KEMRI /CGHR HIV-RESEARCH LABORATORY

Laboratory Handbook

Written by	Reviewed By	Approved By
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Document Revision History

Version	Description of change	Author	Effective Date
01	New	Emily Anyango	January 2017
02	Added Turn around Time table	Emily Anyango	October 2021
03	Changed the document presentation lookout, added reference ranges, lab activities, complaints channels, aligned the document as per requirements of ISO 15189:2022	Emily Anyango	May 2024

Reference documents

1.Kit inserts

2. Lab standard Operating Procedures

3.ISO 15189:2022 Standard

4. Good Clinical Laboratory Practice (DAIDS GCLP) Version 4.1

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INTRODUCTION

It's with great hope that this handbook, will aid you in caring for your patients/participants by ensuring that all samples are managed properly and that persons collecting samples have access to the required information on laboratory tests and services that are offered at the KEMRI CGHR HIV-Research Laboratory.

This handbook is intended to provide you with information on patient/participant preparation, specimen collection materials and specimens handling procedures. We strive to ensure that you receive accurate, reliable, meaningful, and timely laboratory results with minimal requirements for repeat testing due to specimen integrity concerns (e.g. for improper specimen collection).

We also wish to promote optimal utilization of laboratory resources through appropriate test ordering practices. We strongly encourage you to consult with us especially for unusual situations or special requests. If the test is not available in our lab, yet is important for patient care/study, then we will advice you on other options or make the necessary arrangements to send the specimen to the appropriate referral laboratory. The directory in this handbook provides our contact information.

Since changes to specimen requirements and frequency of testing do occur, we will endeavour to frequently update this handbook so as to keep the information as current as possible. Hence, this document is to be used for reference purposes only.

Reference ranges may change when a method of testing or technology is changed. For this reason, we request the user to refer to the appropriate electronic or paper lab test report for proper interpretation of results.

Selected tests are offered on a Short TurnAroundTime (STAT) basis. Test turnaround times for these tests are usually within an hour. However, we request the users to use this category of test request judiciously and limit the use of STAT request to emergent and urgent situations (critical values).

The use of proper specimen collection techniques, specimen container, and appropriate specimen volume are some important pre-analytic factors needed to ensure integrity of test results. Please consult these sections for your guidance. As well, correctly identified specimens are very important to ensure patient safety.

For information regarding any test or procedure not listed in the handbook, please call one of the telephone numbers provided in this hand book.

KEY LABORATORY TELEPHONE NUMBERS

CRC HIV-R LAB +254 706 582 303

KISIAN HIV-R LAB +254 799 403 184

LABORATORY PHYSICAL ADRESS, WORKING HOURS AND CONTACTS

The Laboratory has two locations:

KEMRI-CGHR Kisian Campus,

Along Kisumu-Busia Road,

Opposite Kisian Primary School,

P.O.Box 1578 – 40100, Kisumu,

Kenya.

AND

KEMRI-CGHR Clinical research Center (CRC)

Along Kisumu-Kakamega Road,

Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) Grounds,

P.O.Box 1578 – 40100, Kisumu,

Kenya.

COMPLAINT HANDLING

CONTACT LINES

For queries, complaints, comments, and complements, call/ sms or email the following persons:

Official Laboratory email: KisumuHIVRLAB@kemri.go.ke

Laboratory Director: Dr Valarie Opollo +254 723 903 176 Vopollo@kemri.go.ke

Laboratory Supervisor Kisian: Grace Akinyi +254 786 568 091 gakinyi@kemri.go.ke

Laboratory Supervisor CRC: Boaz Oyaro +254 737 950 319 Boyaro@kemri.go.ke

Quality Assurance Supervisor: Emily Anyango +254 733 963 168 Eanyango@kemri.go.ke

Other complaint recourse options available include the suggestions boxes strategically put at the two laboratories or complaint forms issued at the QA supervisor office

The laboratory functions from Monday 8.00hrs to 17.00 hrs and Friday 8.00 hrs to 16.00hrs.

