MISSION STATEMENT

We champion the provision of the highest standard of medical laboratory services through the application of relevant and appropriate technology for clinical care, research, capacity development and quality management.

VISION STATEMENT

To be a model in the provision of the highest quality of medical laboratory diagnostic and clinical research services in Nigeria and the West African sub-region

DRL QUALITY POLICY

The Defence Reference Laboratory is an excellent reference Laboratory with staff that are committed to the provision of medical laboratory testing services of high international standards, in line with the principles of good clinical laboratory practice. DRL management is committed to the provision of accurate, reliable, credible, relevant and timely laboratory results obtained from validated and/or verified test methods that are fit for intended use.

Tests are carried out at all times in accordance with documented procedures and in tandem with client requirements while complying with the requirements of ISO 15189. Management will continually undertake annual reviews of the performance of the Quality Management System and quality objectives to ensure their effectiveness, continuing relevance and suitability in ensuring production of high quality laboratory results. All DRL personnel are familiar and acquainted with the content and requirements of the Quality Management System documentation and implement the policies and procedures as laid down in all work processes.

LOCATION AND ADDRESS

DRL a centre of excellence for diagnosis and research is Located inside Mogadishu Military Cantonment [beside the Defence Headquarters Medical Center (DHQ MC)] along Abuja – Keffi Road, Asokoro Abuja. The mailing address is PMB 79 GARKI

ABUJA. TEL: +234 706 338 6864 and +234 908 722 3640 E-mail Address: defencereferencelaboratory@gmail.com

CORE VALUES

The DRL vision statement is hinged on 4 core values, which are

Professionalism and accountability

Commitment to Quality Assurance and Quality Management System

Care and Compassion for all users

Commitment to Research, Disease surveillance, Capacity development, continuing education and training.

MAJOR ROLES OF DRL

Diagnostic Service Provision (Provide specialized diagnostic services to patients)

Infectious Disease Surveillance and Epidemic Response Preparedness

Hub for Programme wide laboratory Quality Assurance Implementation (Design, implement and coordinate EQA program for military health facilities)

Training and Capacity development (Provide appropriate training for medical laboratory personnel in current and emerging diagnostic technology).

Research (Clinical and Operational) (Support clinical research and infectious disease surveillance including preparation of PBMCs and cell pellets). Referral Centre for laboratories in military and non- military medical facilities Assist in determination of national laboratory reference ranges.

Collaborate with relevant agencies in the evaluation and validation of laboratory diagnostic devices.

TABLE OF CONTENT

ABBREVIATIONS

A2LA - American Association for Laboratory Accreditation

CAP - College of American Pathologists

CLSI - Clinical and Laboratory Standards Institute

DBS - Dried Blood Spot

DRL - Defence Reference Laboratory

EIA Enzyme Immuno Assay

EQA - External Quality Assessment

HDRL HIV Diagnostic Research Laboratory

HIP - Health Implementation Program HIV Human Immunodeficiency Virus

ID Identification

IHVN - Institute of Human Virology Nigeria

ISO International Organization for Standardization

LN2 - Liquid Nitrogen

MLS - Medical Laboratory Scientist

MLSCN Medical Laboratory Science Council of Nigeria

NAFDAC National Agency for Food Drug Administration and Control

NMOD Nigerian Ministry of Defence

OIs Opportunistic Infections

PEPFAR Presidents Emergency Plan For AIDS Relief

SOP Standard Operating Procedure S/N Serial Number

STIs Sexually Transmitted Infections

TAT Turn Around Time

TB - Tuberculosis

QA Quality Assurance

QC Quality Control

USDoD United States Department of Defence

WHO AFRO SLIPTA – World Health Organization Africa region Stepwise Laboratory Quality Improvement Toward Accreditation

WRP-N Walter Reed Program Nigeria

NA Not Applicable

1.0 INTRODUCTION

1.1 Defence Reference Laboratory (DRL) is the apex medical laboratory of the Nigerian military with state-of-the-art diagnostic and research facilities. It is a product of militaryto-military partnership between the NMOD and the USDOD as part of PEPFAR. It was borne out of the desire to establish a laboratory that meets international standards of quality. The DRL is a centre of excellence for diagnosis and research Located inside Mogadishu Military Cantonment Abuja. It is saddled with onsite support, mentorship, monitoring and evaluation of the Program site laboratories, manpower /capacity development, QA QC activities/ quality management, provision of high standard medical laboratory services in clinical care/ research, handling of referrals, and strive to become ISO accredited. Currently, DRL is ISO 15189:2012 accredited lab through the American Association for Laboratory Accreditation (A2LA).

1.2 Clients depend on the DRL for quality results which ccurate diagnosis for proper management of patients and research purposes. It is therefore necessary for DRL to provide clients with adequate information pertaining to their services to enable them utilize the lab optimally.

1.3 This client's handbook is designed to provide relevant information to clients on services available at the (DRL) Abuja. It is also important to note that quality process in sample analysis starts with proper completion of request forms and sample collection. Since some clients (especially clinicians) sometimes have to draw samples for investigation and research purposes, this handbook also provides guidelines for sample collection as well as sample rejection criteria. This is to minimize the number of occasions that samples have to be rejected.

1.4 Technical Sections include

Sample Processing and Repository

Main Diagnostic Section (Chemistry Bench; Haematology Bench and Flow

Cytometry Bench)

Molecular Section

Serology Section

Malaria Section (under development)

Tuberculosis Modular Laboratory

1.5. Technical teams include

Quality Assurance Team

Safety Team

Logistics Team

Training Team

Facility Maintenance Team

2.0 HOURS OF OPERATION /GUIDING INSTRUCTIONS 2.1 HOURS OF OPERATION

The operation time of the laboratory is from 0800 Hours (8:00am) to 1600 Hours (4:00pm) Monday to Thursday and from 0800 Hours (8:00am) to 1330 Hours (1:30pm) on Friday. The lab collects or receives urgent samples (research or referral samples) at any time of the day. However, routine samples are only collected or received between 0830 and 1300 on weekdays only. The laboratory is closed on weekends and public holidays but have facilities to receive referred samples during weekends and public holidays

2.2 GUIDING INSTRUCTIONS

The guiding instructions for all staff of DRL are contained in the administrative orders attached to this handbook as enclosure 2 as issued by the Director DRL. Clients are expected to adhere to these instructions.

3.0 SERVICES OFFERED AND TEST MENU

The services offered and Scope of Investigations in DRL includes: Phlebotomy Routine Haematology and Clinical Chemistry assays Rapid testing using Nigerian national algorithm EIA (4thing generation and Western blott NA & DNA) d APs B Virus s C Virus, TIMA assay

PCR technology (R PANTHER an (Automated platform for STIs)

Hepatiti

Hepatiti

STIs– [Neisseria gonorrhea (GC), Syphilis]

See Annex A for Details on types of clinical services offered by the laboratory including examinations referred to other laboratories

3.1 LABORATORY TEST MENU AND PRECAUTIONS

The laboratory test menu and special precautions to be observed for each test are contained in the table at Annex A which is enclosed as well as guidelines on phlebotomy. As a general rule, do not draw blood from an arm receiving infusion.

4.0 FILLING THE REQUEST FORM (INSTRUCTIONS FOR COMPLETION OF THE REQUEST FORM)

4.1 It is important that the client or clinician completes the laboratory forms properly to assist the lab staff to produce accurate, reliable and reproducible quality results. Information such as the age of the patient in specific terms, sex of the patient, Identification number, name of research, purpose of investigation, provisional diagnosis as well as any previous medication or management received are part of relevant information that helps the Medical Laboratory Scientist (MLS) arrive at an accurate diagnosis. This places the MLS in a position to offer advice to the client/clinician. It is also important for the clients/clinicians to restrict themselves only to standard medical abbreviations in order not to confuse any other party that has to make contribution to the management of the patient and efficient handling of research samples. Requests to the various sections/departments in the laboratory should be entered on separate laboratory request forms for ease of processing. Where the requests are entered on the same form, the laboratory would open fresh forms to separate the investigations or photocopy made to accompany the samples to the various benches /workstations. All request forms must be signed and the clinician's name and contact stated in case there is need to get back to him.

