



Document Title: PRIMARY SAMPLE COLLECTION MANUAL

Document No. NPHL/SCM/01

Effective Date: 13.02.2021

Version. 4

Control Copy No. 1

Section: Quality Office

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

(MoH)



NATIONAL PUBLIC HEALTH LABORATORY

(NPHL)

PRIMARY SAMPLE COLLECTION MANUAL

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1. INTRODUCTION

This manual is designed to give an overall view of the services available in the NPHL as well as to give a detailed explanation of how sample are collected from patients and transported to NPHL which is a referral Laboratory. It is intended as a quick reference guide for all NPHL users across Tanzania for use in the collection of referral samples.

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2. SCOPE

This manual applies to all sample collection points where samples are forwarded to the NPHL for referral testing. This manual shall be reviewed from time to time and is a controlled document for NPHL and therefore all users are requested to check with NPHL for the latest copy of the Primary Sample Collection Manual.

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3. GENERAL INFORMATION

3.1 Contact Location

NPHL Head office is located at Mabibo External off Mandela road

Ubungo municipal

The address and contact information:


National Health Laboratory (NPHL),

P.O.BOX 9083

Dar es Salaam

3.2 NPHL Opening hours

Section	Opening Hours
Laboratory Reception	Monday to Friday 07:30hrs – 15:30hrs
Director	Monday to Friday 07:30hrs – 15:30hrs
Laboratory Manager	Monday to Friday 07:30hrs – 15:30hrs
Quality Officer	Monday to Friday 07:30hrs – 15:30hrs

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3.3 Types of clinical services offered by NPHL

Turnaround Time (TAT): This is defined as the time when the samples received at the reception area until the time results are authorized or verified and are ready for dispatch.

NOTE: TAT does not include weekends and public holidays. For samples received during the weekends and public holidays TAT should start to be calculated from next working day at 08:00 hrs.

Name of Test	Procedure Used	Normal Ranges	Critical values	Units	Turnaround Time	Urgent TAT	Time limit for additional requests
Clinical Chemistry							
Liver function tests							
Alanine aminotransferase (ALT)	Procedure for analysis of transaminases using cobas integra 400 plus	2 – 41 Male 2 – 33 Female	NA	U/L	24 hours	4 hours	48 hrs
Albumin	Procedure for analysis of substrates using cobas integra 400 plus	35 – 52	NA	g/L	24 hours	4 hours	48 hrs
Alkaline Phosphate	Procedure for running enzymes using cobas integra 400 plus	40 – 129 Male 35 – 104 Female Children Aged 1 day <250 Aged 2 -5 days <231 Aged 6 days – 6 months <449 Aged 7months – 1 year <462 Aged 1-3years <281 Aged 4– 6years <269 Aged 7 – 12 years <300 Aged 13 – 17 years (M) <390 Aged 13 – 17 years (F) <187	NA	U/L	24 hours	4 hours	48 hrs



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Name of Test	Procedure Used	Normal Ranges	Critical values	Units	Turnaround Time	Urgent TAT	Time limit for additional requests
Aspartate Aminotransferase	Procedure for analysis of transaminases using cobas integra 400 plus	2 – 40 Male 2 – 32 Female	NA	U/L	24 hours	4 hours	48 hrs
Bilirubin – Direct	Procedure for analysis of substrates using cobas integra 400 plus	0 – 3.4	NA	µmol/L	24 hours	4 hours	48 hrs
Bilirubin – Total	Procedure for analysis of substrates using cobas integra 400 plus	0 – 21 General	Newborn 24hours ≥ 137 48hours ≥ 222 84hours ≥ 290 One week to one month ≥ 342 Remaining age ≥ 105	µmol/L	24 hours	4 hours	48 hrs
Total Protein	Procedure for analysis of substrates using cobas integra 400 plus	66 - 87	NA	g/L	24 hours	4 hours	48 hrs
Gamma Glutamyl Transferase	Procedure for running enzymes using cobas integra 400 plus	8 – 61 Male 5 – 36 female	NA	U/L	24 hours	4 hours	48 hrs
Renal function tests							
Creatinine	Procedure for analysis of substrates using cobas integra 400 plus	62 – 106 Male 44 – 80 Female	Patient with no dialysis ≥ 645	µmol/L	24 hours	4 hours	48 hrs
Urea	Procedure for	Less than 8.3	≥ 37	mmol/	24 hours	4 hours	48 hrs



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Name of Test	Procedure Used	Normal Ranges	Critical values	Units	Turnaround Time	Urgent TAT	Time limit for additional requests
	analysis of substrates using cobas integra 400 plus			L			
Lipid profile							
Cholesterol Total	Procedure for analysis of substrates using cobas integra 400 plus	Less than 5.2	NA	mmol/L	24 hours	4 hours	48 hrs
HDL - Cholesterol	Procedure for analysis of substrates using cobas integra 400 plus	≥1.45 Male ≥1.68 Female	NA	mmol/L	24 hours	4 hours	48 hrs
LDL – Cholesterol	Procedure for analysis of substrates using cobas integra 400 plus	2.59 – 3.34	NA	mmol/L	24 hours	4 hours	48 hrs
Triglycerides	Procedure for analysis of substrates using cobas integra 400 plus	Less than 2.26	For children less than 2 years ≥ 8.0	mmol/L	24 hours	4 hours	48 hrs
Electrolytes							
Sodium (Na)	Procedure for running electrolytes using cobas integra 400 plus	136 – 145	Less than 125 More than 160	mmol/L	24 hours	4 hours	48 hrs
Potassium (K)	Procedure for running electrolytes using cobas integra 400 plus	3.5 – 5.1	Less than 2.5 More than 6.0	mmol/L	24 hours	4 hours	48 hrs
Chloride (Cl)	Procedure for running electrolytes using cobas	98 - 107	Less than 80 More than	mmol/L	24 hours	4 hours	48 hrs



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Name of Test	Procedure Used	Normal Ranges	Critical values	Units	Turnaround Time	Urgent TAT	Time limit for additional requests
	integra 400 plus		120				
Other enzymes							
Amylase Total	Procedure for running enzymes using cobas integra 400 plus	28 - 100	NA	U/L	24 hours	4 hours	48 hrs
Creatine Kinase (CK)	Procedure for running enzymes using cobas integra 400 plus	39 – 308 Male 26 – 192 Female	≥ 600	U/L	24 hours	4 hours	48 hrs
Lactate dehydrogenase (LD)	Procedure for running enzymes using cobas integra 400 plus	135-225 Male 135-214 Female	NA	U/L	24 hours	4 hours	48 hrs
Lipase	Procedure for running enzymes using cobas integra 400 plus	13-60	NA	U/L	24 hours	4 hours	48 hrs
Other Tests							
Calcium	Procedure for analysis of substrates using cobas integra 400 plus	2.15 -2.55	Less than 1.15 More than 3.25	mmol/L	24 hours	4 hours	48 hrs
Glucose	Procedure for analysis of substrates using cobas integra 400 plus	4.11 - 6.72	Less than 2.22 More than 27.78	mmol/L	24 hours	4 hours	48 hrs
Iron	Procedure for analysis of substrates using Cobas Integra 400 plus	10.6 - 28.3 Male 6.6 - 26 Female	NA	µmol/L	24 hours	4 hours	48 hrs
Uric acid	Procedure for analysis of substrates using	202.3 -416.5 Male 142.8 – 339.2	NA	µmol/L	24 hours	4 hours	48 hrs



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	cobas integra 400 plus	Female					
<p>Note: TAT for study/project samples will be determined by the size of the batch and stated on MoU/MoA as per the PR02_Establishing and Reviewing of Service agreement procedure.</p>							
Serology and Immunology Tests							
DBS	ELISA	NA	NA	N/A	120hours	NA	2 weeks
HIV	ELISA	NA	NA	NA	24 hours	NA	2 weeks NR (2-8°C) 2 Months (-20 °C)
	Rapid Test, Alere determine	NA	NA	NA	6 hours	NA	2 weeks NR (2-8°C) 2 Months (-20 °C)
	Rapid Test, Unigold	NA	NA	NA	6 hours	NA	2 weeks NR (2-8°C) 2 Months (-20 °C)
Hepatitis B Screen	ELISA, Rapid Test	NA	NA	NA	24 hours	12 hours	(2-8°C) for 3 days
Hepatitis C Virus	ELISA, Rapid Test	NA	NA	NA	24 hours	12 hours	(2-8°C) for 3 days
Measles	ELISA, Rapid Test	NA	NA	NA	24 hours	12 hours	3 days (2-8°C) Longer period =Frozen
Rubella	ELISA, Rapid Test	NA	NA	NA	24 hours	12 hours	3 days (2-8°C) Longer period =Frozen
Toxoplasma	Rapid Test	NA	NA	NA	6 hours	NA	NA
Pregnancy	Rapid Test	NA	N/A	NA	6 hours	NA	1 day
Anti-streptolysin O Titer	Microtiter	NA	NA	NA	12 hours	NA	NA