The samples are to be received in the lab from 8.00hrs to 3.00pm unless there is a prior arrangement to receive the samples late.

The laboratory supports MOH HIV VL/EID programmatic activities as appropriate in 3 counties within the former Nyanza region, also provides support for HIV DRT in the country and regionally as well as HIV and STI research. It is also a WHO designated regional reference Laboratory for HIV drug resistance testing and a WHO prequalified laboratory for IVD performance evaluations.

LAB ACTIVITIES:

Table 1: Laboratory scope

Medical Field	Examination Technique	Equipment	Specimen	Components/ Analytes	Test Location
Chemistry	Automated	COBAS 311 / _COBAS Integra 400 Plus	Serum	Albumin Alkaline Phosphatase (ALP) Aspartate Aminotransferase (AST) Bicarbonate Liquid Urea Aspartate Transaminase (ALT) Bilirubin Total Cholesterol Total Creatinine kinase (CK) Glucose Inorganic Phosphate Triglycerides Lactate Protein Total Chloride potassium Sodium Calcium total amylase HDL LDL	KEMRI CGHR HIV-R laboratory CRC
Haematology	Automated	Sysmex 330 XN	Whole blood	Full Blood Count and Differential	KEMRI CGHR HIV-R laboratory CRC
	Automated	Coulter DXH 520	Whole blood	Full Blood Count and Differential	KEMRI CGHR HIV-R laboratory CRC

Medical Field	Examination Technique	Equipment	Specimen	Components/ Analytes	Test Location
	Manual	N/A	Whole blood	Differential cell count	KEMRI CGHR HIV-R laboratory CRC
Immunology	Flow cytometry_ Automated	Facs Calibur	Whole Blood	CD3, CD4, CD8, CD45	KEMRI CGHR HIV-R laboratory CRC
	Flow Cytometry	Alere Pima	Whole Blood	CD4	KEMRI CGHR HIV-R laboratory CRC
Endocrinology	Immunochromatographic	N/A	Serum/Urine	Rapid Beta Human Chorionic Gonadotrophin (βHCG) (Pregnancy Test)	KEMRI CGHR HIV-R laboratory CRC
Urinalysis	Dip Stick	N/A	Urine	Urine Analytes	KEMRI CGHR HIV-R laboratory CRC
Clinical Microscopy	Manual	Microscope	Urine	Urine Deposits	KEMRI CGHR HIV-R laboratory CRC
Serology	Immunochromatographic	N/A	Serum/Plasma/Whole Blood	HIV 1/2- Rapid Test	KEMRI CGHR HIV-R laboratory CRC
	ELISA	ELISA Reader ELISA Washer Incubator	Serum / Plasma	HIV1/2	KEMRI CGHR HIV-R laboratory CRC
	ELISA	ELISA Reader ELISA Washer Incubator	Serum / Plasma	Hepatitis B Surface Antigen (HBsAg)	KEMRI CGHR HIV-R laboratory CRC
	ELISA	ELISA Reader ELISA Washer Incubator	Serum / Plasma	Hepatitis C	KEMRI CGHR HIV-R laboratory CRC
	ELISA	ELISA Reader ELISA Washer Incubator	Serum / Plasma	Anti-HBc (Total)	KEMRI CGHR HIV-R laboratory CRC