4.2 Determination of the Identity of the Patient

Before collecting any sample from the patient, authorised sample processing Laboratory (SPL) staff collecting the sample would first confirm the identity of the patient. This would be done by confirming the identity of the patient by asking the patient and comparing with the identity on the requisition form. For unconscious patients, SPL staff would identify the patient's relative or the patient's next of kin and get the patient's details from them.

4.3 Verification that the patient meets pre-examination requirements

Before collecting any sample(s) from the patient, confirm that the patient has met all pre examination requirements as applicable to all assay to be conducted;

Fasting status

Medical status (time of last dose, cessation)

Sample collection at pre-determined time or time intervals (2hpp)

4.4 Completing the Request Forms

DRL request forms must be completely filled before they are presented at the reception in Sample processing Laboratory. The following essential information on the request form must be documented in a legible manner:

Patient's service Number (Where applicable if not fill Not applicable (NA)) o Rank/Rating (Where applicable if not fill Not applicable (NA))

Forenames/ First Name

Surname

Ward number (Where applicable if not fill Not applicable (NA)) o Unit

Date of Birth o Age o Sex

Laboratory Specimen o Examination Required o Diagnosis

Short Statement (Case, treatment and progress) o Date of collection o Time of collection o Date of receipt o Time of receipt o Name of recipient o Date of request o Patient's contact o Doctors contact o Phlebotomist

Name of Medical Officer in charge of case o Signature of medical officer o A clear indication of whether the tests requested are urgent- Marked in Red.

4.5 Diagnosis

Relevant clinical information appropriate for the test(s) requested must be given e.g diabetic or hypertensive condition, antenatal history, blood transfusion history etc. This is useful as it guides the Medical Laboratory Scientist conducting the assay in verifying the results to ensure they are in coherence with the clinical history before results are released.

NOTE: External users, from other hospital or laboratories may use their own request forms provided that criteria for completing the request form as listed above are adhered to (all columns are filled appropriately and all necessary information supplied). DRL will receive these request forms and file a copy at the testing bench.

5.0 SAMPLE COLLECTION

Sample collection is a critical aspect of patients care and therefore needs to be standardized. The idea is to delineate responsibilities in order to avoid indiscriminate collection which could introduce lapses. All patients shall have their samples taken by the phlebotomist on duty. Each patient/participant sample should be accompanied with a request form which should contain: Patients' name; Gender; Age; Hospital or Enrolment number; Type of sample; Date and Time of collection; Clinical Diagnosis; Required tests; Name of requesting Clinician, address, phone number and e-mail address.

5.1 Labelling the sample container

The sample container must be labelled with at least these minimum essential information in a LEGIBLE manner: a. Patients full name

b. DRL unique number (for routine and clinical samples)

Study ID (for research samples)

Date of sample collection

Test requested (for routine and clinical samples)

5.2 Vacutainer blood collection system

The vacutainer system consists of a double-pointed needle, a plastic holder or adaptor and a series of vacuum tubes with rubber stoppers of various colours. The stopper

Vacutainer blood collection system

colours indicate the type of additive present. The blood goes from the patient directly into the appropriate test tube.

5.3 Vacutainer Colour System

Colour code	Tube Type	Volume(ml)	Number of inversion for mixing	Determinations	Special Instructions
 Light Blue	Sodium Citrate	6ml	8	Coagulation Studies, D-Dimer, Factor Assays, Thrombophilia Screen (4 tubes) Lupus Screen (2 tubes) MAC Cultures for AAFB (Virology)	Must be filled to the line
 Gold	SST	6ml	8	U + E, LFT, Bone Profile, Magnesium, Lithium, Therapeutic drug monitoring (TDM), Hormones, Tumour Markers, Trop T, Most Biochemistry Tests and Immunology	Not to be used for copper zinc and copper and Parathyroid hormone (PTH).
 Green	Heparin & PST	6ml	8	coronary care unit (CCU) Specimens for Urea, Electrolytes and other routine chemistry	NA

 Lavender	EDTA	6ml	8	FBC Profile, DCT, Malaria Screen, ESR (not Alex), Hb Electrophoresis, CD4, HBA1C, Blood Ammonia, HCV PCR, Hep C PCR, Viral Loads and Genotyping, Meningo PCR, PTH	NA
 Grey	Fluoride Oxalate	3ml	8	Blood Glucose and Lactate CSF Glucose and Lactate Fluid Glucose	NA

5. 4 Sample Collection, Transport and Storage Requirement

a. Clinical Chemistry Samples

Name of Test	Sample type required	Patient Preparation procedures	Sample Collection Guidelines and primary sample volume	Transport device	Condition and time to reach the lab	Special considerations/requirement for the specific samples
Alanine aminotranferase(ALT) Aspatate Aminotransferase (AST) Alkaline phosphate Gamma GT Total protein Creatinine Urea Cholesterol Triglycerides Sodium (Na^+) Potassium(K) Chloride(Cl) Calcium Uric Acid	Serum Clot activator silicone coated (plastic or plain)	Advisable not to collect sample from infusion hand when patient is on infusion	Serum collected in red capped vacutainer tubes free from haemolysis Sample volume should be 5ml of venipuncture blood	The primary container shall be put into another container (storage box) and placed in a cool transport box during the transportation	Within 2hours of collection at 15 -25^{0}C	EDTA, Citrate and fluoride inhibit the enzyme

Glucose	Serum plasma CSF	For fasting sample the patient shall be fasting at least for 12-14 overnight hours	Serum or plasma (Li-heparin or fluoride) sample volume should be <2mL. CSF should be collected in a sterile bottle	The primary container shall be put into another container (storage box) and placed in a cool transport box during the transportation	<2hours at 15-25°C,	
Bilirubin- Direct Bilirubin -Total	Serum	Not applicable	Serum collected in red capped container tubes. sample shall be free from haemolysis and lipemia. Sample volume should be up to 1.0ml	The primary container shall be put into another container (storage box) during the transportation	Within 2 hours at 15-25°C	Protect samples from exposure to light.
Urinalysis	Urine	Patient is instructed to collect random urine collection and transport to the laboratory immediately	Pass specimen directly into a clean wide- mouth urine container.	Clean wide- mouth container, 5-10ml volume	Urine should be transported in a well tightened cap at room temperature to laboratory within 30 minutes after collection	Unpreserved <30minutes at room temperature

b. Hematology/CD3 and 4 Tests

Name of Test	Sample type required	Patient Preparation procedures	Sample Collection Guidelines and primary sample volume	Transport device	Condition and time to reach the lab	Special considerations/requirement for the specific samples
Complete Blood Count	EDTA Whole Blood	Advisable not to collect sample from infusion hand when patient is on infusion	Venipuncture blood should be collected in EDTA vacutainer and labelled Volume 3-4ml (2ml accepted for pediatric)	The primary container shall be put into another container (Sample rack/storage box) and placed in a cool transport box during transportation	At room temperature under 2hours collection	Transportation should be smooth to be positioned upright in a sample rack, as too much shaking can hemolyse the cells
CD4/CD3	EDTA Whole Blood	Not Applicable	Venipuncture puncture blood should be collected in 2mL EDTA vacutainer and labelled	The primary container shall be put into another container (Sample rack/storage box) and placed in a cool transport box during transportation	At room temperature under 2Hours	Transportation should be smooth to be positioned upright in a sample rack, as too much shaking can hemolyse the cells

c. Sexually Transmitted Infection (STI)

