic trophozoites begin to degenerate 1-2 hours after passage, as do flagellate trophozoites. Cysts wwell deteriorate if the fecal specimens were left standing for many hours or overnight, especially at high temperatures. Helminth eggs and larvae were less affected by the age of the specimen than were protozoa. Nevertheless, changes may occur that could affect their identification. e.g., hookworm larvae may become embryonated and larvae may hatch from the eggs risking confusion with Strongyloides larvae. Larvae themselves may disintegrate thus making their identification difficult.

To ensure that good specimens were provided for examination, it is important to note the following points.

1. A clean dry container must be used for the collection of fecal samples. Urine and water wwell destroy trophozoites, if present, and the presence of dirt also causes identification problems.
2. Ideally the specimen should be brought to the lab as soon as it is passed, to avoid deterioration of protozoa and alterations of the morphology of protozoa and helminths.
3. The specimen container should be clearly labeled with the patient's name, date, and time of passage of the specimen.
4. An amount of stool adequate for parasite examination should be collected and a repeat sample requested if too little is supplied.
5. Diarrhea specimens, or those containing blood and mucus, should be examined promptly on arrival in the laboratory. The specimens may contain motile amoebic or flagellate trophozoites and may round up and thus be missed if examination is delayed. Where amoebic dysentery is suggested, the laboratory should be informed that a "hot stool" is being supplied so that it can be examined within twenty minutes of being passed.

Visual observation of the fecal sample

Types of stool

Type of stool Likely reason

- Watery Diarrhea
- Clay colored Obstructive jaundice or presence of barium sulfate
- Reddish colored Blood from lower gastrointestinal tract, beef consumption
- Black Bleeding from upper gastrointestinal tract, Iron, charcoal.
- Green Ingestion of Spinach, antibiotics.

Procedure for the microscopic examination of fecal samples for parasites

1. place a drop of saline a clean slide.
2. place a small piece of stool on the slide and mix with saline, cover with a cover slip. If
1. the specimen contain mucus, the examination prefer to be done without saline. The
2. mucus is put on the slide and covered with cover slip.
3. examine under 10X and 40X objectives.
4. report the presence of :
    - ❖ Large numbers of pus cells
    - ❖ RBCs
    - ❖ Amoebas, flagellates
    - ❖ Eggs, larvae & cysts.

Using of Saline: Normal saline (0.85%) is used for routine examination of stool samples, as it is isotonic.

ABO blood grouping

1. Purpose

To determine the correct ABO group of an individual and ensure the reliability of the

result

5. MATERIALS REQUARED:

5.1 Equipment

- Refrigerator to store samples and reagents at 2 – 8 0 C
- General purpose centrifuge

5.2 Specimen

- Blood samples

5.3 Reagents

- Anti-A, anti-B, anti-AB anti-sera
- (* All reagents must be used in accordance with the manufacturer's instructions.)

5.4 Glasswwere

- Plastic pipette
- Glass slides for microscopic reading

5.5 Miscellaneous

- Disposal bucket with Na hypochlorite
- Plastic beakers - 2

6. ROCEDURE:

6.1 Principle:

ABO system is the only system in which there is a reciprocal relationship between the antigens on the red cell and the naturally occurring antibodies in the serum. The procedure is based on the principle of agglutination of antigen positive red cells in the presence of antibody darected towards the antigen.

6.2 Cell testing:

- Label the tiles with patient & donor number and test identification
- Add 2 drops of anti-A, anti-B and anti-AB reagent in the labeled areas
- Add 1 drop of participant red cells to be tested
- Gently mix the contents
- Examine for agglutination within 2-4minutes

6.4 Results:

- Depending on presence (+) or absence (-) of agglutination, the test is described as positive or negative.
- Observe anti AB as positive control and O cell as negative control.

- Confirm the cell grouping results with those obtained in serum grouping and vice versa.

6.5 **Interpretation**

- Agglutination of tested red cells and serum constitute positive test results. Positive reactions characteristically show 3+ to 4+ agglutination.
- Absence of agglutination represents negative test result.

DOCUMENTATION:

Enter the results of participant grouping in the grouping register

Blood film

BACKGROUND

Venous blood samples treated with EDTA can be used to prepwere thin and thick blood films

SUPPLIES, MATERIALS AND EQUIPMENT

- cleaned glass slides, 25 x 75 mm, with one frosted end for labeling, preferably with ground edges, and of good quality
- a syringe with needle (gauge 21 or 23), one per patient;
- a vacuum tube containing an anticoagulant such as EDTA, 4–5-mL capacity, one per patient;
- 70% ethyl alcohol or alcohol swabs;
- dry cotton (cotton ball, swab or gauze);
- protective latex gloves (powder-free);
- a tourniquet;
- a biohazard container or any puncture-resistance sharps container
- an infectious wastes
- a micro-pipette;
- pipette tips;
- a smear preparation template;
- a drying rack;
- record forms (i.e. malaria register) and
- a lead pencil or permanent marker pen.