Medical Field	Examination Technique	Equipment	Specimen	Components/ Analytes	Test Location
	ELISA	ELISA Reader ELISA Washer Incubator	Serum / Plasma	Anti-HBs	KEMRI CGHR HIV-R laboratory CRC
	Microtitration-Macroscopic	Macro-Vue RPR TPPA SD Bioline	Serum	Syphillis	KEMRI CGHR HIV-R laboratory CRC
	PCR	HIV DNA PCR GeneXpert	EDTA Whole Blood / Dry Blood Spot	HIV	KEMRI CGHR HIV-R laboratory CRC
	PCR	HIV RNA PCR GeneXpert	Plasma	HIV	KEMRI CGHR HIV-R laboratory CRC
	Immunochromatographic	N/A	Vaginal Swab	Trichomonas Vaginalis	KEMRI CGHR HIV-R laboratory CRC
Clinical Microscopy	Vaginal wet prep	Microscope	Vaginal Swab	Trichomonas Vaginalis	KEMRI CGHR HIV-R laboratory CRC
Immunology	Cryopreservation_ Automated	DXH Haematology Analyzer	Whole Blood	Peripheral Mononuclear Cells	KEMRI CGHR HIV-R laboratory CRC
	Cryopreservation_ Manual	Manual cell counting Chamber, Neubauer Hemacytometer Microscope	Whole Blood	Peripheral Mononuclear Cells	KEMRI CGHR HIV-R laboratory CRC
	PCR	GeneXpert	Urine / Swab	Chlamydia Trachomatis (CT) / Neisseria Gonorrhea (NG)	KEMRI CGHR HIV-R laboratory CRC
	PCR	COBAS 6800	Dry Blood Spot	HIV DNA	KEMRI CGHR HIV-R laboratory Kisian
	PCR	COBAS 6800/8800	Plasma	HIV RNA	KEMRI CGHR HIV-R laboratory Kisian

Medical Field	Examination Technique	Equipment	Specimen	Components/ Analytes	Test Location
Molecular	PCR	Hologic Panther	Plasma	HIV RNA	KEMRI CGHR HIV-R laboratory Kisian
	Genotyping	ABI3730XL-Thermofisher Genotyping System	DBS / Plasma	HIV RNA	KEMRI CGHR HIV-R laboratory Kisian
	Genotyping	ABI 3730XL -In-house Genotyping System	DBS/Plasma	HIV RNA	KEMRI CGHR HIV-R laboratory Kisian

TURN AROUND TIME (TAT)

This is the time when laboratory receives specimen until when results are released. In the HIV-R laboratory TAT of different tests are as follows;

Table 2: TEST TURN AROUND TIMETABLE

KISIAN			
SECTION	**TEST**	**ROUTINE TAT**	**STAT**
	HBV DNA PCR	10 Working Days	5 Working Days
	HCV RNA PCR	10 Working Days	5 Working Days
VIRAL LOAD	HIVRNA PCR	10 Working Days	5 Working Days
	NAAT	10 Working Days	5 Working Days
EID	DNA PCR	5 Working Days	3 Working Days
DRUG RESISTANCE	Sequencing	10 Working Days	5 Working Days
CRC			
SECTION	**TEST**	**ROUTINE TAT**	**STAT**
CELL SEPARATION	PBMC Processing	30 HOURS	NA
	Plasma harvesting and storage	Within 8 hours of collection	1 HOUR
	Dried Blood Spot (DBS) preparation	12 HOURS	6 HOURS
	Cord Blood	Within 8 hours of collection	1 HOUR
	Breast milk processing	Same day of collection	NA
	Semen processing	Within 4 hours of collection	
	Cervical vaginal lavage	Within 4 hours of collection	
HEMATOLOGY	Automated CBC	24 Hours	1 Hour
	PBF Manual differentials	24 Hours	1Hour 30 Mins
PARASITOLOGY BIOCHEMISTRY	Malaria Blood Films	24 Hours	24 Hours
	Stool for O/C	24 Hours	45 Minutes
	Automated Chemistry tests	24 Hours	1 Hour
	Urinalysis	24 Hours	40 minutes
	Rapid HIV	24 Hours	40 minutes
Fertility Tests	FSH and Progesterone	24 Hours	40 minutes
IMMUNOLOGY	CD3/CD4/CD8/CD45	24 Hours	24 Hours
SEROLOGY	HIV ELISA	10 Working Days	5 Working Days
	SARS COV-2	10 Working Days	5 Working Days
	HIV-Incidence Assay	10 Working Days	5 Working Days
	HBsAg ELISA	10 Working Days	5 Working Days
	Salivary Estradiol	10 Working Days	5 Working Days
	Diasorin Anti-HBs ELISA	10 Working Days	5 Working Days
	Murex Anti-HBs Total ELISA	10 Working Days	5 Working Days
	HIV DNA / RNA PCR GeneXpert	10 Working Days	5 Working Days
	HCV RNA PCR	10 Working Days	5 Working Days
	HCV -Antibody	10 Working Days	5 Working Days
STI	RPR Syphilis	10 Working Days	5 Working Days
	HSV-2	10 Working Days	5 Working Days
	CT/NG PCR	10 Working Days	5 Working Days
	SD-Bioline Syphilis	10 Working Days	5 Working Days
	Wet Mount Microscopy	NA	Within 30 minutes of Sample Collection

