**DETERMINATION OF RED BLOOD CELL INDICES AND CLINICAL CHEMISTRY NORMAL RANGES FOR HEALTHY BLOOD DONORS IN KAKAMEGA**

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**DECLARATION**

This report is my original work and has not been presented in any institution leading to the award of a degree or any other award.

Sign…………………………………………… Date…………………………………………

Nimrod Khisa.

I confirm that this proposal was written by the above named student and has been submitted with our approval as supervisor.

Name:

Sign……………………………………………. Date………………………………………………

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# Section 1 : ABSTRACT

Reference ranges or normal ranges are the results that are expected in the general healthy population 95% of the time for a particular laboratory test. A range is necessary, instead of a specific value because of differences in the population due to age, race and gender. Geographical locations may also affect the reference range, as will the testing methods used by the laboratory. In all of medicine, there is use of reference intervals for laboratory variables to define disease states and inform treatment decisions. Many hematological variables including hemoglobin, platelets and red blood cells are often reported to be different on the basis of a person’s race or ethnicity. This simply means that if an individual is tested for a certain hematological parameter, chances are that even if the results indicate an extreme value, either high or low, the individual could possibly be on his or her “own” normal range and the individual could be healthy and does not necessarily need any treatment from that particular diagnosis. To determine the normal ranges on hematological indices for adults in Kakamega county, blood from healthy adults will be tested and the results will be compared with the existing normal ranges. Tests will be done on hematological analyzers. This study will show that there is a difference in hematological normal ranges for adults living in Kakamega.

# Section 2: INTRODUCTION

* 1. **Background Information**

Normal ranges varies from one individual to another due to factors such as race, lifestyle, posture, analytical method of testing, gender and geographical distribution. Clinical and Laboratory Standard Institute (CLSI) recommends that each laboratory establishes its own reference intervals specific for the population they serve**.** It is, therefore, critical to establish region-specific reference values in order to inform clinical decision-making. A normal value in one laboratory could be abnormal in another. This could mean that people from Kakamega county have a different normal range for hemoglobin from those in middle East countries. June Otieno and colleagues did a study in Kisumu County which highlights the variations in comparable settings, accentuating the requirement for region-specific reference values to improve patient care, scientific validity, and quality of clinical trials in Africa. Therefore, finding a normal range that suits a certain group of people could mean proper treatment. In America, the average results of some laboratory measurements including the hemoglobin, serum transferritin saturation and white blood cell count of African-Americans differ from those of whites. Hence the hemoglobin of the people in Kakamega could be different and need their own reference ranges for them to be diagnosed accordingly. This study focuses on the reference ranges.

* 1. **Statement of the Problem**

Laboratory results are key to giving proper diagnosis, monitoring and treatment. As such, the haematology and clinical chemistry results need to be accurate. And this also includes having a correct normal range in the respective analyzers. Most of the laboratory equipments and machines are imported from foreign countries in which there are high chances that the normal ranges are obtained from their country persons. And for that matter, having a normal range for the healthy blood donors in Kakamega could improve the health care services in the county by offering appropriate treatment to individuals in the area.

**1.3 Objectives**

**1.3.1 General Objective**

1. To determine the normal ranges for red blood cells indices and clinical chemistry for healthy blood donors in Kakamega.

**1.3.2 Specific Objectives**

i) To determine the normal range for MCH and MCV.

ii) To determine the normal range for alanine transferase.

# Section 3: LITERATURE REVIEW

The results of a clinical laboratory tests are an essential component of medical decision making. And to guide the interpretation, the results come along with reference intervals in which 95% of the values occurs in the healthy individuals. Laboratories often set their own reference range to accommodate variation in local population and instrumentation. Studies have shown differences in reference ranges among different racial and ethnic groups. According to National Health and Nutritional Examination Survey (NHANES) 2011-2012 data, participants aged 18-65 whose health was referred to as “Excellent” with known ethnicity as white, Hispanic and Asian, significant differences were found in nearly all laboratory tests on normal ranges. This result further confirms that racial subpopulations have unique reference intervals**.** Reference intervals (RIs) currently being used in Ethiopia are derived from western populations (Bamlaku Enawgaw, 2018). There is a high chance that also in Kenya the RIs used are from the western countries and hence the urge for population specific RIs. The reference intervals established in that study differed from others and thus should be used for the interpretation of laboratory results in diagnosis and safety monitoring in clinical trials in Amhara.

# Section 4: MATERIAL AND METHODS

**3.1 Study Site**

Kakamega County Hospital will be suitable for the study.

**3.2 Study Design**

A cross-sectional study will be used.

**3.3 Study population**

Healthy adults in Kakamega will be the sole participants.

3.3.1 **The Inclusion criteria**

Adults 18-55 years of age.

Should be healthy

3.3.2 **The Exclusion criteria**

Anyone below the age of 18.

Anyone with signs of illness.

**3.4 Sample Size Determination**

A total of 240 participants will be studied.

**3.5 Laboratory Procedures**

The participants will be subjected to venipuncture process and the collected blood will be taken to their respective benches, that is hematology and biochemistry for them to be analyzed.

**3.6 Data Management**

Data collected will be stored in a computer software which is capable of calculating the same data. Excel will be used in this situation for tabulation and any calculation if need be.

**3.8 Limitation of the Study**

No limitations encountered.

**3.9 Data Analysis and Presentation**

For each red blood cell indices and clinical chemistry parameter on each participant’s blood, a range will be determined. Then determination of mean for each parameter’s lowest value and highest value to find the range.

The results will be presented in a table form. All this will be done on the computer software.

**3.10 Ethical Consideration**

Each participant will be well informed of the all possible benefits and risks that might occur during the study. They are also informed about the context of the study and its importance and their personal information and involvement will be confidential**.**

**3.11 Budget**

|  |  |
| --- | --- |
| **Item** | **Cost** |
| **Purple tops** | **1500** |
| **Red tops** | **1500** |
| **Blood bags** | **3500** |
| **Gloves** | **500** |
| **Tourniquets** | **1000** |
| **Stationery** | **500** |
| **Cyber services** | **300** |
| **Total** | **Ksh 10300** |

**3.12 Workplan**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Activity** | **Dec** | **Jan** | **Feb** | **Mar** | **Apr** |
| **Proposal development** |  |  |  |  |  |
| **Data collection** |  |  |  |  |  |
| **Thesis development** |  |  |  |  |  |
| **Manuscript writing** |  |  |  |  |  |
| **Defense** |  |  |  |  |  |

# Section 5 : REFERENCE

Constance L. L. & Elizabeth A.Z., 2012, *Essentials of medical laboratory practice*

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Nadav, R., Hyong, P., Ruth, T., 2018, ‘Comparing Ethnicity-Specific Reference Intervals for clinical laboratory tests from EHR Data’, www.researchgate.net