Name of Test	Sample type required	Patient Preparation procedures	Sample Collection Guidelines and primary sample volume	Transport device	Condition and time to reach the lab	Special considerations/requirement for the specific samples
Chlamydia, Trachomatis, Neisseria Gonorrhoea	Rectal swab	Patient should be informed about the procedure to avoid any form of contamination with anal skin flora.	Use cleaning swab to clean the rectum. insert the collection swab to collect the rectum particles by swabbing in anticlockwise direction. Carefully insert the swab beyond the anal sphincter, gently rotate the swab to collect sample for about 10 seconds faeces should be visible on the swab then put the swab back into the 2.5ml of preserved cyst solution in APTIMA container and tighten very well	Package the tubes in a rack/box then transport in a cool sample transport bag to lab	<24h, room temp	Not Applicable

	Urine	The patient should not have passed urine for about 2 hours before specimen is collected.	Provide urine collection bottle for the patient. Instruct patient to void a mid stream urine into the bottle. In your Lab use pasture pipette to transfer 2ml of the urine into APTIMA bottle.	Package the tubes in a rack/box then transport in a cool sample transport bag to lab	<24h, room temp	
	Oral pharyngeal (OPH) swab	Provide mouth rinse free of alcohol to the patient to rinse mouth	Pass a sterile swab into the mouth until it touches the larynx, then collect the sample by swabbing.	Package the tubes in a rack/box then transport in a cool sample transport bag to lab	<24h, room temp	

d. Serology

Name of Test	Sample type required	Patient Preparation procedures	Sample Collection Guidelines and primary sample volume	Transport device	Condition and time to reach the lab	Special considerations/ requirement for the specific samples
Hepatitis screening (HBsAg,HCV) ELISA	Serum	Not Applicable	Vein puncture blood should be collected in plain vacutainers. 3 to 4mL whole blood needed	The primary container shall be put into another container (Sample rack/box) and placed in a cool transport box during transportation	At room temperature <4 hours of collection	Not Applicable
RPR (Rapid Plasma Reagin) HIV screening (Rapid) HIV ELISA HBsARapid HBsAg ELISA HBsAg confirmatory test Ortho HCV ELISA Syphilis CAPTIA Tuberculosis Quantiferon (QFT-TB-GOLD) Geenius HIV Confirmatory HCV Innolia	Serum or plasma	Not Applicable	Vein puncture blood should be collected in plain or EDTA vacutainer 3 to 4mL whole blood needed	The primary container shall be put into another container (Sample rack/box) and placed in a cool transport box during transportation	At room temperature <4 hours of collection	Not Applicable Note: For QFT-TB Gold 3 tub need to be collected for: - Antigen -Mitogen } 3ml each - Nil

e. Molecular

Name of Test	Sample type required	Patient Preparation procedures	Sample Collection Guidelines and primary sample volume	Transport device	Condition and time to reach the lab	Special considerations/requirement for the specific samples
HIV-1 RNA Viral Load	Plasma	Not applicable	Vein punctured, collect 10mL whole blood in EDTA, spin and separate plasma in triplicate of 1.5mL each at 800-1200g for 20mins within 2hr and freeze immediately for transport to testing Lab within 1 week. (Refer to collection, processing and shipment SOP)	Arrange each triplicate vials per patient in a cryo box, then place the box(es) in a cold box with sufficient icepacks to keep the samples frozen with temp logger or thermometer to DRL under 3 hours transport radius	Under 3hours of transportation time in frozen state	Lipemic & lysed blood must be avoided plasma must be at least 1.2ml per vial

HIV-1 DNA	DBS (DRY BLOOD SPOT)	Not applicable	Finger/Heel prick, squeeze a drop (70ul) of blood into each of the 5 circles on the 903 whatman filter paper and allow to air dry for over 3 hrs before packaging individual card for temporary storage or shipment. (Refer to DBS collection, drying, packaging and storage/shipment SOP)	Not more than 10 Individual glycine enveloped samples into a Ziplock bag with at least 10 desiccants and 1 humidity card. Envelope the Ziplock bag and address to DRL	Deliver in Ziplock bags at room temp	Store DBS cards in individual resealable bag with desiccant sachet in each Ziplock bag at room temperature for up to one month

5.5 SAMPLE COLLECTION PROCEDURES

Blood collection procedure

The following are guidelines to use when collecting samples. a. Principle

The patient`s vein is punctured with a sterile needle attached to an aspirating device. This allows the drawing of venous blood with the least amount of patient discomfort and trauma.

Safety and Infection control

It is important to follow safety and infection control procedures.

i. PROTECT YOURSELF

Practice universal precautions:

Wear gloves when handling blood/body fluids. • Change gloves after each patient or when contaminated

Wash hands frequently.

Dispose of items in appropriate containers

Dispose of needles immediately upon removal from the patient`s arm.

Clean up any blood spills with a freshly made 1% bleach disinfectant (Sodium Hypochlorite Solution).

ii Protect the patient

• Place blood collection equipment away from patients especially children.

Equipment

THE FOLLOWING ARE NEEDED FOR ROUTINE VENIPUNCTURE

Vacutainer collection tubes- the tubes are designed to fill a predetermined volume of blood by vacuum. The rubber stoppers are colour coded according to the additive the tube contains. Blood should NEVER be poured from one tube to another since the tube can have different additives or coatings.

Needles- The gauge number indicates the bore size: the larger the number, the smaller the needle bore.

Holder- Use with the vacutainer system

Tourniquet- Wipe off with alcohol and replace frequently

Alcohol wipes- 70% Isopropyl alcohol or 70% methylated spirit

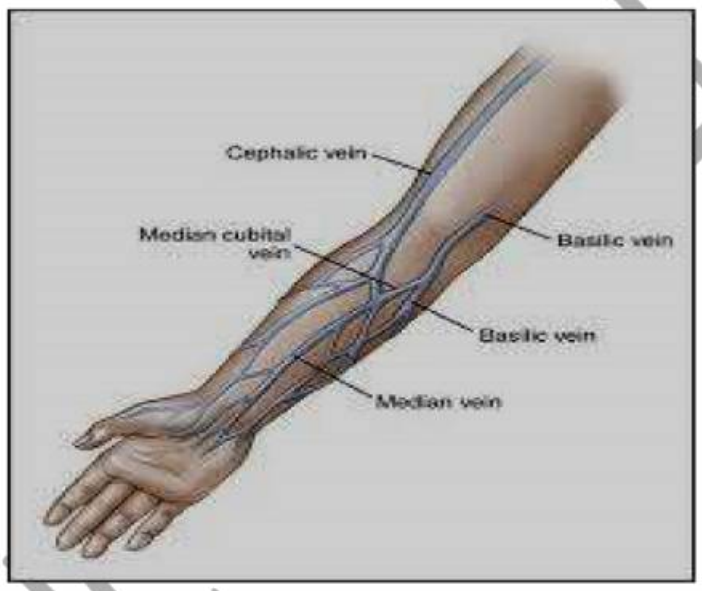
Needle disposal unit- Needles should NEVER be broken, bent or recapped. Needles should be placed in a sharp container immediately after use.

Gloves- Can be made of latex, rubber or vinyl and are worn to protect the patient and the phlebotomist.

Syringes- May be used in place of the evacuated collection set for special circumstances.

iii Procedure for vein selection:

The median cubital and cephalic veins of the arm are used most frequently. See diagram below:



Palpate and trace the path of veins with the index finger. Arteries pulsate, are most elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord like, and roll easily.

If superficial veins are not readily apparent, you can force blood into the vein by massaging the arm from wrist to elbow, tap the site with the index and second finger, apply warm, damp washcloths to the site for 5 minutes, or lower the extremity to allow the veins to fill.

5.6 Procedure for phlebotomy

Position the patient so he or she is comfortable and safe in case the patient faints and falls.

Recommended needle size: 20G, 21G or 23G.

Closed vacutainer system is recommended.

Select tube or tubes appropriate for type of samples desired.

Select site for venepuncture

Put gloves

Prepare venipuncture site with alcohol prep. Cleanse in a circular fashion, beginning at the site and working outward.

DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.

Allow site to dry.

- Apply the tourniquet 3-4 inches above the selected puncture site. Do not place too tightly or leave on more than 2 minutes.
- Remove needle shield. Perform venipuncture **WITH PATIENT`S ARM IN A DOWNWARD POSITION AND TUBE STOPPER UPPERMOST**
- This reduce the risk of backflow of any anticoagulant into the patient`s circulation.