REQUESTS FOR LABORATORY INVESTIGATIONS

All samples sent to the laboratory for analysis MUST be accompanied with request in laboratory investigation and reporting form showing ALL the following information; ***failure to that may lead to specimen rejection***
Patient Identification.Test Requested, Identity of the requester, Date of collection, Sample type, facility name, patient age, gender, collection tube e.t.c

The HIV-R laboratory does not allow oral requests. The clinical trials and research studies shall have participants sign consents, and the consent records shall be stored with respective studies at the clinic, however for the program activities, the request form shall serve both consent and agreement purposes.

SPECIMEN IDENTIFICATION

All specimens must be clearly identified with a labelling done at the time of collection. Identifiers must include patient ID (unique number), the date and time of collection and the identification of the person collecting the specimen must be noted on the accompanying requisition form. The appropriate requisitions must accompany all specimens, must be fully completed and must match the specimens.

Those delivering, recciving and examining specimen must be informed if the results are needed urgently, hence the request form should be marked URGENT

Table 3: Guidance on specimen collection

#	Test/Assay	Type of tube	Volume	Special Instructions
1	Full Hemogram / PBF (FHG)/ESR	EDTA Anti-coagulated Blood. Use PURPLE top tube	4ml	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
2	HIV Viral Load	EDTA anti-coagulated Blood. Use PURPLE top tube	5ml	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with CCC/HAART/ studynumber number (as appropriate), Age, Sex and Date and time collected
3	CD4	EDTA Anti - coagulated Blood. Use PURPLE top tube or CD4 Stabilizer	2ml	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time collected.

		tubes	2ml	
4	HBSag/HCV	Plain tube (RED top tube) or SST tube (yellow top tube with clot activator).	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
5	DNA PCR	Dry Blood Spot	5 Spots	Do not oversaturate the spots, Do not touch the circles on the DBS, do not pack wet cards, Dry well and pack well in single Ziplock bags with desiccants and humidity indicators.
6	Urine Analysis	Universal container	10 to 15 ml	Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection (Instruct if first catch/ mid-stream / or just urine)
7	PDT/HCG (Pregnancy Test)	Urine in Universal Container Plain tube (RED top tube) or SST tube (yellow top tube with clot activator).	At least 2ml 2ml	Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
8	Biochemistry	Urine in Universal Container Plain tube (RED top tube) or SST tube (yellow top tube with clot activator).	4ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
9	Chlamydia Trachomatis (CT) /	Urine in Universal	1 tube/	Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of

	Neisseria Gonorrhea (NG)	Container swab collection kit	2.5 ml	collection
10	RPR	Red Top (Plain) Tube	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
11	TPPA	Red Top (Plain) Tube	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
12	SD Bioline Syphilis	Red Top (Plain) Tube	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
13	Direct wet mount for Clue Cells, T.vaginalis and Candidiasis	Plain Sterile tube	Dry swab	Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
14	OSOM (T.Vaginalis)	Plain Sterile tube	Swab	Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
15	HIV 1/2	Plain tube (RED top tube) or SST tube (yellow top tube with clot activator).	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
16	Anti-HBc (Total)	Plain tube (RED top tube) or	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after