4. SAFETY PRECAUTIONS

- Wear protective latex gloves before starting blood collection and when handling slides for personal protection and to avoid leaving oil on the slide that might interfere with smear preparation. Wear gloves when handling blood, and remove them before leaving the work area or when writing notes.
- Always use a new needle and syringe for each patient.
- Avoid getting blood, wet or dry, on your fingers or hands.
- Cover cuts or abrasions on your hands with a waterproof dressing.

- Avoid accidentally pricking yourself when handling sharp instruments that have been in contact with blood.
- Thoroughly wash your hands with soap and water as soon as you finish a job.
- If you get blood on your skin, quickly wipe it off with a cotton swab dampened with alcohol; then wash the affected area with soap and water as soon as possible.

4.2. Preparation of thick and thin blood films

1. Gently mix collected venous blood in a vacuum tube containing EDTA before use.
2. Place a clean, labeled microscope slide on a standardized thick (1.2 cm or 12 mm in diameter) and thin blood film-slide preparation template (see Fig. 1).
3. Transfer 6 µL of blood with a micropipette and fitted tip onto the larger circle of the slide. With the tip of the micropipette, swirl the blood, making a circle about 1 cm in diameter, and prepwere the thick film; three to six quick strokes with the tip were sufficient.
4. Collect an additional 2 µL of blood with a micro-pipette and fitted tip, and transfer the blood onto the small circle of the slide template.
5. To prepwere the thin film, place the edge of a clean "spreader" slide at a 45^0 in front of the blood drop intended for the thin film.
6. Slowly pull the "spreader" back until it touches the drop of blood and the blood spreads along the edge of the spreader.
7. Rapidly push the spreader forwards (away from the center) in a smooth, continuous motion, until the spreader leaves a "feathery" end for the thin film.
8. Dry the prepwered slides horizontally. Poor adherence is a problem with EDTA-treated blood. If rapid drying is requared, dry the films with low heat from a hair-dryer at some distance. Do not place the blood films too close, as the film might be fixed by heat.

6. PROCEDURE NOTES

- Blood collected in EDTA-containing tubes should not be kept for more than 4 h before preparing thick and thin blood films, because the anticoagulant wwell affect the morphology of the parasite

- If venous blood is collected elsewhere than in the laboratory where the thick and thin blood films wwell be prepwered, it must be transported immediately (ideally within 1 h), without cooling or refrigeration, to the laboratory.
- Thick films should be dried flat and be protected from dust and flies.
- Thick films may be auto fixated if exposed to extreme heat; they should therefore be stained immediately.
- A thick film can be gently dried with a hair-dryer set at warm or by other methods, but cwere must be taken to avoid heat fixation, which can occur quickly. Issue a hair-dryer to technicians with demonstrated competence in use of this method.
- Do not use a ballpoint or gel pen to label slides, as the ink wwell spread when the film is fixed.
- Correctly made slides leave little blood on the spreader, which can be used for making thick and thin slides from the next patient, while another clean slide from the package is used as a fresh spreader.

Dummy table

Comparison of our result with other Caucasians

Parameter	**Our result**	**Caucasians studies**			
Wbc (x109)					
Rbc (x 1012)					
HG (g/dl)					
Hct (%)					
Mcv (fl)					
Mch					
Mchc					
Plt					

Lymphocyte (%)					
Neutrophil (%)					
Monocyte(%)					
Basophil (%)					
Eosinophil (%)					
Lymphocyte (#)					
Neutrophil (#)					
Monocyte(#)					
Basophil (#)					
Eosinophil (#)					

Comparison of our results with other African results

Parameter	**Our result**	**Africans studies**			
Wbc (x109)					
Rbc (x 1012)					
HG (g/dl)					
Hct (%)					
Mcv (fl)					
Mch					
Mchc					
Plt					
Lymphocyte (%)					
Neutrophil (%)					
Monocyte(%)					
Basophil (%)					

Eosinophil (%)					
Lymphocyte (#)					
Neutrophil (#)					
Monocyte(#)					
Basophil (#)					
Eosinophil (#)					

Comparison of our results with other studies on pregnant

Parameter	**Our result**	**Other studies**			
Wbc (x109)					
Rbc (x 1012)					
HG (g/dl)					
Hct (%)					
Mcv (fl)					
Mch					
Mchc					
Plt					
Lymphocyte (%)					
Neutrophil (%)					
Monocyte(%)					
Basophil (%)					
Eosinophil (%)					
Lymphocyte (#)					
Neutrophil (#)					
Monocyte(#)					

Basophil (#)					
Eosinophil (#)					

Comparison of our results with other studies gender specific

Parameter	**Our result**		**Africans studies**			
	Male	female	male	Female	Male	Female
Wbc (x10^9)						
Rbc (x 10^{12})						
HG (g/dl)						
Hct (%)						
Mcv (fl)						
Mch						
Mchc						
Plt						
Lymphocyte (%)						
Neutrophil (%)						
Monocyte(%)						
Basophil (%)						
Eosinophil (%)						
Lymphocyte (#)						
Neutrophil (#)						

Declaration

I, the undersigned, declwere 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: **Endalkachew befekadu (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.

Advisor: **Zemenu Tamir (MSc, PhD candidate)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.