- Push the tube onto the needle, puncturing the stopper.
- REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE, within 2minutes of venepuncture. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE STOPPER DURING THE PROCEDURE.
- When first tube has filled to its stated volume, remove it from the holder,

Place succeeding tube in holder puncturing stopper to initiate flow.

While each successive tube is filling invert previous tube GENTLY according to anticoagulant`s contents. DO NOT SHAKE. Vigorous mixing can cause haemolysis.

When all tubes of blood have been collected, remove the last tube from the vacutainer holder, place a cotton ball or gauze over the site and withdraw the needle in a smooth and cautious manner so as not to bruise the vein.

After withdrawing the needle fully, apply pressure to the cotton ball. Over the puncture site and hold pressure. If patient is able ask them to apply pressure for 3 to 5 minutes until the bleeding stops.

Discard the needle of the vacutainer into the biohazard sharp container WITHOUT RECAPPING the needle.

Immediately invert the last tube GENTLY according to anticoagulant`s contents as described above.

5.7 Instructions for patient-collected samples

Refer to section 5.4; Sample Collection, Transport and Storage Requirements for specific instructions for patient collected samples like urine, stool, sputum etc. in addition to the procedure described below

5.7.1 Procedure for Sputum Collection

Explain the specimen collection procedure to the patient

Provide patient with the screw- capped container. Instruct patient to cough deeply and spit up sputum (phlegm) into the screw-capped sputum container, and then seal the specimen container tightly.

Label each specimen immediately with identifying information- patient identification (PID), date, etc.

Fill out lab request/report form for each specimen with date time and names of collector.

Check that PID on the specimen container matches with that on the lab request/ report (Check specific name of form) form. NOTE: This labelling and matching is the primary responsibility of the collector and must be done carefully and precisely.

Place collected specimen in a transport container at room temperature, transport to the laboratory/ testing section immediately.

Enter specimen information into your laboratory sample reception log.

5.7.2 Procedure for Stool Sample Collection

Explain the specimen collection procedure to the patient

Provide patient with a wide-mouth plastic, screw- capped stool container

Instruct patient to deposit approximately one spoonful (spoon provided) into the screw-capped stool container instruct patient to seal the specimen container tightly.

Label each specimen immediately with identifying information – patient identification (PID), date of collection.

Fill out lab request form for each specimen with date, time and names of collector.

Check that PID on the specimen container matches with that on the lab request/ report (Check specific name of form) form. NOTE: this labelling and matching is the primary responsibility of the collector and must be done carefully and precisely.

Place collected specimen in a transport container at room temperature, transport to the laboratory immediately.

Enter specimen information into sa mple reception log in the laboratory.

Place collected specimen in a transport container at room temperature and send specimen to the laboratory testing area.

5.7.3 Procedure for Urine Sample Collection

a. Routine Urinalysis

Explain the specimen collected procedure to the patient.

Provide the patient with the collection container (Approximately 25ml volume container) and the patient to void at least 10ml of urine into the container.

Instruct the patient to tightly seal the filled specimen container and to return filled container to the laboratory.

b. Mid- stream Urine Collection

Provide patient with sterile urine collection container. (Approximately 25ml volume container)

Instruct the patient to pass a small amount of urine into the toilet or latrine and to collect about 20ml of urine in the bottle.

Instruct the patient to tightly seal the filled specimen container and to return filled container to the laboratory.

First- morning collection is ideal. Babies and infants shall have site cleaned prior to collection.

Label each specimen immediately with identifying information – patient identification (PID) and date of collection.

Fill out lab request /report form for each specimen with date, time and names of collector.

Check that PID on the specimen container matches with that on the lab request/report (check specific name of form) form. NOTE: this labelling and matching is the primary responsibility of the collector and must be done carefully and precisely.

Place collected specimens in a transport container at room temperature, transport to the laboratory immediately.

Enter specimen information into sample reception log in the laboratory.

Place collected specimens in a container at room temperature and send specimen to the laboratory testing area. ransport co

5.7.4 Procedure for blood sample collection by finger pricking

Position hand palm- side up. Choose whichever finger is least calloused

Apply intermittent pressure to the finger to help the blood to flow

Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area and allow on the fingertip

Firmly press the lancet to puncture the fingertip.

Wipe away the first drop of blood with a sterile gauze pad or cotton ball

Collect the specimen. Blood may flow best if the finger is held lower than the elbow.

Apply a gauze pad or cotton ball to the puncture site until the bleeding stops. Properly dispose of all contaminated supplies

Label each specimen immediately with identifying information- patient identification (PID) and date of collection.

Check that PID on the specimen container matches with that on the lab request/report (check specific name of form) form. NOTE: This labelling and matching is the primary responsibility of the collector and must be done carefully and precisely.

Place collected specimen in a transport container at room temperature, transport to the laboratory immediately.

Enter specimen information into sample reception log.

Place collected specimen in a transport container at room temperature and send specimen to the laboratory and send specimen to the laboratory testing area.

5.8 SAMPLE REJECTION CRITERIA

The following are a general listing of common situations in which a specimen may be rejected for processing. a. Specimen not labelled.

Specimens labelled with incorrect patient identification (Note: At least 2 identifiers must be written on each vial).

Sample tube is broken, damaged, or leaking

Sample tube is not labelled or there is no enough information on the tube to match with the paperwork

Paperwork does not match sample

Clotted Blood Specimen

Lysed blood Specimen

Specimen collected with improper preservative or anticoagulant.

Quantity specimen not sufficient to perform assay

Presence of clot in ed anticoagulat blood Specimen in vacutainers upon visual examina tion.

Lavender ematology vacutainers for ha analysis with less than one-third filled in the tub e.

Specimens which are hemolyzed, lipemic or contain particulate matter.

Specimens which are obviously or subsequently prove to be contaminated.

Serum specimens not separated from the clot and left at room temperature or refrigerated for a test requested not grossly time, which exceeds the protocol for the o. Specimens transported appropriately to the lab e.g leaking or contaminated specimens on the exterior portion of container and specimens not in compliance with Universal Precautions.

5.8.1 More Causes for Rejection of Sample

The quality of laboratory results are directly affected by the quality of the sample obtained from the patient. Samples may be rejected as unacceptable for the following reason:

Haemolysis – this is usually caused by a procedural error such as using too small of a needle or pulling back too hard on plunger of a syringe used for collecting the sample.

Clotted – failure to mix or inadequate mixing of sample s collected into an additive tube.

Insufficient sample- certain additive tubes must be filled completely. When many test are ordered on the same tube, to be sure to know the amount of sample needed for each test.

Wrong- tube collected for test ordered

Tube not labelled before transporting to lab.

Samples held too long in a facility before transporting.

Submitting specimens in expired collection tubes. It is the responsibility of the submitter to ensure that specimens are collected in tubes that have not expired.

Unlabelled sample container and or sample request form

Incomplete filling-in of the sample request form

Illegible handwriting

Leaking sample containers

Mismatching information between the sample and the request form

Sample without a request form

5.8.2 Compromised samples

Compromised and irreplaceable samples such as cerebrospinal fluid, biopsies, fine needle aspirates, bone marrow aspirates and samples from neonates shall not be subjected to the normal rejection criteria.

Upon receiving such samples, communication shall be made to the requesting clinician on how the quality of the sample is compromised and how it might affect results.

If the clinician is able to collect another sample, they shall be given the opportunity to do so.

If another sample cannot be collected, the compromised sample will be processed and analysed.

After processing and analysis, the result are accompanied with a comment on how the sample was compromised.

5.9 SAMPLE ACCEPTANCE CRITERIA

Samples must be shipped to the laboratory in the right containers, properly labelled with at least 2 identifiers and under conditions that are appropriate for subsequent processing and testing as described in section 5.4(Sample Collection, Transport and Storage Requirements).

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Each sample MUST be accompanied by a requisition form and relevant documents

The sample integrity must be optimal with respect to the correct volume of blood, no haemolysis and containers must not be broken or leaking.