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Name of Test	Procedure Used	Normal Ranges	Critical values	Units	Turnaround Time	Urgent TAT	Time limit for additional requests
Syphilis	RPR	NA	NA	NA	6 hours	NA	7 days (2-8°C)
	TPHA	NA	NA	NA	6 hours		More than 7 days (-20°C)
Salmonella	Widal Test	NA	NA	NA	12 hours	NA	NA
Helicobacter pylori	Rapid Test	NA	NA	NA	6 hours	NA	NA
Rheumatisms (Rh Factor)	Microtiter	NA	NA	NA	12 hours	NA	NA
CD4 Count	Flow Cytometry	500-1500	<200 cells/ul	Cells/ul	25 hours	NA	6 hours at room temperature
Dengue	ELISA	NA	NA	NA	24hours	12 hours	(2-8 °C) for 3 days
	Rapid test				6 hours	6 hours	
Rotavirus	ELISA	NA	NA	NA	24 hours	12 hours	Long period if frozen
Parasitological Tests							
Blood Slide for Malaria Examination	Giemsa stain	NA	1000 and above	Parasites/200 WBCs	4 hours	2 hours	Whole blood = 5 days Slides = 7 days
Malaria Rapid Diagnosis	Immunochromatography Technique (ICT)	NA	NA	NA	2 hours	1 hour	5 days
Examination of Blood Microfilaria	Haemoconcentration (Direct preparation and Giemsa Stain)	NA	NA	NA	24 hours	12 hours	5 days
Examination of Skin Microfilaria	Direct Preparation and Giemsa stain	NA	NA	NA	24 hours	12 hours	NA



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Examination of Trypanosomes	Direct preparation and Giemsa stain	NA	NA	NA	12 hours	6 hours	5 days
Stool examination	Direct preparation and Concentration	NA	NA	NA	12 hours	6 hours	4 hours
Urine analysis	Microscopy	NA	NA	NA	4 hours	2 hours	4 hours
Haematology							
Full Blood Count							
WBC total count	Automatic	4.6-10.2	<1.5 and >30	10 ⁹ /L	24 hours	1hour	72 hours
RBC count	Automatic	4.04-6.13	<2 and >7.5	10 ¹² /L	24 hours	1hour	72 hours
HGB	Automatic	12.2-18.1	<7 and >18	g/dl	24 hours	1hour	72 hours
HCT	Automatic	37.7-53.7	<20	%	24 hours	1hour	72 hours
MCV	Automatic	80-97	NA	fl	24 hours	1hour	72 hours
MCH	Automatic	27-31.2	NA	pg	24 hours	1hour	72 hours
MCHC	Automatic	31.8-35.4	NA	%	24 hours	1hour	72 hours
RDW	Automatic	11.6-14.8	NA	%	24 hours	1hour	72 hours
PLT	Automatic	142-424	<20 and >1000	K/ul	24 hours	1hour	72 hours
MPV	Automatic	0.00-99.9	NA	%	24 hours	1hour	72 hours
PCT	Automatic	0.00-9.99	NA	%	24 hours	1hour	72 hours
PDW	Automatic	0.00-9.99	NA	GSD	24 hours	1hour	72 hours
Neutrophils	automatic/Manual technique	37-80	NA	%	24 hours	1hour	72 hours
Lymphocytes	automatic/Manual technique	10-50	NA	%	24 hours	1hour	72 hours
Monocytes	automatic/Manual technique	0.00-12	NA	%	24 hours	1hour	72 hours
Eosinophils	automatic/Manual technique	0.00 – 7	NA	%	24 hours	1hour	72 hours
Basophils	automatic/Manual technique	0.00-2.5	NA	%	24 hours	1hour	72 hours
Neutrophil	automatic/Man	2-6.9	NA	K/ ul	24 hours	1hour	72 hours



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s	ual technique						
Lymphocytes	automatic/Manual technique	0.6-3.4	NA	K/ ul	24 hours	1hour	72 hours
Monocytes	automatic/Manual technique	0.00-0.9	NA	K/ ul	24 hours	1hour	72 hours
Eosinophils	automatic/Manual technique	0.00-0.7	NA	K/ ul	24 hours	1hour	72 hours
Basophils	automatic/Manual technique	0.00-0.2	NA	K/ ul	24 hours	1hour	72 hours
Prothrombin Time (PT)	Automatic	Variable (Change from lot to lot of reagents)	>30	second (s)	24 hours	1hour	72 hours
Thrombin Time (TT)	Automatic	Variable (Change from lot to lot of reagents)	NA	seconds (s)	24 hours	1hour	72 hours
Activated Partial Thromboplastin (APTT)	Automatic	Variable (Change from lot to lot of reagents)	NA	seconds (s)	24 hours	1hour	72 hours
Fibrinogen	Automatic	Variable (Change from lot to lot of reagents)	<1	g/L	24 hours	1hour	72 hours
Viral load Test							
Viral Load Test	COBAS AmpriPrep / TaqMan 48	NA	NA	Copies/ml	7 days	NA	6-12 months
HIV Early Infant Diagnosis							
HIV-1 DNA PCR Test	Roche Amplicor HIV1 DNA version 1.5	NA	NA	NA	7-10 days	NA	2 years or indefinite
Genotyping and Sequencing Tests							
ARV Drug Resistance Test	CDC Inhouse HIV-1 Genotyping System	NA	NA	NA	21 days Note: TAT for project samples will be determined by the size of the batch	NA	2 years



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					and stated on MoU/MoA		
Rotavirus genotyping	Rotavirus genotyping	NA	NA	NA	21 days Note: TAT for project samples will be determined by the size of the batch and stated on MoU/MoA	N/A	2 Years
Dengue test	Dengue sequencing	NA	NA	NA	14 days	NA	2 years

Name of Test	Procedure Used	Critical Results	Turnaround Time	Urgent TAT	Time limit for additional requests
Microbiology Test					
Enteric Bacteriology Tests					
<i>Salmonella ssp</i>	Conventional culture and Identification	N/ A	72 hours	NA	6-12 months
<i>Shigella ssp</i>	Conventional culture and Identification	Positive	72 hours	NA	6-12 months
<i>Vibrio Cholera ssp</i>	Conventional culture and Identification	Positive	72 hours	48hours	6-12 months
<i>E.coli 0H157:H7</i>	Conventional culture and Identification	Positive	72 hours	NA	6-12 months
<i>Campylobacter jejuni/coli</i>	Conventional culture and Identification	N/ A	72 hours	NA	6-12 months
General Bacteriology					
<i>Bacterial Meningitides</i>	Conventional culture and Identification	Positive	72 hours	72 hours	7 days
<i>Fungal</i>	Conventional culture and Identification	N/A	7 Days	NA	14 days
<i>Yesinia pestis</i>	Conventional culture and Identification	Positive	72 hours	NA	72 hours
Identification and Susceptibility testing	Biochemical and serological tests	N/ A	72 hours	NA	72 hours



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Name of Test	Procedure Used	Critical Results	Turnaround Time	Urgent TAT	Time limit for additional requests
	Kirby- Bauer (disc diffusion-test) and Agar dilution.				
Environmental and Public Health					
Water Purity Testing	Membrane filter technique	N/ A	120 hours	NA	1 month
	Standard Plate Count	N/ A	120 hours	NA	1 month
	Presence- Absence	N/ A	120 hours	NA	1 month
Food Bacteriology	Enrichment Methods	N/ A	120 hours	NA	1 month
	Selective methods	N/ A	120 hours	NA	1 month
	Standard Plate Count	N/ A	120 hours	NA	1 month
Sexually Transmitted Diseases					
<i>Neisseria gonorrhoea</i>	Conventional culture and Identification	N/ A	120 hours	NA	6-12 months
<i>Haemophilus ducreyi</i>	Conventional culture and Identification	N/ A	120 hours	NA	6-12 months
<i>Candida albicans</i>	Conventional culture and Identification	N/ A	72 hours	NA	6-12 months
Identification and Susceptibility testing	Biochemical and serological tests, Kirby- Bauer (disc diffusion-test) and Agar dilution	N/ A	72 hours	NA	6-12 months
Emerging and Re Emerging					
Influenza viruses	RT PCR	Positive AH5	24 hrs during outbreak, one week in surveillance	24 hours	12 month if negative and if positive indefinite
Yellow fever virus	RT PCR	positive	24 hours	24 hours	12 month if negative and if positive indefinite
Dengue virus	RT PCR	Positive	24 hours	24 hours	12 month if negative and if positive indefinite
Rift valley fever virus	RT PCR	Positive	24 hours	24 hours	12 month if negative and if positive indefinite
Chikungunya virus	RT PCR	Positive	24 hours	24 hours	12 month if negative and

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Name of Test	Procedure Used	Critical Results	Turnaround Time	Urgent TAT	Time limit for additional requests
					if positive indefinite
Corona virus	RT PCR	Positive	24 hours	24 hours	12 month if negative and if positive indefinite

NOTE:

The following will be considered as Urgent samples

- a. CSF
- b. Blood slides or whole blood for malaria
- c. Haemoglobin
- d. Blood Glucose
- e. Electrolytes
- f. Serum Creatinine
- g. Bilirubin Total for infants
- h. Bilirubin Direct for infants
- i. Serum Chloride

4.0 Laboratory Request Forms, Sample Containers


4.1 General Information

This section deals with the information that is required to be documented on the laboratory request form and the sample container, upon sample collection


4.2 Completing the Request Form

The following essential information must be documented in a legible manner on the request form (F063) which is available on page 67 of this sample collection manual.