		SST tube (yellow top tube with clot activator).		mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection
17	Hepatitis B	EDTA Anti - coagulated Blood. Use PURPLE top tube	4ml	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time collected
18	Hepatitis C	EDTA Anti - coagulated Blood. Use PURPLE top tube	4ml	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time collected
19	HIV Drug resistance genotyping	EDTA Anti - coagulated Blood. Use PURPLE /Lavender top tube	4ml	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time collected
		Dry Blood Spot	5 Spots	Do not oversaturate the spots, Do not touch the circles on the DBS, do not pack wet cards, Dry well and pack well in single Ziplock bags with desiccants and humidity indicators.
20	Malaria Test	Giemsa Stained thick and thin film Malaria microscopy	1 ml EDTA Whole Blood	Mix gently by inverting 8-10 times immediately after collection to prevent clotting. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time collected
21	Fertility Test 1. FSH 2.Progesterone	RED top tube) or SST tube (yellow top tube with clot activator).	1 ml SST/RED TOP TUBE	
22	SARS-COV-2	Nasopharyngeal swab	Swab in viral transport medium	Insert swab into either nostril, passing it into the posterior nasopharynx. Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab

			or saline	into a tube containing 3ml of Viral transport media (VTL), or 3ml of saline. Break the swab at the indicated break line and cap the specimen collection tube tightly
		nasal swab	Swab in saline	Insert a nasal swab 1:1.5 cm into a nostril. Rotate the swab into the inside of the nostril for 3 seconds, while applying pressure with a figure to the outside of the nostril. Do not touch the swab tip to avoid contamination. Remove and place the swab into a tube containing 3ml of Viral transport media (VTL), or 3ml of saline. Break the swab at the indicated break line and cap the specimen collection tube tightly
23	Bio-Rad Geenius HIV test	Plain tube (RED top tube) or SST tube (yellow top tube with clot activator).	2ml	Mix gently by inverting 5-6 times immediately after blood draw. Keep tube in an upright position after mixing. Label legibly with Patient Identification number (PID) and Age, Sex, Date and time of collection

Note:

1.The 4 ml blood required for single Chemistry Parameter is also enough for all parameters to be requested.

2. TAT (Turnaround Time) is an estimated minimum time the laboratory needs to perform the requested examinations.

METHODS OF SPECIMEN SUBMISSION TO THE LABORATORY

1. Direct submission to the laboratory
2. Submission to the laboratory via other hospital pathology departments/research partners, in this case, an agreement must be reached with the hospitals/collaborators involved and specimens must be appropriately labelled
3. Submission to the laboratory via courier DBS Specimens can be submitted to the laboratory by post provided they are packaged according to current postal regulations.
4. Submission to the laboratory using an agreed courier.

SPECIMEN REJECTION

- Demographic information on the requisition MUST match that on the specimen.
- Unlabelled specimens or specimens with labels that do not match the requisition will be rejected. The submitting facility shall be notified to collect a repeat specimen and the laboratory will record the incident in the comments section of the request form.
- Sample shipped in wrong temperature conditions
- Double Packaging of DBS
- Wrong Container.
- Unlabeled/mislabeled Specimen.
- Insufficient Volume.
- Improper preservation.
- Clotted sample.
- Insufficient Patient Information.
- Wrong Specimen.
- Haemolysed Specimen.
- Illegible hand writing.
- Specimen identification discrepancy
- Prolonged (late/delayed) transportation.
- Specimen Uncovered/ exposed to air.
- Not protected from sunlight as needed.