Dried Blood Spot (DBS) samples: Whatman filter paper 901 type is acceptable. Ensure that at least 3 of the 5 circles are 100% filled with blood from skin puncture for capillary blood or spotted from syringe unlayered. Allow at least 3 hours of cool air dry in a dust free environment before packaging in individual envelopes. These may be stored at room temperature or at cold temperature before shipment to DRL in a 3 layer packaging.

Swabs for STI (APTIMA): APTIMA swab collection device MUST be used for oral or anal swab collection s for STIs.

Urine for STI (APTIMA): APTIMA urine collection tubes MUST be used to send urine samples to DRL for STI investigation using APTIMA.

5.10 SAMPLE TRANSPORT AND PRECAUTIONS

All samples to be transported to the DRL shall be in appropriate storage conditions prior to transportation (plasma/serum must be kept frozen or as specified by appropriate SOP).

All specimen must be in leak proof containers/vials and well arranged in a sample cryobox and must be serially arranged to match with the manifest.

Label the cryobox properly and put absorbent material over all the vials before covering the box and use a rubber band or cello-tape to hold it in place. d. Transfer the box in tertiary material with lots of wads to hold it in place.

Put sufficient amount of ice pack where needed.

Label the tertiary container with signs of pathological specimen, bioharzard signs, upright direction signs, the type of sample, recipient contact number, inform DRL before the sample is transported.

Samples requiring LN2 vapour transportation shall be transported in charged Dry-shipper.

Samples requiring room temperature shipment must be transported without any form of cold material.

Attach sample manifest to all shipment and send a soft copy of the manifest in advance.

PRECAUTION

Ensure that the icepack has been at -20oC to -80oC for the past 24hrs before use.

Dryshippers must be fully charged before use.

Avoid direct contact with LN2

Use cryogenic gloves and aprons while handling LN2.

Handle all sample as pathogenic capable of transmitting infection..

NOTE: All plasma and serum sample must arrive DRL frozen. Samples for PBMC must arrive DRL less than 2hrs after collection.

5.11 DELIVERY, PACKING, AND TRANSPORTATION OF SAMPLES

All specimen and samples should be treated as potentially infectious or high risk. Therefore, we advise all to take universal precautions in the collection, packaging and delivery of specimens being sent to the DRL for analysis.

5.11.1 Specimen Delivery to the DRL

The requirement stated below apply to all specimen or samples directed to the DRL. All samples should be received within 4 hours after collection for analysis (for plasma and serum or DBS samples that may not be sent immediately, they should be stored at an appropriate temperature(-800C for plasma and serum and room temperature for DBS samples) prior to transportation), and not exposed to extreme temperatures (Samples must be transported to DRL within the appropriate temperatures as stated in SOPs and MOPs) as well as in a safe manner using triple packaging for the person carrying the samples and the public. Therefore transport all samples either in a cool box material or at room temperature depending on what is required.

Note: DRL would provide clients with specimen transport packaging instructions.

L for more information regarding the

rocedure for the Transport of Diagnostic

5.1

on Infectious)

1.2 Packing P Specimen to be sent should be stored in a secure preferably plastic) primary

Sp ecimen (N container.

Put (on your Personal protective equipment

Wrap the container in tissue or cotton wool, which will act as absorbent material

in the event of any spillages This will be placed in a biohazard bag.

Place the biohazard bag with the sample

in a padded (jiffy bag) envelope.

Label the envelop with a hazard warning

label "BIOHAZARD"

Place the name, address and contact number of the destination Laboratory, (DRL) on the outside of the envelop.

Place the name, address and contact number of the originator on the outside of the envelope.

The specimen can be transported or posted as appropriate.

5.11.3 Procedure for the Transport of Infectious or suspected infectious specimen

Wash hand with soap and water.

Wear appropriate personal protective gears i.e. gloves, respirator, laboratory coat etc.

Ensure that each specimen has 2 patient ID, Date of Collection, and Name of sending facility.

NOTE: Use three (triple) packaging layers – First packaging layer should be leakproof and all layer should contain absorbent material in case there are many leaks.

Wrap primary container on an absorbent material like paper towels and place it in a cushion multiple tubes

Place the primary container into a second container (secondary container, then into a leak – proof larger tertiary container).

Place the tertiary container into a cooler box.

Place adequate frozen ice packs (from the -20oC compartment of the refrigerator), one at the top, and one on each side to maintain 2-8oC temperature if the transportation requires a cold chain.

Place shipping document in Ziploc bag to keep from becoming contaminated or wet.

Place a thermometer in the cooler box to monitor temperature change during transportation.

Close and seal the cooler box by packing tape.

Label the cooler box with destination facility, contact information (both for shipper and receiver) and affix “Infectious Substances’’ label or BIOHAZARD label.

Disinfect the outside part of the cooler box with 0.5% bleach.

Contact the referral lab on specimen delivery.

Transport the sample to the laboratory

5.11.4 Disposal of waste Material used in Specimen Collection

All materials used in specimen collection should be treated as potentially hazardous. All sharps must be discarded in sharps containers, noninfectious wastes must be discarded in the black coloured waste bag, infectious wastes must be discarded in yellow or red coloured bag depending on the lab policy.

5.12 MISCELLANEOUS REQUIREMENTS

5.12.1 Repeat Examination due to Analytical Failure In the event of analytical failure DRL will:

Repeat the test using a back-up instrument or

Store the specimens in appropriate conditions until the cause of the analytical failure is identified and corrected and then repeat the test.

5.12.2 Differences in comparability of results

In the events of differences in comparability of results DRL shall notify users in writing and follow-up with telephone call of these differences and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. Cholesterol glucose) and when examination methods are changed.

5.13 REPORTING OF RESULTS

Once investigations have been concluded, result are reviewed and released for pick up within the turn-around-time. The dispatch of laboratory result is handled in the following manner:

Generally, results will be available at the Sample Reception Laboratory (SPL) as soon as they are ready. SPL will contact all clients via telephone to inform them that results are ready for them to come and pick it up.

Unexpected and marked abnormal result will be routinely communicated directly to the clinician concerned personally or via phone call immediately by the DRL POC.

Result of urgent request will be communicated to the clinician via phone call if so indicated on the request form

5.14 REFERENCE RANGES (BIOLOGICAL REFERENCE INTERVALS)

Reference range for quantitative tests are described in Annex D. Reference ranges shall be included for investigations that have established reference ranges. It should however be noted that the stated reference ranges are values obtained from literature and may not represent the local population. The laboratory will publish local reference ranges as soon as they are determined for the local population.

5.15 ADVISORY SERVICE

DRL has authorised its qualified and trained MLS to provide advice on choice of examinations: the use of services including repeat frequencies: the required type and volume of sample and in situations where laboratory results reveal that further analysis is required. Clients should contact the laboratory Director for advice on other disciplines offered.

5.16 COMPLAINT & REMEDIAL ACTIONS PROCEDURE

Complaints about lab services provide excellent opportunity for improvement. The laboratory management welcomes constructive criticisms and complaints and is committed to resolving any such to ensure improve quality and satisfaction. When there is need to resolve any issues bordering on lab results, turnaround time or any aspect of laboratory services, the Director or Designee should be contacted. Similarly, the Laboratory Manager or supervisors of the respective laboratory units could also be contacted if the Director could not be reached. In addition, clients are advised to document all complaints about laboratory services using the Client Complaint Form. This would enable a systematic approach involving root cause analysis, corrective actions, preventive actions and continuous monitoring. The list of laboratory focal persons is at Annex C while a sample of the Clients Complaint Form is enclosed.

Any Client wishing to raise a complaint against the laboratory is requested to follow the step below:

All clients are free to complain to the DRL management

The complainant is required to complete the complaints form (which is available at the SPL) and forward it to DRL management or submit at the SPL.