- Patient's Identification Number
- Patient's Full Name (Surname, Forename)
- Patient's Full Home Address
- Patient's Age
- Patient's Location (Hospital Ward or room number).
- Patient's gender
- The name of the requesting Clinician and contact details
- Sample type and anatomical site where appropriate
- Condition for Transportation and transport medium
- Collection date, time and name of the person who collected the specimen
- Transportation date and time
- Examination(s) required

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- Date and time of sample collection
- Relevant clinical information appropriate to the test(s) requested must be supplied e.g. history of administration of drugs, antenatal history, blood transfusion history etc. The minimum clinical information supplied relevant to the patient must include gender and date of birth for interpretative purposes. A clear indication as to whether the tests requested are urgent or routine.
- The signature of the person completing the form

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Example of completed request form



MINISTRY OF HEALTH AND SOCIAL WELFARE
National Health Laboratory – Quality assurance and Training Centre
Laboratory Request form
 Address: 2448 Luthuli Road/ Sokoine drive 3rd Floor NIMR Building. Dar es Salaam. Tanzania
 Telephone: (+255) 22 2126390

TDS0013617 [FORM]

 GASPAR, JOYCE 18/10/13
 SUPRN. 381449 NHL/13/7566
 TDS0013617
 TDS0013617
 GASPAR, JOYCE

A. Clinician Information
 Name: FADHL KWEDILIMA Position: M.O Signature: [Signature for Dr. Fadhl]
 Contact details: BOX 413 SUMBAWANGA Tel(Bus): - Cell: 0716681583
 Health Facility: SBA REG. HOSP. District: SUMBAWANGA Region: RUKWA

B. Patient information
 Patient identification number: 38 14 99
 Name: JOYCE GASPAR Age: 21 (years) Sex: Male Female
 Address: CHANJI
 Occupation of patient: Entrepreneurship
 Clinical Information/History: Headache, Fever, Neck stiffness & Pa.

C. Sample Information
 Anatomical Site: Lumbar Puncture Nature of specimen: C.S.F.
 Transport medium: Charcoal Medium Conditions for transportation: Room temperature
 Collection Date: 12.10.2013 Time: 14:59 Collected By: Dr. Fadhl
 Transportation date: 15.10.2013 Time: 10:00
 Examination requested: Culture sensitivity and serotype.


NHL-QATC Laboratory Use only
 Specimen laboratory number: NHL/13/7566 Date Received (dd/mm/yy): 17/10/13 Time: 14:30
 Name of receiving officer: Christine Signature: [Signature]
 Condition upon receipt: Good Transportation temperature: off R
 Comments: Acceptable

Results:

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4.3 Determination of the identity of the patient

Before collecting any sample from the patient, member of staff collecting sample should first confirm the identity of the person from whom the sample(s) are to be collected. This will be done by confirming the details on the identity card, if the patient does not have Identity card, it can be done by asking the patient his/ her name. For unconscious patients determination of the patient identity can be done by asking their relatives or next of kin.

4.4 Verification that the patients meet the pre examination requirements

Before collecting patient sample(s) confirm from the patient about pre examination requirements;

- Fasting status
- Medical status (time of last dose, cessation)
- Sample collection at pre determined time or time intervals

4.5 Labelling the Sample Container

The following **essential** information should be documented in a **legible** manner on the sample Container before collecting samples:-

1. Patient's full name
2. Patient Identification number
3. Date and time of sample collection

4.6 Quality of Blood Samples


NPHL Laboratory personnel shall inspect each blood sample received for testing for:-

- Evidence of Haemolysis
- Gross Lipemia
- Presence of clots in all samples requesting full blood count and coagulation tests
- Within an acceptable time frame for the test concerned,
- Within acceptable condition (broken, hemolysed etc)
- Within temperatures acceptable for test performance;

In a safe manner, to protect the carrier, the public and the laboratory personnel. In such instances, a second sample may be requested or the issued report will have an appended comment noting the presence of haemolysis, lipemia or clots as appropriate.

4.7 Advice on ordering of examination and on interpretation of results

NPHL Technical staffs are always available to offer Laboratory clients with any information regarding correct collection of patient samples to ensure that Laboratory results are produced by the Laboratory. Advice is also offered in terms of proper interpretation on of patient results. Clients in need of advice should contact NHLQATC through the contact details provided above.

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4.8 Protection of personnel information

NPHL all members of staff have signed Confidentiality and conduct undertaking form and are bound not to release any patient information. Member of staff are also required to follow PR 15_Protection of confidential information Procedure. Any breach of this will results in disciplinary action.

4.9 Laboratory complaints procedure

- Any customers who are not happy with the service received from NPHL are free to complain to the NPHL.
- The Complainant is required to complete the complaints form (NPHL/M/FM013) attached on page on page 68-69 of this primary sample collection manual.
- Complainants can communicate directly with NPHL Quality Officer or any member of staff through contact details provided at the beginning of this document.
- NPHL will acknowledge the receipt of complaint to the complainant upon receipt and will follow NPHL/SP/06_resolution of complaints procedure to handle complaints.
- After successfully resolution of complaints NPHL will contact complainants and inform him/her about the results achieved.

5.0 SAMPLE COLLECTION, TRANSPORT AND STORAGE REQUIREMENTS

5.1 Clinical Chemistry Samples

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Alanine aminotransferase (ALT)	Serum or Plasma (Li-heparin or EDTA only)-	NA	Serum or Plasma collected in standard tubes free from haemolysis Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C or 72hours at 2 to 8°C	3 days at 15 -25°C, 7 days at 2 to 8°C and >7days at -70 °C	Citrate and fluoride inhibit the enzyme activity Calcium dobesilate, doxycycline HCl, isoniazid and hydroxocobalamin drugs cause artificially low ALT values and it may cause unreliable results to the patient with Waldenstrom's macroglobulinemia
Albumin	Serum or Plasma	NA	Serum collected in standard tubes or Plasma collected into the Heparin (Li-,Na-,NH ₄ ⁺ -) or EDTA(K ₂ -, K ₃ ⁻) tube Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	2.5 months at 15 -25°C and 5 months at 2 to 8°C	It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia
Aspatate Aminotransferase	Serum or Plasma	N/A	Serum collected in standard tubes or Plasma collected into Li- heparin or EDTA tubes only.	The primary container shall be put to another container (storage	Within 8 hours at 15 - 25°C	1 days at 15 -25°C and 7 days at 2 to 8°C	It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
			<p>Sample shall be free from haemolysis</p> <p>Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers</p>	<p>box) during the transportation</p> <p>Minimum volume = 0.5ml</p>	OR 72hours at 2 to 8°C		
Bilirubin – Direct	Serum or Plasma	N/ A	<p>Serum collected in standard tubes or Plasma samples should be collected into Li- heparin tubes only.</p> <p>Sample shall be free from haemolysis and lipemia</p> <p>Protect samples from exposure to light</p> <p>Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers</p>	<p>The primary container shall be put into another container (storage box) during the transportation</p> <p>Minimum volume = 0.5ml</p>	<p>Within 8 hours at 15 - 25°C</p> <p>OR 72hours at 2 to 8°C</p>	2 days at 15 -25°C, 7 days at 2 to 8°C and 6 months at (-15 to -25°C)	It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia
Bilirubin – Total	Serum or Plasma	N/ A	<p>Serum or Plasma collected in standard tubes free from</p>	<p>The primary container shall be put into another</p>	<p>Within 8 hours at 15 - 25°C</p>	1 day at 15 -25°C, 7 days at 4 to 8°C and 6 months at (-15) to (-25) °C	hydroxocobalamin drugs may cause false- high results



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			<p>haemolysis and lipemia Protect samples from exposure to light</p> <p>Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers</p>	<p>container (storage box) during the transportation</p> <p>Minimum volume = 0.5ml</p>	<p>OR 72hours at 2 to 8°C</p>		<p>Also it may cause unreliable results to the patient with Waldenstrom's macroglobulinemia</p>
Total Protein	Serum or Plasma	Keep the patient upright position during collection	<p>Serum collected in standard tubes or Plasma collected into Li- heparin or K₃-EDTA</p> <p>Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers</p>	<p>The primary container shall be put into another container (storage box) during the transportation</p> <p>Minimum volume = 0.5ml</p>	<p>Within 8 hours at 15 - 25°C</p> <p>OR 72hours at 2 to 8°C</p>	<p>One month at 2 to 8°C and 6 months at (-15) to (-25) °C</p>	<p>Separate plasma within 4 hours from clot or cells</p>
Gamma Glutamyl Transferase	Serum or Plasma	N/ A	<p>Serum collected in standard tubes or Plasma collected into Heparin (Li-,Na-,NH₄⁺-) or EDTA(K₂-, K₃-) tubes</p> <p>Sample volume should be 0.5mls for serum/plasma</p>	<p>The primary container shall be put to another container (storage box) during the transportation</p> <p>Minimum volume =</p>	<p>Within 8 hours at 15 - 25°C</p> <p>OR 72hours at 2 to 8°C</p>	<p>7 days at 15 -25°C and 2 to 8°C And One year at (-15) to (-25)°C</p>	<p>EDTA plasma values are approximately 6% lower than serum</p> <p>It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia</p>



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			or 5mls of venipuncture blood collected from the above containers	0.5ml			
Creatinine	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma (Li- heparin or EDTA). Sample shall be free from lipemia and haemolysis. Protect samples from exposure to light. Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation. Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	7days at 15 -25°C, days and 2 to 8°C 3 months at (-15) to (-25) °C	Cephalosporin antibiotics leads significant false-high values It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia
Urea	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma (Li- heparin, EDTA or fluoride). Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation. Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	7 days at 15 -25°C and 2 to 8°C and one year at (-15) to (-25) °C	Ammonium ion may cause erroneously elevated results
Cholesterol	Serum or	N/ A	Serum collected in	The primary	Within 8	7 days at 15 -25°C and 2	Do not use container with



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
	Plasma		standard tubes or Plasma (Li- heparin or K ₃ -EDTA) Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	hours at 15 - 25°C OR 72hours at 2 to 8°C	to 8°C and 3 months at (-15) to (-25) °C	citrate, oxalate or fluoride It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia
HDL – Cholesterol	Serum or Plasma	For fasting sample the patient shall be fasting at least 8 hours	Serum collected in standard tubes or Plasma collected into the Heparin (Li-,Na-,NH ₄ ⁺ -) or EDTA(K ₃ -) tubes Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	7 days at 2 to 8°C And 30 days (-70)°C	Store plasma at 4°C prior analysis.
LDL – Cholesterol	Serum or Plasma	For fasting sample the patient shall be fasting at least 8 hours	Serum collected in standard tubes or Plasma collected into the Heparin (Li-,Na-,NH ₄ ⁺ -) or EDTA(K ₃ -) tubes Sample volume should be 0.5mls for serum/plasma	The primary container shall be put to another container (storage box) during the transportation Minimum volume =	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	7 days at 2 to 8°C And 30 days (-70)°C	Store plasma at 4°C prior analysis.