Factors known to significantly impact the performance of the examination or the interpretation of the results may include but not limited to:

1. The causes of errors include inappropriate test requests, order entry, misidentification of patient and specimen, sample collection errors, haemolysis, clotting, insufficient quantity, inappropriate container, handling, storage, and transportation.
2. Factors affecting laboratory performance
   The factors that affect the performance of a laboratory include incompetency of phlebotomy, high workloads, inappropriate workflow, machine breakdown, delay in analyser maintenance, , poor specimen transportation, shortage of resources, lack of knowledge and skills, power supply interruption e.t.c

Note: Consult with the lab before sending samples for more rejection criteria depending on the nature of sample using the contact numbers provided in this hand book.

Table 4: REFERENCE RANGE HEMATOLOGY

Hematology Reference Ranges Verified in November 2022 from Walter Reed Project Kericho reference ranges that were derived from: Kibaya RS, Bautista CT, Sawe FK, Shaffer DN, Sateren WB, et al. (2008) Reference ranges for the clinical Laboratory derived from a rural population in Kericho, Kenya. PLoS ONE 3

#	HEMATOLOGY ANALYTE	REFERENCE RANGE	CRITICAL LOW	CRITICAL HIGH
1	White Blood cells (WBC) Male, Female	(2.7-7.7) , (3.0-9.1) 10^3/ul	< 2.0	> 40
2	Red Blood Cells (RBC) Male, Female	(4.4- 6.3), (3.7- 5.6) 10^6/ul	N/A	N/A
3	Hemoglobin, (Hgb): male, Female	(13.3-18.1), (9.5-16.1) g/dl	< 8.0 , < 7.0	> 20
4	Hematocrit, (Hct): male, Female	(39-53), (28.3-46.8) %	< 24 , < 7.0	> 60 , > 50
5	Mean Cell Volume, (MCV)	76-96 fl	N/A	N/A
6	Platelets: male, Female	(115-370), (124-444) 10^3/ul	< 81	> 1000
7	Lymphocytes; Absolute: male, Female	(1.098-3.16),(1.26-3.94) 10^3/ul	0.35-0.5	N/A
8	Neutrophils; Absolute: male, Female	(0.87-4.368), (0.96-5.55) 10^3/ul	0.75 -1.00	N/A
9	Eosinophils Absolute Male, Female	(0.03- 1.08), (0.03-1.21) 10^3/ul	N/A	N/A
10	Monocytes Absolute Male, Female	(0.13-0.592), (0.16-0.64) 10^3/ul	N/A	N/A
11	Basophils Abs Male, Female	(0.01-0.09), (0.01- 0.09) 10^3/ul	N/A	N/A
12	Lymphocytes; Percent : male, Female	(25.1- 62.2), (23-8- 62.0) %	N/A	N/A
13	Neutrophils; Percent: male, Female	(28.4-64.6),(24.4-65.9) %	N/A	N/A
14	Eosinophils Percent Male, Female	(0.8-20), (0.8-20.2) %	N/A	N/A
15	Monocytes Percent Male, Female	(3.2-11.7), (3.3- 10.9) %	N/A	N/A
16	Basophils Percent Male, Female	(0-0.5), (0.25-1.13) %	N/A	N/A
17	MCH: Male, Female	(27-32), (24.8-30.2) pg	N/A	N/A
18	MCHC: Male, Female	(31-35) g/dl	N/A	N/A
19	MPV Male, Female	(6-10) fl	N/A	N/A
20	RDW Male; Female	(11-16) %	N/A	N/A

(10): e3327doi:10.1371/journal. pone0003327 and the manufacturer)

Table 5: CD4 REFERENCE RANGE

Flow cytometry Reference Ranges adopted from Walter Reed Project Kericho reference ranges and University of Nairobi (used at KNH HIV Vaccine studies, as developed from Uganda and African Americans) and KEMRI (CGMRC) welcome Trust, Kilifi (IAVI protocol)