Complainants can also communicate directly with Laboratory Director of DRL or any member of staff through contact details provided in this document OR direct the complaints to the DRL email address; defencereferencelaboratory@gmail.com

DRL Lab will acknowledge the receipt of complaint upon receipt and will follow resolution of complains procedure to handle all complaints

After successful resolution of complaints, DRL will contact the complainant and inform him or her about the result achieved.

5.17 PATIENT CONSENT

Consent of patients and users are obtained orally prior to phlebotomy/sample collection. All research samples are consented to by participants at the sites/points of counselling and phlebotomy. This implies that all samples handled in the DRL has been consented to and can be used for the research to which consent has been obtained. Further researches

could be conducted on these samples without seeking for a fresh consent. However ethical approval should be sought from a recognised - Institutional Review Board (IRB).

In addition, consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed is obtained from the patient in writing before the release of such information by the DRL.

DRL trained and Qualified MLS shall provide information for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), All these and other detailed requirements as deemed fit by the supervisor in charge shall be explained to the patient, Clinicians and other users of the Laboratory.

5.18 FACTORS THAT AFFECTS THE PERFORMANCE OF THE EXAMINATION

OR THE LABORATORY RESULTS INTERPRETATION

Gender (Sex), Age, Tribe/ place of origin and place of habitation of patients or research subjects.

Patient/ Participants' history including current treatment; and probable reason/ purpose of conducting the test.

Type of sample relative to test required.

Sample integrity (time of collection and condition of patient)

Biological variations due to rhythms and physiological changes such as pregnancy, menstrual circle, fasting, diet/nutritional status,, exercise, medication, habits and life styles.

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6.0 QUALITY ASSURANCE

6.1 QA/QC and QMS

DRL observes all the elements in the QMS. Routine internal quality controls (IQCs) are done to detect, evaluate and correct errors before patient or research samples are reported. We participate in external quality assessment proficiency testing (EQA PT) and have been performing excellently well. This qualifies us to participate in numerous international researches.

6.2 CLINICAL ADVICE ON ORDERING OF TESTS AND ON

INTERPRETATION OF TEST RESULTS

DRL provides clinical advice to clients with regard to ordering of tests and interpretation of laboratory results. This is done by only qualified MLS.

6.3 POLICY ON PROTECTION OF PERSONAL INFORMATION

All information about patients' results and research findings are treated with strict confidentiality. There is a policy and SOP on confidentiality of information for all DRL staffs. All DRL staff and auditors that have access to patients/research volunteer's information are bound by the contents of this policy. To ensure that they protect patient confidential information, all staff and auditors/assessors are made to read and sign confidentiality of information statement before accessing patients/volunteers information. All staff, auditors/assessors understand the implications of breaching confidentiality.

7.0 TURN AROUND TIMES (TAT)

The established TATs for all parameters in DRL are contained in annex A which is attached to this handbook.

8.0 REPORTING OF RESULTS

The DRL Abuja shall adopt standardized reporting formats in reporting results. As much as possible, the System Internationale (SI) Units or any other unit provided by a globally recognised standardization organisation will be used. A conversion table from conventional to SI units for common parameters is contained in the table at Annex B.

9.0 PROCESSING URGENT/EMERGENCY REQUESTS

The DRL places priority in handling urgent or emergency requests to ensure that they receive accelerated attention. Urgent requests are however to be clearly marked urgent preferably in red ink. It is important that emergency requests are really urgent in order not to place undue pressure on the laboratory. It is also necessary for a designated staff of the sample source to follow up such sample to ensure prompt dispatch of aspects or all of the result.

10.0 HANDLING OF CRITICAL RESULTS

Critical Values are analytical results that suggest a clinical condition that may be life-threatening and may require immediate clinical intervention. Critical limits of laboratory results need urgent notification to the clinician because they are basis for immediate intervention. The list of critical values is at Annex D. The following procedures shall be followed by the Laboratory in handling critical results:

the clinician would be notified immediately by the lab supervisor/designee by phone call . The supervisor shall send the result directly to the clinic/site and state clearly that the result is critical and should be acted upon as rapid as possible.

Appropriate documentation shall be maintained by filling the result in the critical results form with patient's ID, date and time, and laboratory staff initials.

11.0 REFERRAL LABORATORY

Due to certain challenges, DRL may be unable to provide all laboratory testing services required for patients and research subjects. In such circumstances, DRL is responsible to refer the samples to selected laboratories. The designated referral laboratories have been assessed and have been found to operate an acceptable quality management system following the evaluation and selection of referral laboratory procedure The referral

d. Memorandum

13.0 CONCLUSION

This DRL laboratory handbook for clients and clinicians has provided basic information on laboratory services, in order to enable clinicians optimizes the use of the lab and also contribute to the quality of its output. It is hoped that the brief guidelines stated therein would be adhered to as the clinicians work with the lab in the interest of the patients

Annexes:

A. Laboratory Test Menu TAT and Precautions.
B. Conversion Table for Common Parameters.
C. List of Laboratory Focal Persons.
D. List of Reference Ranges and Critical Values.
E. List of Referral laboratories.

Enclosures:

1. Clients Complaint Form.
2. DRL Administrative Instructions

laboratories are listed at Annex E

12.0 COMMUNICATION

DRL has an effective and efficient communication system with all its clients. Communication is done through:

Phone calls and text (SMS) messages

Electronic mails (e-mails)

Meetings and notifications

A. B. C.

D.

E.

1.

2.

ANNEX A TO

DRL/QMS 407V2

LABORATORY TEST MENU TAT AND PRECAUTIONS

Investigation	Type of Sample	Specimen Bottle	Volume of Sample	Precaution	Procedure/Eqpt.	TAT	Urgent TAT	Time limit for additional assay	Unit of reporting	Remark
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(g)
HAEMATOLOGY										
CBC	WB	EDTA	3-4mls	Mix well	Automated	24 Hours	4 Hours	1 HOUR		
FLOWCYTOMETRY										

CD4/C43	WB	EDTA	3-4mls	Mix well	Automated	24 Hours	8 Hours	NA	Cells/µl	
SEROLOGY										
HIV Screening	WB/Serum	EDTA	3-4mls	Mix well	Rapid ELISA / ELX 405/808	24 2 Weeks	6 Hours 2 Weeks	1 HOUR	Reactive or Non-Reactive	
HBaAg Rapid Screening	WB/Serum	EDTA	3-4mls	Mix well	Rapid	24 Hours	6 Hours	1 HOUR	Reactive or Non-Reactive	
HIV Confirmatory	WB/Serum	EDTA	3-4mls	Mix well	Immunochromatography	2 Weeks	1 Week	1 HOUR	Positive or Negative	

RPR(Syphilis)	WB/Serum	EDTA or Plain	3-4mls	in Collection sterile condition	Agglutination	2 Weeks	1 Week	1 HOUR	Reactive or Non-Reactive	

DATED: 3 APR 19

Syphilis Confirmatory	WB/Serum	EDTA or Plain	3-4mls	Collection in sterile condition	ELISA	2 Weeks	1 Week	1 HOUR	Positive or Negative	
Hepatitis C Virus	Serum or Plasma	Plain Heparinized	3-4mls	Mix well	ELISA	2 Weeks	1 Week	1 HOUR	Reactive or Non-Reactive	
Hepatitis C Virus Confirmatory	Serum or Plasma	Plain Heparinized	3-4mls	Mix well	Western Blot	2 Weeks 2 Weeks	1 Week 1 Week	1 HOUR	Positive or Negative	
Hepatitis B surface Antigen Elisa	Serum or Plasma	Plain Heparinized	3-4mls	Mix well	ELISA			1 HOUR	Reactive or Non-Reactive	
Hepatitis B surface Antigen Confirmatory	Serum or Plasma	Plain Heparinized	3-4mls	Mix well	ELISA	2 Weeks	1 Week	1 HOUR	Positive or Negative	
CHEMISTRY										