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			or 5mls of venipuncture blood collected from the above containers	0.5ml			
Triglycerides	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma collected into Li- heparin or EDTA tubes Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	0.1 days at 2 to 8°C and 3 months at (-15) to (-25) °C Several years at (- 80)°C	EDTA tube that is less than ½ full may cause unreliable results
Sodium (Na)	Serum or Plasma	N/ A	Serum collected in standard tubes or lithium heparin plasma free from haemolysis Volume same to other test	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	7 days at 15 -25°C, and at 2 to 8°C, it will be stable for long time at (-15) to (-25)°C	If heparinised tube is used, ensure that collection tube is filled with correct volume of blood
Potassium (K)	Serum or Plasma	N/ A	Serum collected in standard tubes or lithium heparin plasma free from haemolysis and lipemia Volume same to other	The primary container shall be put to another container (storage box) during the	Within 8 hours at 15 - 25°C OR 72hours	7 days at 15 -25°C, and at 2 to 8°C, it will be stable for long time at (-15) to (-25)°C	If heparinised tube is used, ensure that collection tube is filled with correct volume of blood



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			test	transportation Minimum volume = 0.5ml	at 2 to 8°C		
Chloride (Cl)	Serum , Plasma or Urine	N/ A	Serum collected in standard tubes or lithium heparin plasma free from haemolysis Volume same to other test Urine: Collect 24 hours urine 2.5 L bottle without addition of preservatives/ or stabilizers. Store refrigerated during collection	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5m 24 hrs urine 2.0L	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	7 days at 15 -25°C, and at 2 to 8°C, it will be stable for long time at (-15) to (-25)°C	If heparinised tube is used, ensure that collection tube is filled with correct volume of blood
Calcium (Ca)	Serum, Plasma or Urine	Fasting sample Patient not under EDTA treatment	Fresh serum or plasma (Li- heparin) it should be separated as soon as possible after collection Urine: should be collected in acid- washed bottle. 24hours specimens should collected in containers containing 5ml of 6mol/L HCl. If specimen is collected	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	Serum/plasma 7 days at 15 -25°C, 3 weeks at 2 to 8°C And 8 months at (-15) to (-25)°C For urine 2 days at 15 - 25°C, 4 days at 2 to 8°C And 3 weeks at (-15) to (-25)°C	Complexing anticoagulants such as citrate, oxalate and EDTA cause unreliable results, also it may cause unreliable results to the patient with Waldenstrom's macroglobulinemia



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
			without acid, the pH should be 3 to 4 with 6 mol/L HCl. Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood				
Glucose	Serum , Plasma Urine or CSF	For fasting sample the patient shall be fasting at least 8 hours	Serum or Plasma (Li-heparin, EDTA or fluoride)- which collected by venipuncture using an evacuated tube system Sample volume should be 0.5mls for serum/plasma Or 5ml of blood Urine which collected in a dark bottle, for 24-hour urine preserved urine by adding 5ml of glacial acetic acid to the container before collection CSF	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml of serum/plasma	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	8 hours at 15 -25°C, 72 hours at 2 to 8°C	Sample should be free from haemolysis The stability of glucose in specimen is affected by storage temperature, bacterial contamination and glycolysis. Serum/plasma samples without preservative should separated from the cells or clot within half an hour of being drawn, CSF should transported immediately after collection it may cause unreliable results to the patient with Waldenstrom's



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
							macroglobulinemia
Alkaline Phosphate	Serum or Plasma	Not applicable	<p>A clear serum which collected from standard serum collection tube or Plasma that collected into the Heparin (Li-,Na-,NH4⁺-) tube</p> <p>Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers</p>	<p>The primary container shall be put to another container (storage box) during the transportation</p> <p>Minimum volume = 0.5ml</p>	<p>Within 8 hours at 15 - 25°C</p> <p>OR 72hours at 2 to 8°C</p>	<p>7days at 15 -25°C and 2 to 8°C</p> <p>And 2 months at (-15 to -25) °C</p>	<p>It may cause unreliable results to the patient with Waldenstrom's macroglobulinemia</p>
Amylase Total	Serum or Plasma	N/ A	<p>A clear serum which collected from standard serum collection tube or Plasma that collected into the Heparin (Li-,Na-,NH4⁺-) or EDTA(K₂-, K₃-) tube</p> <p>Urine collected without additive</p> <p>Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers</p>	<p>The primary container shall be put to another container (storage box) during the transportation</p> <p>Minimum volume = 0.5ml</p>	<p>Within 8 hours at 15 - 25°C</p> <p>OR 72hours at 2 to 8°C</p>	<p>7days at 15 -25°C and one month at 2 to 8°C</p> <p>For urine 2 days at 15 to 25 °C and 10 days at 2 to 8°C</p>	<p>EDTA plasma values are approximately 5-10% lower than serum</p> <p>Icodextrin – basd drugs may lead to decreased amylase value</p>



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Creatine Kinase (CK)	Serum or Plasma	N/ A	Serum or Plasma (Li-heparin or EDTA only)- sample shall be free from haemolysis Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	2 days at 15 -25°C, 7 days at 2 to 8°C And 4 weeks at (-15) to (-25) °C	Lipemic samples may cause unreliable results Calcium dobesilate and hydroxocobalamin drugs cause artificially low CK values Also it may cause unreliable results to the patient with Waldenstrom's macroglobulinemia
Uric Acid	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma that collected into the Heparin (Li-,Na-,NH4 ⁺ -) or EDTA(K ₂ , K ₃ -) tube Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put to another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15 - 25°C OR 72hours at 2 to 8°C	0.½ days at 2 to 8°C And 0.½ months at (-15) to (-25)°C	EDTA plasma values are lower for 8% than serum values
Iron	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma collected into Li-Heparin. Sample volume should be 0.5mls for serum/plasma	The primary container shall be put into another container (storage box) during the transportation	Within 1 day at 15-25°C OR 72hours at 2-8°C	7 days at 15-25°C and 3 weeks at 2 – 8°C	



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			or 5mls of venipuncture blood collected from the above containers	Minimum volume = 0.5ml			
Lipase	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma collected into Li-Heparin. Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put into another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8hours at 15-25°C OR 72hours at 2-8°C	7 days at 15-25°C and 2 – 8°C	
Lactate dehydrogenase (LD)	Serum or Plasma	N/ A	Serum collected in standard tubes or Plasma collected into Li-Heparin. Sample shall be free from haemolysis and lipemia Sample volume should be 0.5mls for serum/plasma or 5mls of venipuncture blood collected from the above containers	The primary container shall be put into another container (storage box) during the transportation Minimum volume = 0.5ml	Within 8 hours at 15-25°C Do not refrigerate or freeze	7 days at 15-25°C Do not refrigerate or freeze	Do not refrigerate or freeze the specimen for determination of LD
HbA1c	Whole blood	N/ A	Collect venous blood into tubes with Li-Heparin, K ₃ EDTA, Na-citrate, K-oxalate or Na-fluoride or capillary blood.	The primary container shall be put into another container (storage box) during the	Within 12 hours at 15-25°C OR	1 week at 15-25°C 4 weeks at 2-8°C,	



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
				transportation Minimum volume (venous blood)= 0.5ml	<4 weeks at 2-8 °C	12 weeks at -20 °C	

5.2 Microbiology tests

Name of Test	Sample	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or minimum volume	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Note: Samples should be taken before antimicrobial treatment has been started							
Enteric pathogens	Faeces	Patient should collect a sample during acute stage of diarrhoea and avoid contamination with urine, transfer a portion (about a spoonful) of specimen containing mucus, pus or blood.	Pass specimen directly into clean, disinfectant free, dry and wide-necked container, transport to Microbiology lab within 1 hour of collection or transfer to Carr-Blair holding medium and label the Patient Id,type of sample, date and time	Clean, leak-proof, disinfectant-free, wide mouth container or transfer to Carry-Blair holding medium(>2g)	Unpreserved: <1 h at RT, In Transport medium <7days in cold chain	Unpreserved: <1 h at RT <30days in cold chain Note Shigella spp stays <7days	Note: Outbreak and study samples may be received and processed within 30days provided it is kept in transport media and cold chain and there is evidence of difficulties in transportation logistics



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Enteric pathogens	Rectal swab	Patient should be explained about the procedure to avoid contamination with anal skin.	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	Leak-proof container with Carry Blair	Unpreserved: <1 h at RT, In Transport medium <7days in cold chain	Unpreserved: <1 h at RT <30days in cold chain Note Shigella spp stays <7days	Note: Outbreak and study samples may be received and processed within 30days provided it is kept in transport media and cold chain and there is evidence of difficulties in transportation logistics
Mycobacterium tuberculosis	Sputum	Patient should rinse or gaggle with water to remove excess oral flora cough deeply to produce sputum not saliva. Collect the early morning sputum	Cough deeply to produce sputum not saliva. Collect the early morning sputum into clean, dry, wide-necked, leak-proof container.	Leak-proof, clean and dry container >1ml	<24 hrs,RT >24hrs in cold chain	<24 hrs,RT >24hrs in cold chain	Do not process sputum which has much saliva.
Mycobacterium tuberculosis	Sputum	Patient should rinse or gaggle with water to remove excess oral flora cough deeply to produce sputum not saliva. Collect the early morning sputum	Cough deeply to produce sputum not saliva. Collect the early morning sputum into clean, dry, wide-necked, leak-proof container.	Leak-proof, clean and dry container >1ml	<24 hrs,RT >24hrs in cold chain	<24 hrs,RT >24hrs in cold chain	Do not process sputum which has much saliva.