#	IMMUNOLOGY ANALYTES	REFERENCE RANGE	CRITICAL LOW	CRITICAL HIGH
1	CD4%	24.6 – 53 % (Percent)	N/A	N/A
2	CD4 Absolute	474 – 1355 Cells/ul	N/A	N/A
3	CD8%	10.1 – 38.6 % (Percent)	N/A	N/A
4	CD8 Absolute	236 – 1335 Cells/ul	N/A	N/A
5	CD4/CD8 Ratio	0.46 – 2.99	N/A	N/A

Table 6: CLINICAL CHEMISTRY REFERENCE RANGE

Chemistry Reference Ranges Verified in November 2022 from Walter Reed Project Kericho reference ranges that were derived from: Kibaya RS, Bautista CT, Sawe FK, Shaffer DN, Sateren WB, et al. (2008) Reference ranges for the clinical Laboratory derived from a rural population in Kericho, Kenya. PLoS ONE 3 (10): e3327doi:10.1371/journal. pone0003327 and the manufacturer)

CLINICAL CHEMISTRY ANALYTE	REFERENCE RANGE	CRITICAL LOW	CRITICAL HIGH
ALB2	35.7 - 48.10 g/l	<20g/l	N/A
ALP2S	35.0 – 129.0 U/L	N/A	>612 U/L
ALT	1.0 - 42.0 U/L	N/A	>75 U/L
AST	1.0 - 37.0 U/L	N/A	>80 U/L
BIL-T	0 – 17.0 ummol/L	N/A	>257 ummol/L
CHOL	3.6 – 6.47 mmol/L	N/A	N/A
CKL	0 – 170 U/L	N/A	>1500 U/L
CO2-	17.7 – 28.5 mmol/L	<10.9 mmol/L	N/A
CREAJ	44 – 97 umol/L	N/A	>884 ummol/L
GLUC	3.9 – 5.8 mmol/L	<2.7 mmol/L	>22.2 ummol/L
LIPC	13.0 – 60 U/L	N/A	>800 U/L
PHOS2	0.84 – 1.45 mmol/L	N/A	N/A
TRIGL	0.41 – 1.71 mmol/L	N/A	N/A
UREA	1.720 – 8.30 mmol/L	N/A	42.8 mmol/l
LACT2	1.50 – 3.90 mmol/L	N/A	>7.8 ummol/l
TP2	64.0 - 83.0 g/L	40 g/l	> 90 g/l
Cl-	100 - 111 mmol/L	<70 mmol/L	>130 ummol/L
K-	3.3 – 4.7 mmol/L	<2.8 mmol/L	>6.5 ummol/L
NA+	136.0 – 145.0 mmol/L	<120 mmol/L	>160 ummol/L
CA2	2.15 – 2.50 mmol/L	N/A	N/A
HDLC3	0.87 – 1.85 mmol/L	N/A	N/A
LDL-C	3.37 – 4.12 mmol/L	N/A	N/A
TPC3	15.0 – 45.0 mg/dl	N/A	N/A
CRPL2	1.0 - 200 mg/L	N/A	N/A
AMYL2	28.0 – 100.0 U/L	N/A	N/A
GGT2	0 – 45 U/L	N/A	N/A

Urinalysis Reference Ranges adopted from the manufacturer reference ranges	
Urine Dipstick Reference ranges	
PARAMETER	**EXPECTED VALUES**
Glucose	Normal
Bilirubin	Negative
Ketone	Negative
Blood	Negative
Protein	Negative
Leukocytes	Negative
PH	5-8
SG	1.010-1.025
UBG	Normal
Nitrite	Negative
Urine Microscopy Reference Ranges	
WBC	0-3/HPF
RBC	0-3/HPF
Epithelial cells	0
Crystals	0-3/HPF
Yeasts	0
Trichomonas	0
Casts	0
Bacteria	0-5/HPF
Fats	0

REPORTING OF RESULTS

The results will be transmitted via the following avenues:

1. Electronically
2. Hard copy

Reference documents

1.Kit inserts

2. Lab standard Operating Procedures

3.ISO 15189:2022 Standard

4. Good Clinical Laboratory Practice (DAIDS GCLP) Version 4.1