Glucose	Plasma	Fluoride oxalate	3-4mls	Mix well	Automated	24 Hours	6 Hours	3	mmol/L	
Electrolytes (Na/K/Cl)	Serum Plasma	Plain Heparinized	3-4mls	Avoid lysis	Automated	24 Hours	6 Hours	3	mmol/L	
Urea/ Creatinine	Serum Plasma	Plain/Heparinized	3-4mls		Automated	24 Hours	6 Hours	3	mmol/L	
Calcium/ Phosphorus	Serum Plasma	Heparinized Plain	3-4mls		Automated	24 Hours	6 Hours	3	mmol/L	
Bilirubin(Total and Direct)	Serum Plasma	EDTA/Heparinized Plain	3-4mls	Protect from light	Automated	24 Hours	6 Hours	3	µmol/L	
LFTs (ALP/ALT/AST/GGT)	Serum Plasma	Plain Heparinized	3-4mls		Automated	24 Hours	6 Hours	3	U/L	

Alanine Transaminase (ALT)	Serum Plasma	Plain Heparinized	3-4mls		Automated	24 Hours 24 Hours	6 Hours 6 Hours	3	U/L	
Aspartate Transaminase (AST)	Serum Plasma	Plain Heparinized	3-4mls		Automated			3	U/L	
Total Cholesterol /Triglyceride/HDL LDL (Lipid profile)	Serum or Plasma	Plain Heparinized	3-4mls		Automated	24 Hours	6 Hours	3	mmol/L	
Serum Amylase	Serum or Plasma	Plain Heparinized	3-4mls		Automated	24 Hours	6 Hours	3	U/L	
Uric Acid	Serum or Plasma	Plain Heparinized	3-4mls		Automated	24 Hours	6 Hours	3	mmol/L	
Microscopy	Urine (EMU)	Sterile bottle	5mls	Early morning urine	Microscopy	24 Hours	6 Hours	3		

MOLECULAR (PCR)										
STIs (Sexually Transmitted Infections) CT/GC	Urine/Rectal Swabs/Oral pharyngeal Swab	Preserved Cyst Bottle Collection in Aptima	2.5-3.5 mls	Avoid food particles and sputum, fecal particles	Automated	2 Weeks	2 Weeks	NA	Negative or Positive	
HIV 1 RNA Viral load	Plasma	EDTA	10 mls		Automated	2 Weeks	2 Weeks	NA	Copies/ml	
EID (HIV 1 DNA) (DBS)	DBS	DBS Cardboard	5 spots/card		Automated	2 Weeks	2 Weeks	NA	Negative or Positive	

Note: All test on this menu may be referred to referral lab as need arise.

ANNEX B TO DRL/QMS 407V2

DATED: 3 APR 19

CONVERSION TABLE FOR COMMON PARAMETERS

Serial	Parameter	Conventional Unit	Conversion Factor (x)	SI Units
(a)	(b)	(c)	(d)	(e)
1.	Alkaline Phosphatase	IU/L	1.0	U/L
2.	Alanine Transaminase	U/L	1.0	U/L
3.	Albumin	g/dl	10.0	g/L
4.	Ammonia	µg/dL	0.5872	µmol/L
5.	Amylase	Somogyi Units	1.85	U/L
6.	Aspartate Transaminase	U/L	1.0	U/L
7.	Bilirubin	mg/dL	17.1	µmol/L
8.	Calcium	mg/dL	0.25	mmol/L
9.	Carbon Dioxide	mEq/L	1.0	mmol/L
10.	Chloride	mEq/L	1.0	mmol/L
11.	Cholesterol	mg/dL	0.026	mmol/L
12.	Cortisol	µg/dL	0.0276	mmol/L
13.	Creatine Kinase	IU/L	1.0	U/L
14.	Creatinine	mg/dL	88.4	µmol/L
15.	Fibrinogen	mg/dL	0.01	g/dL
16.	Glucose	mg/dL	0.055	mmol/L
17.	Iron, Binding	µg/dL	0.179	µmol/L
18.	Iron Total	µg/dL	0.179	µmol/L
19.	Lipase	IU/L	1278	U/L
20.	Magnesium	mEg/L	0.5	mmol/L
21.	Osmolality	Osm/kg	1.0	mmol/L
23.	Potassium	mEg/L	1.0	mmol/L
24.	Total Protein	g/dL	10.0	g/L
25.	Sodium	mEg/L	1.0	mmol/L
26.	Triglycerides	mg/dL	0.011	mmol/L
27.	Tri-iodothyronine (T3)	µg/dL	15.6	nmol/L
28.	Thyroxine (T4)	µg/dL	12.87	nmol/L
29.	Urea nitrogen	mg/dL	0.357	mmol/L
30.	Uric acid	mg/dL	0.059	mmol/L
31.	Urine protein /creatinine ratio	g/g	0.113	g/mmol

ANNEX C TO DRL/QMS 407V2

DATED: 3 APR 19

CONTACT DETAILS OF LABORATORY FOCAL PERSONS

Name	Appointment	Phone Number	e-mail Address
(a)	(b)	(c)	(d)
Brig Gen M Ebie	Director	07033064006	mikemedics1@yahoo.com
Mr Sunday Odeyemi	Associate Director	08055192253	sodeyemi@wrp-n.org
Maj Y Musa	General Laboratory Manager	08066927151	yamus188088@yahoo.com
Lt OE Alao	Admin Officer/ QA Officer	08037991022	oluwasinaalao@yahoo.com
Lawrence Umeji	SPL Supervisor	07034181204	lumeji@wrp-n.org
Mrs Juliet Joseph	Safety Officer	08034967467	julygirl79@yahoo.com
Mrs Chisara Okolo	Logistics Officer	08055192265	cokolo@wrp-n.org
Mr Dogonyaro Bege	Facility Supervisor	07034181210	bdogonyaro@wrp-n.org
Wg Cdr ST Buseni	MDL Manager	08032810268	Buseni2007@yahoo.com
Nicholas Innocent Eigege	Molecular Supervisor	07034181220	inicholas@wrp-n.org
Okeke Ndubuisi	Serology Supervisor	08055192266	nokeke@wrp-n.org

[redacted]

ANNEX D TO

DRL/QMS 407V2

DATED: 3 APR 19 LIST OF REFERENCE RANGES AND CRITICAL VALUES

IMMUNO-HAEMATOLOGY

S/N	TEST	REF RANGE	CRITICAL VALUE (LOW)	CRITICAL VALUES (HIGH)	REMARKS/ COMMENT
	Hb (g/dL)	12-15g/dL(Female 13-18g/dL(Male)	7g/dL	20g/dl	excluding newborns
	PCV (%) 9	36-45%(Female) 40-54%(male) 9	0.21 L/L (<21 %)	0.70 L/L (>70%)	
	Total WBC(x10 /L)	3.8-11.0 (x10 /L)	2.0 x 109/L	20 x 109/ L	
	Total RBC (x1012/L)	3.0-5.5 (x1012/L)	2.0x1012/L	12x1012/L	
	MCV(fL)	76-100 fL			
	MCH (pg)	26-34 pg			
	MCHC (g/dL)	32-36g/Dl			
	PLT(x109/L)	140-400(x109/L)	50 x 109/L	1500 x 109/L	
	NEUTROPHILS	40-75 %			

	LYMPHOCYTES	20-45 %			
	MONOCYTES	2-8 %			
	EOSINOPHILS	1-6 %			
	BASOPHILS	0-1 %			
	ABSOLUTE NEUTROPHILS	(0.8 -5.0 x109/L)	0.5 x 109/L	10 x 109/L	
	ABSOLUTE LYMPHOCYTES	(0.5 -1,5x109/L)	0.2x109/L	3 x 109/L	
	ABSOLUTE MONOCYTES	(0.05-0.8x 109/L)			
	ABSOLUTE EOSINOPHILS	0.02-0.6x109/L)			
	ABSOLUTE BASOPHILS	(0-0.02x109/L)			
1	CD4+ LYMPHOCYTE ABSOLUTE COUNT (Cells/µL)	400 -1500	<50cells/µL		
2	CD3+ LYMPHOCYTE ABSOLUTE COUNT (Cells/ µL)	800 -5000	<100cells/µL		
3	CD4+ LYMPHOCYTE PERCENTAGE COUNT (%)				
4	CD8+ LYMPHOCYTE ABSOLUTE COUNT (Cells/µL)	NOT APPLICABLE			