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Septic wound	Pus swab	Specimens should be collected by a medical officer or an experienced nurse, pus is best collected at the time the abscess is incised and drained	Aspirate or pass a swab deep into the lesion to firmly take the specimen	Swab transport media	<2h, RT	<24h, RT	-Samples of the base of the lesion and abscess wall are most productive -Avoid contamination of with commensal organisms from the skin
Sexually transmitted infection	Urethral swab	The patient should not have passed urine for about 1 hour before specimen is collected. Clean round the urethral opening using swab moistened with sterile saline	Gently massage the urethra from the above downwards and collect the sample of pus on a sterile cotton swab. For females massage the urethra against the pubic symphysis through the vagina	Insert the swab in a container of Amies with charcoal transport medium breaking off the swab stick to allow the bottle top to be replaced tightly.	<2h,RT	<24h,RT	
Sexually transmitted infection	Cervical swab	Moisten a vaginal speculum with sterile warm water and insert into the vagina. Clean the cervix using a swab moistened with sterile saline	Pass a sterile swab into endocervical canal and gently rotate the swab to obtain a specimen	Insert the swab in a container of Amies with charcoal / stuart transport medium breaking off the swab stick to allow the bottle top to be replaced tightly.	<2h, RT	<24h,RT	If no discharge can be obtained, wash the periurethral area with Betadine soap and rinse with water. Insert a small swab 2-4cm into the urethra, rotate it, and leave it in place for at least 2 s to facilitate absorption.



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Sexually transmitted infection	Vaginal swab	Wipe away old secretions and discharge. Obtain secretions from mucosal membrane of the vaginal wall with sterile swab	Collect a sample of vaginal discharge on a sterile swab by gently rotating the swab to obtain a specimen from mucosal membrane of the vaginal wall	Insert the swab in a container of Amies/ Stuart transport medium breaking off the swab stick to allow the bottle top to be replaced tightly	<2h, RT	<24h, cold chain	For intrauterine devices, place entire device into a sterile container and submit at RT. Gram stain is recommended for bacterial vaginosis.
Sexually transmitted infection	Genital swab	Clean around the ulcer using a swab moistened with sterile saline	While pressing the base of the lesion's surface, firmly rub base with sterile swab to collect fluid.	Swab transport.	<2h, RT	<24h, cold chain	
Bacterial meningitis	Cerebral spinal fluid	CSF is collected by an experienced medical officer	The fluid is collected by lumbar puncture and drip into two dry sterile containers for culture and cell count	Screw cap Container	<2h, RT Note In trans-isolate media can stay for 7days	<24h, RT	-If CSF is purulent or markedly cloudy, make immediately Gram staining and report as soon as possible
Septicaemia	Blood	Blood should be taken before antimicrobial treatment has been started	Sterile the skin with 70% alcohol and use disposable syringe to punch the vein.	Blood culture medium	<7days in Incubator or RT	<7days, Incubator	Note, Consider appropriate ratio of blood and culture broth i.e. 1:10
Bacterial Identification	Isolates	N/ A	Inoculate Pure isolate in TSA/ CA Slant, Dorset Agar or Skimmed milk	Pure isolate in TSA/ CA Slant, Dorset Agar, Skimmed milk or other storage media	1-2 weeks, RT in TSA/ CA Slant or Dorset Agar, 1-2 weeks, in Skimmed milk at 2-8°C	1-2 months, 2-8°C in TSA/ CA Slant or Dorset Agar, 0.5 months to 1 year, in Skimmed milk at -70 to -80°C	Note, The colonies are tested within 72hours as a fresh culture



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Susceptibility testing	Isolates	N/ A	Single colony from purity plate	Pure isolate in TSA/ CA Slant, Dorset Agar, Skimmed milk or other storage media	1-2 weeks, RT in TSA/ CA Slant or Dorset Agar, 1-2 weeks, in Skimmed milk at 2-8°C	1-2 months, 2-8°C in TSA/ CA Slant or Dorset Agar, 0.5 months to 1 year, in Skimmed milk at -70 to -80°C	Do not use mixed colonies
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5.3 Haematological tests

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/ or amount of primary sample	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Full Blood count							
FBC (RBC Count MCV ,PCV WBC Total count Neutrophil Lymphocytes Monocytes Eosinophils Basophils Thrombocytes cont MCH MCHC)	Whole Blood	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Invert the tube gently to mix the blood for about five times.	K ₂ -EDTA 2.5-3ml (50-60% of 5ml tube)	For best results less than 8hours of transport at room temperature	16 hours at 15-25°C	Sample should be gently mixed and should not have clots. Place on a roller for up to 30minutes before analysis.
Hb electrophoresis	Whole Blood	Explain the procedure to the client. Make sure he/she is sitting comfortably,	Vein puncture blood should be collected in a vacutainer tube with EDTA. Invert	K ₂ -EDTA 2.5-3ml (50-60% OF 5ml tube)	Less than a week at 2-8°C	1 week at 2-8°C OR Store haemolysate 3 weeks at 4-8°C or up to three months frozen	Specimen should be bacteria free, Not haemolysed Not lipemic



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		the arm placed on a flat table.	the tube gently to mix the blood for about five times.				
G6PD test	Whole Blood	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Invert the tube gently to mix the blood for about five times.	K ₂ -EDTA 2.5-3ml (50-60% OF 5ml tube) OR In Heparin OR ACD	Less than 6 hours, best performance within 1 hour, Can go up to 7days at 2 – 8°c in ACD	1 week at 2-8°c	Sample should be kept away from sunlight For anaemic patients use plasma reduced blood, with at least a 0.4 PCV Sample should not be collected during a haemolytic crisis.
Prothrombin time (PT)	Whole Blood	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Invert the tube gently to mix the blood for about five times.	3.2% Buffered sodium citrate tubes, normally tubes are fully filled (to the fill mark which is 9:1 blood to anticoagulant ratio)	Unopened tubes should be transported at 2-4°c for less than 24 hours	Unopened tubes should be kept at 2-4°c for less than 24 hours OR Platelet poor plasma should be removed from cells and frozen at -20°c for up to 2weeks or at -70°c for up to 6months	Glass tubes should not be used as they may induce contact activation of coagulation cascade Volume of Sample with Hematocrit values > 55% or less than 20% must be specially adjusted to avoid spurious coagulation results
Activated Partial Thromboplastin (APTT)	Whole Blood	Explain the procedure to the client. Make sure he/she is sitting comfortably,	Vein puncture blood should be collected in a vacutainer tube with EDTA. Invert	3.2% Buffered sodium citrate tubes, normally tubes are fully filled (to the fill mark which is 9:1	Unopened tubes should be transported at 2-4°c for less than 4 hours	Unopened tubes should be kept at 2-4°c for less than 4 hours, Avoid freeze-thawing	When obtaining specimen from intravenous line that may contain heparin, the line should be flushed with 5ml saline and 5ml of blood,



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		the arm placed on a flat table.	the tube gently to mix the blood for about five times.	blood to anticoagulant ratio)		aPTT samples	In case of multiple sampling, the coagulation sample should be collected only second to Blood culture tube.

5.4 Parasitological Tests

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary sample	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
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Stool Examination	Stool (faecal material), Rectal swab.	The patient is instructed to collect specimen before barium is used for radiological examination or taking antibiotics such as Tetracycline	<p>Pass specimen directly into a clean, dry container, secure a lid. Ask the patient to keep the outside of the container clean and never contaminate with urine or antiseptic. Transport to the laboratory as early as possible.</p> <p>For rectal swab, inform the client about the procedure of sample collection and get the informed consent first.</p>	<p>Clean, wide mouth containers with a tight- fitting lid. About 1 teaspoonful of stool sample is required.</p> <p>Place a rectal swab into a wet (with physiological saline) clean container with a tight fitting container.</p>	Specimen should be transported in wide mouth container with tight fitting lid in the following time range; Liquid within 30 min. Soft (semi formed) and rectal swab ≤ 1hour. Formed within 24hrs after passage at room temperature	Faecal specimen should never be incubated or frozen prior examination Stool can be preserved in 5% Formalin at room temperature	<p>Tetracycline and barium modify the gastrointestinal tract flora thus interfere with detection of intestinal protozoa.</p> <p>Watery and blood stained stool samples should be examined within 1 hr of collection to detect for: Red cells, white cells, macrophages. Bacteria with characteristic shape and motility, motile trophozoites of protozoa.</p> <p>Stool samples for ova, cysts and helminth larvae within 24 hrs.</p> <p>Sample for live parasites should not be preserved with formalin.</p> <p>Rectal swab is used to collect ova of Enterobius vermicularis from the anal skin.</p>



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Blood slide for malaria	Blood (Venous)	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Add 2 to 4 ml of blood. Invert the tube gently to mix the blood for about five times.	EDTA vacutainer tube. 2 to 4 ml of blood per vacutainer tube.	Sample is transported in EDTA Vacutainer tube within 24 hours at room temperature	Blood is stored in EDTA vacutainer at a temperature of 4 to 8 °C. Process the sample within one week.	Malaria parasites shrink as sample stays longer.
	Blood (Finger prick)	Explain the procedure to the client. Ask client to warm up his/her fingers by rubbing together fingers prior to collection of sample. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Finger prick blood should be smeared on a clean grease free slide. Allow to dry on a flat dust free surface, and away from reach of insects (flies).	Dry blood smears arranged properly in slide box.	Time is not critical to fixed blood smear	Fixed smear is stored in a humid and dust free environment. Slides can be frozen for long term storage	
Malaria Rapid Diagnostic Test	Blood (venous)	As explained above.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Add 2 to 4 ml of blood. Invert the tube gently to mix the blood for about five times.	EDTA vacutainer tube. 2 to 4 ml of blood per vacutainer tube.	Sample is transported in EDTA vacutainer tube within 1hr after collection at room	Blood is stored in EDTA vacutainer at a temperature of 4 to 8 °C. Process the sample within one week.	Fresh whole blood is recommended.