ANNEX E TO

DRL/QMS 407V2

DATED: 3 APR 19

DRL TEST MENU, TAT FOR SAMPLES REFERED TO OTHER LABORATORY AND IN HOUSE TAT

SECTION		STAT	TAT	TAT FOR SAMPLES REFFERED TO OTHER LABS	COMMENT
MOLECULAR	HIV-1 RNA Viral Load Qualitative	2 Weeks	2 Weeks	3weeks	Clinical and Research
	HIV-1 DNA qualitative	2 Weeks	2 Weeks TAT	3weeks	Clinical
				3weeks	
	Neisseria gonorrhea Qualitative assay	2 Weeks	2 Weeks		Research
	Chlamydia trachomatis Qualitative assay	2 Weeks	2 Weeks	3weeks	Research
SEROLOGY	HIV RAPID TEST	6 Hours	24 hours	48 hours	Clinical and Research
	HBsAg RAPID TEST	6 Hours	24 hours	48 hours	Clinical and Research
	HCV- INNOLIA BLOT	1 Week	2 Weeks	3weeks	Clinical and Research

	HIV 1/2+O EIA	1 Week	2 Weeks	3weeks	Clinical and Research
	HIV ½ differential genius	1 Week	2 Weeks	3weeks	Clinical and Research
	HBSAg EIA	1 Week	2 Weeks	3weeks	Clinical and Research
	HCV EIA	1 Week	2 Weeks	3weeks	Clinical and Research
	HBsAg EIA Confirmatory	1 Week	2 Weeks	3weeks	Clinical and Research
	Quaniteron TB Gold	1 Week	2 Weeks	3weeks	Research
	CAPTIA Syphilis	1 Week	2 Weeks	3weeks	Research
	Rapid Plasma Reagin	1 Week	2 Weeks	3weeks	Research
	TPHA	1 Week	2 Weeks	3weeks	Research

MAIN DIAGNOSTICS (SAFETY/MONITORING LAB)

FLOW CYTOMETRY	CD3/CD4 Absolute count	8 Hours	24 hours	48 hours	Clinical and Research
HAEMATOLOGY	COMPLETE BLOOD COUNT	4 Hours	24 hours	48 hours	Clinical and Research
CHEMISTRY	SODIUM	6 Hours	24 hours	48 hours	Clinical and Research

	POTASSIUM	6 Hours	24 hours	48 hours	Clinical and Research
	CHLORIDE	6 Hours	24 hours	48 hours	Clinical and Research
	UREA	6 Hours	24 hours	48 hours	Clinical and Research
	CREATININE	6 Hours	24 hours	48 hours	Clinical and Research
	CALCIUM	6 Hours	24 hours	48 hours	Clinical and Research
	PHOSPHORUS	6 Hours	24 hours	48 hours	Clinical and Research
	CHOLESTEROL	6 Hours	24 hours	48 hours	Clinical and Research
	GLUCOSE	6 Hours	24 hours	48 hours	Clinical and Research
		6 Hours	24 hours	48 hours	
	TOTAL BILIRUBIN				Clinical and Research
	DIRECT BILIRUBIN	6 Hours	24 hours	48 hours	Clinical and Research
	TRYGLYCERIDES	6 Hours	24 hours	48 hours	Clinical and Research
	TOTAL PROTEIN	6 Hours	24 hours	48 hours	Clinical and Research
	AMYLASE	6 Hours	24 hours	48 hours	Clinical and Research
	ALBUMIN	6 Hours	24 hours	48 hours	Clinical and Research

	ALT	6 Hours	24 hours	48 hours	Clinical and Research
	AST	6 Hours	24 hours	48 hours	Clinical and Research
	URIC ACID	6 Hours	24 hours	48 hours	Clinical and Research
				48 hours	
	ALKALINE PHOSPHATASE	6 Hours	24 hours		Clinical and Research
	GAMMA GT	6 Hours	24 hours	48 hours 48 hours	Clinical and Research
	HDL	6 Hours	24 hours		Clinical and Research
	LDL	6 Hours	24 hours	48 hours	Clinical and Research
	LACTATE	6 Hours	24 hours	48 hours	Clinical and Research
SAMPLE PROCESSING UNIT	PBMC PROCESSIN G, CRYO PRESERVATION	6 Hours	6 Hours	Not Applicable	Research
	PHLEBOTOMY				

REFERRAL LABORATORY

1.) DEFENCE HEADQUARTERS MEDICAL CENTRE (DHQ MC) LABORATORY -
-- MOGADISHU CANTONMENT,

KEFFI ROAD ASOKORO ABUJA

TELL: +2348172022776

EMAIL: dhqmedcentre2@gmail.com

2.) 661 NIGERIAN AIRFORCE HOSPITAL (661 NAFH) LABORATORY--- SAM ETHAN AIRFORCE BASE, IKEJA, LAGOS

TEL: +2348022094950

EMAIL: adebelenix@yahoo.com

DEFENCE REFERENCE LABORATORY ABUJA CLIENTS/ CUSTOMERS COMPLAINT FORM

DATE OF COMPLAINT…….. DATE AND TIME OF OCCURRENCE……

COMPLAINANT: PATIENT ☐ CLINICIAN ☐ LAB. STAFF OTHERS ☐

NAME: ……PHONE NUMBER…….....

4.BRIEF DESCRIPTION OF COMPLAINT: ……

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5. REQUIRES IMMEDIATE ATTENTION: YES……. NO……..

6.. CLIENT'S SIGNATURE……..DATE & TIME…….

7.. CORRECTIVE ACTION AND RESPONSE…….

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. . QA MANAGER'S REVIEW……..…SIGNATURE AND DATE...……..

FEEDBACK TO COMPLAINT'S DONE YES NO DATE…….

IF NO, WHY (Brief Explanation)……..
IF YES, BY WHO? (Initial) DATE……..

DIRECTOR'S REVIEW……SIGNATURE/DATE……

DEFENCE REFERENCE LABORATORY ABUJA ADMINISTRATIVE INSTRUCTION

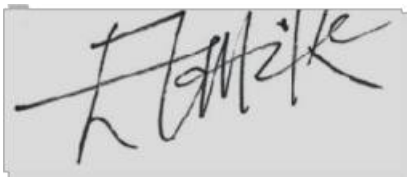
The following administrative instructions are hereby promulgated:

All patients shall have their samples taken in the phlebotomy unit or study sites by the phlebotomist after approval by the Director or Lab Manager or study PI. Samples are to be properly packaged and transported to DRL within the stipulated period as contained in the study protocol and relevant SOPs.

The laboratory is to collect/receive all samples within the working period (between 0830 to 1300 hours on weekdays). referred

On weekends and public holidays, only ples from supported sites shall be received. The Director or Designee must be aware of all weekend/public holiday activitie sam

s in DRL.



Measurement uncertainty for all DRL quantitative assays is available upon request by the client.

M EBIE

Brig Gen

Director

4 Apr 19

References:

Kost, G.J., JAMA , 1990; 263:704

Howanitz, P.J., et al., Archives of Pathology and Laboratory Medicine, 2002; 126:663.

ISLH Concensus rules. http://www.islh.org accessed on 10 Feb 16.

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American Association for Laboratory Accreditation (A2LA) C950– General Checklist: ISO 15189:2012 testing laboratory Accreditation Program

CHRONOLOGICAL REVISION/VERSION HISTORY

Laboratory User Handbook; DRL/QMS 407V1; 26 Mar 16.

Laboratory User Handbook; DRL/QMS 407V2; 3 Apr 19.

Added DRL Quality Policy.

Added vaccutainer colour system (5.3), Sample Collection, transportation and storage Requirements (5.4) and Sample Collection Procedures (5.5) 1.3 Modified Sample Transport and Precautions (5.11) and Referral laboratories.