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					temperature. If more than 1 hour, transport sample under 4 to 8 °C.		
	Blood (Finger prick)	As explained above.	The blood sample is collected and placed directly to the Malaria Rapid Diagnostic test (mRDT) device. Label properly the device and set the time as per manufacturer instructions.	mRDT tests should be examined at the testing area where finger prick has been conducted. Do not transport mRDT devices until you examine and interpret results.	Not applicable	Storage not possible as the mRDT is affected by time and temperature.	Direct finger prick is recommended for mRDT technique
Examination of blood microfilariae	Blood	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Add 2 to 4 ml of blood. Invert the tube gently to mix the blood for about five times.	EDTA vacutainer tube. 2 to 4 ml of blood per vacutainer tube.	Sample is transported in EDTA vacutainer tube within 1hr after collection at room temperature. If more than 1 hour, transport sample under 4 to 8 °C.	Blood is stored in EDTA vacutainer at a temperature of 4 to 8 °C. Process the sample within one week.	For Wuchereria bancrofti, collect blood at night from 10 p.m to 2 a.m (nocturnal periodicity) For Loa loa, collect blood during the day from 10 a.m to 2 p.m (diurnal periodicity) For Mansonella perstans, collect blood at any time (aperiodic)



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Examination of skin microfilaria (Onchocerca volvulus)	Skin snip	Explain the procedure to the client. Make sure he/she is sitting comfortably.	Collect skin snip sample from most likely sites and place into a physiological wet container with lid.	Clean, wide mouth container with a lid preferably wax cartoon. Add physiological saline to wet the container to prevent drying.	Within 1 hour after collection, at room temperature.	One to two days at room temperature.	
Examination of Trypanosomes	Chancre serous fluid	Explain the procedure to the client. Make sure he/she is sitting comfortably.	Examine the skin for a hot, raised, with a visible bite in the centre (chancre). Sterile the area and prick the skin firmly. Collect the fluid on clean glass slide. For wet preparation place a cover slip and send to the laboratory immediately. Or leave the smear to dry.	Pack the dried smears in slide box. Wet prepared smears should be placed in a flat container and sent to the testing room as soon as possible.	Wet preparation \leq 5 min. Dry smears \leq 1 hour. At room temperature.	Storage of samples is not recommended as trypanosomes lyse and disappear within hours. Possible for fixed and stained slides.	During transportation of the wet prepared smears, observe great care, otherwise smears can be disturbed. Stain the dried smears as soon as possible.
	Lymph gland fluid.	Explain the procedure to the client. Make sure he/she is sitting comfortably.	Select a swollen lymph gland preferably at the back or anterior of the neck, or axillae. Sterile the area, leave to dry, insert with sterile needle and squeeze gently. Collect the fluid on clean glass slide. For wet	As for chancre fluid above.	As for chancre fluid above.	As for chancre fluid above.	As for chancre fluid above.



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary sample	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
			preparation place a cover slip and send to the laboratory immediately.				
	Blood (venous)	Explain the procedure to the client. Make sure he/she is sitting comfortably.	Vein puncture blood should be collected in a vacutainer tube with EDTA. Add 2 to 4 ml of blood. Invert the tube gently to mix the blood for about five times.	EDTA vacutainer tube. 2 to 4 ml of blood per vacutainer tube.	Within 1 hour after collection. At room temperature.	As for chancre fluid above.	
Urine Analysis	Urine	Patient is instructed to collect random or spot urine at any time of the day.	Pass urine directly into a clean, wide- mouth container. Secure the lid immediately.	Clean, wide- mouth container with a lid preferably universal bottle. Collect about 20 or ≥10 ml.	Urine should be transported in a well tighten cap container at room temperature to arasitology lab within 1 hour after collection	Unpreserved: ≤ 1 hr at room temp. Preserved with boric acid: ≤ 24hrs, at room temperature	
Urine for Schistosoma haematobium examination	Terminal Urine	Patient is instructed to void most of the urine into the toilet and collect terminal portion of urine. It is advisable to collect urine sample	Pass specimen directly into a clean, wide- mouth container. Secure the lid immediately.	Clean, wide- mouth container with a lid preferably universal bottle. Collect about 20 or ≥10 ml.	Urine should be transported in a well tighten cap container at room temperature to arasitology lab within 1 hour after collection	≤ 1 hr at room temp.	Urine sample for Schistosoma haematobium, should not be preserved with boric acid



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary sample	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
		between 10 to 15 hours. Where applicable, instruct the patient to undergo a little physical exercise prior collection of the sample.					
Urine for Trichomonas vaginalis examination	First Voided Urine	Patient is instructed to void first portion of urine into the container and the remaining into the toilet.	Pass urine directly into a clean, wide- mouth container. Secure the lid immediately	Clean, wide-mouth container with a lid preferably universal bottle. Collect about 20 or ≥10 ml.	Urine should be transported in a well tighten cap container at room temperature to arasitology lab within 1 hour after collection	≤ 1 hr at room temp.	Urine sample for Trichomonas vaginalis trophozoites, should not be preserved with boric acid. First voided urine sample is recommended for males.



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5.5 HIV Early Infant Diagnosis Samples

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Packaging, transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
PCR for HEID	Dried Blood Spot	Patient below 18 months	<ul style="list-style-type: none"> -Instruct the mother to hold the infant with one leg out for the nurse to prick its heel. -Warm the site with soft cloth moistened with water up to 41°C or gently massage the area for three minutes -Cleanse the puncture site with alcohol and allow to air dry for 30 seconds -Keep the heel in horizontal position or below heart level -Puncture heel to a depth less than 2mm using sterile lancet -Using sterile gauze wipe away the first blood drop - Allow one large blood drop to form and apply to surface of filter paper circle. -Fill the remaining circles in the same 	<ul style="list-style-type: none"> -Special filter paper with 5 circles -A minimum volume of 50µL and 60 µL is added to each circle - Place dried DBS into Ziploc bag. -Add desiccant packages with minimum of 2 desiccant packages per specimen -Add humidity indicator card, remove air and seal bag 	Samples are stable after drying, no time limitations for it to reach the NPHL, recommended time is one week after collection	Dry at room temperature for very long time	Too many drops of whole blood on the filter paper makes it hard to wash off the haemoglobin which cause some interferences in sample processing



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Packaging,transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
			manner with successive drops of blood. -Inspcet card to ensure you have collected enough blood and the specimen is valid -Dry specimen at room temperature for 3hours in horizontal position				



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5.6 Viral load test samples

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of the primary sample	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
PCR for Viral Load	Whole blood or plasma	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	Venous blood should be collected in sterile EDTA tubes (Lavender Top) and mixed adequately by inverting four times. Separate plasma from whole blood within 24hrs of collection by centrifugation at 800-1600xg for 3 minutes at room temperature. Transfer plasma into a sterile polypropylene tubes	The primary container shall be put into another container (storage box) during the transportation. Volume is 4ml.	-For effective care and treatment whole blood should reach the test lab within 6hours and plasma and other samples within a week in a cold chain. -In case of logistic difficulties for delivering those samples, delivery can be extended from one week to a year with respect to type of sample and storage conditions applied and this should also appear in the MOU/MOA	-Whole blood must be centrifuged and separated within 6hours . -For labs without centrifuge should transport to testing lab within 6hours for separation. -For plasma samples minimum time of storage without cold chain is 24 hours, if stored at 4 ^o C it has limit time of 5 days, if capable of storage at -20 ^o C it can stay for 1 year and at -80 ^o C it has 5 years.	Sample should be free from haemolysis Use of heparin anticoagulant is prohibited as it can inhibit PCR Separation should occur within 2 – 6 hours from sample collection It is recommended that specimens be stored in 1100-1200ul aliquots in sterile, 2.0ml polypropylene screw- capped tubes. 0.5ml of plasma for drug resistance



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5.7 Genotyping and Sequencing tests samples

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
ARV Drug Resistance Testing	Whole blood or Plasma or serum	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table	Venous blood should be collected in sterile EDTA tubes (Lavender Top) and mixed adequately by inverting four times. Separate plasma from whole blood within 6hrs of collection by centrifugation at 800-1600xg for 3 minutes at room temperature. Transfer plasma into a sterile polypropylene tubes	The primary container shall be put into another container (storage box) during the transportation. The minimum Plasma or Serum Sample volume should be 0.5ml	The whole blood must be transported at room temperature and centrifuged within 6hrs of collection. Plasma/Serum should be transported while frozen	Store whole blood at room temperature for not longer than 6hrs. Plasma/Serum specimens may be stored at -20°C for up to 7days. For longer periods of storage Plasma/Serum should be stored at -80°C.	HIV viral load must be ≥ 1000 copies/ml Sample should be free from haemolysis Use of heparin anticoagulant is prohibited as it can inhibit PCR Separation should occur within 6 hours from sample collection It is recommended that specimens be stored in 1100-1200ul aliquots in sterile, 2.0ml polypropylene screw- capped tubes.
Rotavirus genotyping	Faecal material	No special preparation of the patient is necessary	Collect 3 grams i.e. equivalent to thumb size of faecal material into clean screw cap container	Minimum of 3grams of faecal material Clean screw capped container	Must be transported Within 8 days at 2-8°C	Must be transported Within 8 days at 2-8°C For longer storage freeze it to -20 °C	Do not use container with preservatives
Dengue Sequencing	Whole blood or Plasma or serum	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table	Venous blood should be collected in sterile EDTA tubes (Lavender Top) and mixed adequately by inverting four times. Separate plasma from whole blood within 24hrs of collection by centrifugation at 800-1600xg for 3 minutes at room temperature. Transfer plasma into a sterile polypropylene tubes	The primary container shall be put into another container (storage box) during the transportation. The minimum Plasma or Serum Sample volume should be 0.5ml	The whole blood must be transported at room temperature and centrifuged within 24hrs of collection. Plasma/Serum should be transported while frozen	Store whole blood at room temperature for not longer than 24hrs. Plasma/Serum specimens may be stored at -20°C for up to 7days. For longer periods of storage Plasma/Serum should be stored at -80°C	Sample should be free from haemolysis Use of heparin anticoagulant is prohibited as it can inhibit PCR Separation should occur within 6 hours from sample collection It is recommended that specimens be stored in 1100-1200ul aliquots in sterile, 2.0ml polypropylene screw- capped tubes.



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5.8 Serology and Immunology tests samples

Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
HIV ELISA	Blood/ Serum/ Plasma	Explain the procedure to the client. Make sure he/she is sitting comfortably, the arm placed on a flat table.	<p>Blood should be collected by normal venipuncture technique</p> <p>Use plain vacutainer tube or vacutainer tube with EDTA, Heparin or Citrate as anticoagulant</p> <p>Centrifuge or allow sample to stand on rack to get a clear serum or plasma.</p>	<p>Minimum of 3mls of blood should be collected</p> <p>Sample should be put on the tube rack then placed in container for transportation</p>	Within 24 hrs after collection at RT	<p>Sample should be stored for up to one week at 2 to 8°C</p> <p>For longer storage serum or plasma should be separated and frozen at -20°C or below.</p>	<p>The conditions that favour microbial growth should be avoided after thawing</p> <p>Sample should not be subjected to more than one freeze/thaw cycle</p> <p>The use of other anticoagulants may affect the outcome of the assay</p>
HBsAg ELISA	Blood/ Serum or Plasma	No special preparation of the patient is necessary	<p>Blood should be collected by normal venipuncture technique</p> <p>Use plain vacutainer tube or EDTA tube.</p> <p>Heparin and Citrate do not affect the test results</p> <p>Remove completely all the blood coagulant by</p>	<p>Minimum of 3mls of blood should be collected</p> <p>Sample should be stand on tube rack then placed in container for transportation</p>	Within 24 hrs at 2-8°C	<p>The specimen should be stored at 2-8°C for up to 3 days</p> <p>The specimen should be frozen at -15°C or below for longer term storage</p>	<p>Do not use heated specimen</p> <p>Sample should not be subjected to more than one freeze/thaw cycle</p> <p>The use of other anticoagulants may affect the outcome of the assay</p>



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Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
			centrifugation.				
HCV ELISA	Blood/Serum / Plasma	No special preparation of the patient is necessary	<p>Blood should be collected by normal venipuncture technique</p> <p>Use plain vacutainer tube or anticoagulant vacutainer tube Anticoagulant such as EDTA, Heparin and Citrate do not affect the test results</p> <p>Remove completely all the blood coagulant by centrifugation.</p>	<p>Minimum of 3mls of blood should be collected</p> <p>Sample should be stand on tube rack then placed in container for transportation</p>	Within 24 hrs at 2-8°C	<p>The specimen should be stored at 2-8°C for up to 3 days</p> <p>The specimen should be frozen at -15°C or below for longer term storage</p>	<p>Do not use heated specimen Sample should not be subjected to more than one freeze/thaw cycle</p> <p>The use of other anticoagulants may affect the outcome of the assay.</p>
Alere Determine HIV -1/2 Rapid Test.	Blood/Serum / Plasma	No special preparation of the patient is necessary	<p>Blood should be collected by normal Venipuncture technique.</p> <p>For whole blood and plasma specimen, EDTA collection tube must be used.</p> <p>For serum specimen using plain vacutainer tube.</p>	<p>Sample should be stand on tube rack then placed in container for transportation.</p> <p>Minimum of 3ml of blood should be collected.</p>	Within 24 hrs after collection at RT.	<p>Serum, plasma or Whole blood should be stored at 2-8°C if the test is to be run within 7 days of collection.</p> <p>The specimen should be frozen (-20°C or colder) if the testing is delayed more than 7 days.</p>	<p>Do not freeze whole blood specimen.</p> <p>Avoid repeated freezing and thawing of samples</p> <p>Blood collected by venipuncture should be collected aseptically to avoid hemolysis.</p>



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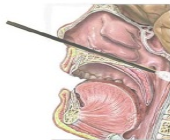
Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Uni-Gold HIV Rapid Test	Blood/Serum / Plasma	No special preparation of the patient is necessary	<p>Blood should be collected by normal venipuncture technique</p> <p>Sample should be centrifuged and retained for future testing</p> <p>Whole blood specimen should be used within 10 minutes of collection for optimum performance.</p>	<p>Minimum of 3ml of blood should be collected</p> <p>Sample should be stand on tube rack then placed in container for transportation.</p>	Within 24 hrs after collection at RT	<p>Specimen should be stored at 2-8°C for up to 3 days.</p> <p>Serum and plasma should be frozen for longer storage</p>	<p>Avoid repeated freezing and thawing of sample</p> <p>Blood collected by venipuncture should be collected aseptically to avoid hemolysis</p>
RPR Card Test for Syphilis detection	Serum / Plasma	NA	<p>Human serum or Plasma should be used</p> <p>Use plain vacutainer tube or EDTA anticoagulant vacutainer tube for sample collection.</p> <p>Use clear, un-hemolysed serum as soon after collection as possible</p>	<p>Minimum of 3ml of blood should be collected</p> <p>Sample should be stand on tube rack then placed in container for transportation.</p>	Transported at 2-8°C for 7 days	<p>Store the serum for 7 days at 2-8°C and -20°C for long storage.</p> <p>Store the plasma at 2-8°C for 48 hrs.</p>	Under no circumstances should specimens be subjected to repeated freeze-thaw cycles.



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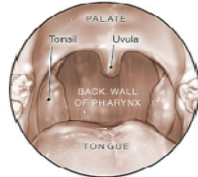
Name of Test	Sample type	Patient Preparation Procedures	Sample Collection Guidelines	Transport device and/or amount of primary samples	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Rotavirus	Faecal material	No special preparation of the patient is necessary	Collect 3 grams i.e. equivalent to thumb size of faecal material into clean screw cap container	Minimum of 3grams of faecal material Clean screw capped container	Must be transported Within 8 days at 2-8°C	Must be transported Within 8 days at 2-8°C For longer storage freeze it to -20°C	Do not use container with preservatives

5.9 Emerging and Re Emerging Disease

Name of Test	Sample	Patient Preparation Procedure	Sample collection guidelines	Transport device and/or minimum vol	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Influenza viruses Testing and other Respiratory Viruses	<ol style="list-style-type: none"> Nasopharyngeal Swab(NP) Oropharyngeal Swab (OP) 	Patient should meet standard case definitions for ; Influenza like illness (ILI) and Severe Acute Respiratory Illness-(SARI) ILI standard case definition- Acute respiratory infections with measured fever of $\geq 38^{\circ}\text{C}$ and cough	Collect Nasopharyngeal Swab (NP): 	NP/OP swabs are placed into the <u>same</u> cryovial containing 3mL VTM or UTM	Transport samples weekly in cold chain (Ice pack or LN)	2-8°C for seven (7) days or -70°C and below for long term storage. In LN up to 30 days.	Do not use rigid shafted swabs for this sampling method. Patient should resist gagging and closing the mouth while the swab touches the back of the throat tongue depressor can be used Follow universal



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Name of Test	Sample	Patient Preparation Procedure	Sample collection guidelines	Transport device and/or minimum vol	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
		<p>with onset within 7 days</p> <p>SARI standard case definition-Acute Respiratory infection with history of fever $\geq 38^{\circ}\text{C}$ and cough onset within 7 days and require hospitalization,</p>	<p><i>Insert flexible, fine- wire or plastic shafted rayon or polyester swab into nostril PARALLEL to the palate upper jaw and straight back to nasopharynx not upward.</i></p> <p>Collect Oropharyngeal Swab (OP):</p>  <p><i>Have the patient open his/her mouth wide open Use a sweeping motion to swab the posterior pharyngeal wall, not the tonsils or tongue. (an up and down motion may be best, but side to side motion is also permissible</i></p>				<p>Safety Precaution.</p> <p>Laboratory staff must be notified before specimens are sent</p>



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Name of Test	Sample	Patient Preparation Procedure	Sample collection guidelines	Transport device and/or minimum vol	Time frame	Transport and Storage Temp and time	Special considerations/ instructions
Viral Haemorrhage fever (Dengue fever, Ebola, Marburg Chikungunya, Crimean-Congo fever, Lassa fever, Rift Valley fever, yellow fever)	Human serum, Plasma, whole blood, Autopsy or Stool	Patient meeting standard case definition for viral haemorrhage fever, OR Patient suspected with VHF Symptoms: acute fever, diarrhoea that can be bloody, and vomiting. Headache, nausea, and abdominal pain. Conjunctival injection, dysphagia, and hemorrhagic symptoms such as nosebleeds, bleeding gums, vomiting of blood, blood in stools,	Acute samples obtained on Day 0-7 and Convalescent samples on Day 8-28. Wear proper personal protective equipment. Venipuncture with needle and syringe Stool and autopsy collection procedures Proper labelling of samples should be followed i.e. patient ID, date and time of collection	Sample should be stand on tube rack then placed in container for transportation. Cool box, Dry shipper or other laboratory transport containers to be used A volume of 4mls whole blood and 2mls of serum or plasma to be collected.	As soon as possible recommend Within 24 hrs after collection Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen	Serum, plasma or Whole blood should be stored at 2-8°C if the test is to be run within 7 days of collection. The specimen should be frozen (-20°C or colder) if the testing is delayed more than 7 days.	Do not freeze whole blood specimen. Avoid repeated freezing and thawing of samples Labeling The outer container with -Sender's name, address and telephone number of person responsible for shipment -Recipient's name and address staff dealing with these specimens must wear protective equipment and follow other safety precautions as specified



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6.0 Phlebotomy Procedures

The venipuncture system should be used for blood collection. These are the guidelines to use when collecting samples.

Vacutainer Blood Collection System

The Vacutainer system consists of a double-pointed needle, a plastic holder or adapter, and a series of vacuum tubes with rubber stoppers of various colours. The stopper colours indicate the type of additive present. The blood goes from the patient directly into the appropriate test tube.

Vacutainer Colour System

		Additive	Minimum Volume	Mix Number of Times	Laboratory Use
Vacutainer® Tubes with Hemogard™ Closure	Vacutainer® Tubes with Conventional Stopper				
 Gold	 Red/Grey	Clot activator and gel for serum separation		5	For serum determinations in chemistry. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease. Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 30 minutes.
 Light Green	 Green/Grey	Lithium heparin and gel for plasma separation		8	For plasma determinations in chemistry. Tube inversions ensure mixing of anticoagulant (heparin) with blood to prevent clotting.
 red	 Red	Silicone coated (glass) • Clot activator, Silicone coated (plastic		0-5	For serum determinations in chemistry. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease. Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 60 minutes



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 Green	 Green	<ul style="list-style-type: none"> • Sodium heparin • Lithium heparin 		8	For plasma determinations in chemistry. Tube inversions ensure mixing of anticoagulant (heparin) with blood to prevent clotting.
 Gray	 Gray	<ul style="list-style-type: none"> • Potassium oxalate/ sodium fluoride • Sodium fluoride/Na₂ EDTA • Sodium fluoride (serum tube) 		8	For glucose determinations. Oxalate and EDTA anticoagulants will give plasma samples. Sodium fluoride is the antiglycolytic agent. Tube inversions ensure proper mixing of additive with blood.
 Lavender	 Lavender	<ul style="list-style-type: none"> • Liquid K3EDTA (glass) • Spray-coated K2EDTA (plastic) 		8	K2EDTA and K3EDTA for whole blood hematology determinations. K2EDTA may be used for routine immunohematology testing, and blood donor screening. Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.
 White		<ul style="list-style-type: none"> • K2EDTA and gel for plasma separation 		8	For use in molecular diagnostic test methods (such as, but not limited to, polymerase chain reaction [PCR] and/or branched DNA [bDNA] amplification techniques). Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.
 Light Blue	 Light Blue	<ul style="list-style-type: none"> • Buffered sodium citrate 0.105 M (≈3.2%) glass 		8	For coagulation determinations. CTAD for selected platelet function assays and routine coagulation determination. Tube



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		0.109 M (3.2%) plastic • Citrate, theophylline, adenosine, dipyridamole (CTAD)			inversions ensure mixing of anticoagulant (citrate) to prevent clotting.
--	--	---	--	--	--

1. 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.

2. Safety and Infection Control:

It is important to follow safety and infection control procedures.

PROTECT YOURSELF

a. 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.
- Clean up any blood spills with a freshly made 1:10 bleach disinfectant.

b. Protect the patient:

- Place blood collection equipment away from patients, especially children.

3. Equipment

- THE FOLLOWING ARE NEEDED FOR ROUTINE VENIPUNCTURE

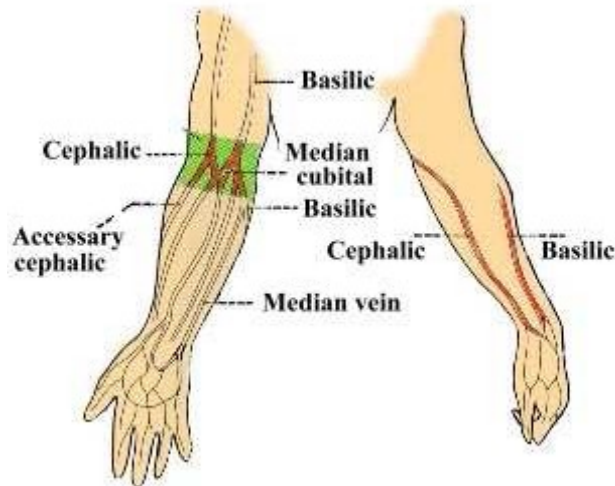
Evacuated collection tubes – the tubes are designed to fill a predetermined volume of blood by vacuum. The rubber stoppers are colour coded according to the additive the tube contains. Blood should NEVER be poured from one tube to another since the tube can have different additives or coatings.

- Needles – The gauge number indicates the bore size: the larger the gauge number, the smaller the needle bore.
- Holder – use with the evacuated system.
- Tourniquet – wipe off with alcohol and replace frequently.
- Alcohol wipes – 70% isopropyl alcohol.
- Adhesive bandages / tape – protects the venipuncture site after collection.
- Needle disposal unit – needles should NEVER be broken, bent, or recapped. Needles should be placed in disposal unit IMMEDIATELY after their 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 tube for special circumstances.



4. 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. Procedure:

- Put on gloves.
- Position the patient so he or she is comfortable and safe in case the patient becomes faint and falls.
- Recommended needle size: 20G, 21G or 22G.
- Closed vacutainer system is recommended.
- Select tube or tubes appropriate for type of samples desired.
- Select site for venipuncture.
- Prepare venipuncture site with alcohol prep. Cleanse in a circular fashion, beginning at the site and working outward. See diagram below.



- 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 reduces the risk of backflow of any anticoagulant into the patient's circulation



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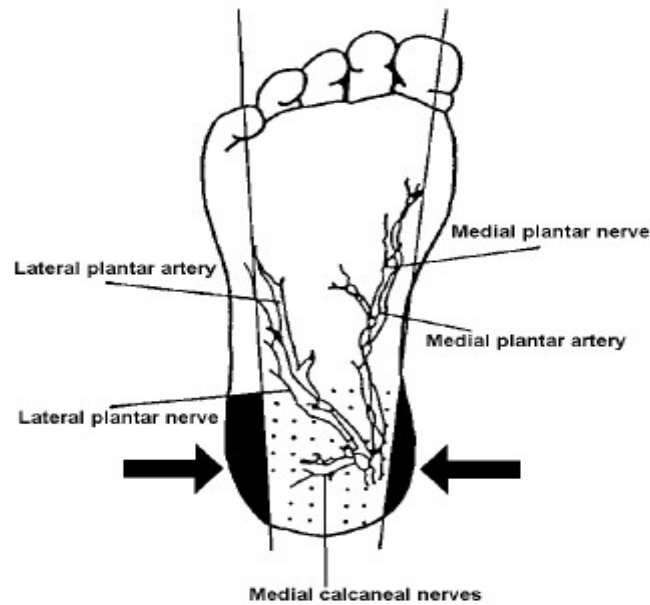


- Push the tube onto the needle, puncturing the stopper.
- REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE, within 2 minutes of Venipuncture. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE STOPPER DURING THE PROCEDURE.
- When first tube has filled to its stated volume, remove it from the holder.
- Place succeeding tube in holder puncturing stopper to initiate flow.
- While each successive tube is filling invert previous tube GENTLY 5 times. 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 container WITHOUT RECAPPING the needle.
- Immediately invert the last tube GENTLY 5 times.

Neonate Capillary Blood Collection (Heel Stab)

Choosing a site for the heel prick

- Use the most medial or lateral portions of the planter surface of the heel (in diagram below areas indicated by arrows). Limit the depth of the puncture wound by using an automated lancet.
- Only consider using the whole plantar surface of the foot (using automated lancets of 2.2mm in length or less) for neonates over 33 weeks' gestation if they are having multiple/frequent heel pricks



Preparation of the neonate

- Methods to reduce pain for the neonate: • Skin-to-skin contact with the mother, • Swaddling/containment, Breastfeeding, Administration of oral Sucrose
- Position the neonate: ensure the foot is lower than the body.

Taking the blood sample


- Choose a puncture site – do not use a previous puncture site.
- Clean the heel site (i.e. gauze and water) if the foot appears unclean (e.g. faecal material)
- Encircle the foot with the palm of the hand and the index finger.
- Make a quick puncture with the automated lancet device
- Wipe off the first drop of blood with a gauze swab
- Allow enough time for capillary refill of the heel and only gently “pump” the heel if necessary to continue the blood flow.
- Apply gentle digital pressure with a gauze swab to puncture site if bleeding continues after procedure
- Wipe the heel and apply gauze over the puncture site holding until the bleeding stops.
- Document as required.

6.1. Rejection Criteria for Samples

Causes for Rejection of Sample

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

- Haemolysed.
- Clotted.
- Insufficient sample. When many tests are ordered on the same tube, be sure to know the amount of sample needed for each test.
- Wrong tube collected for test ordered.
- Samples not processed before shipping to lab.
- Samples held too long in facility before shipping.

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- 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.
- Missing or in adequate identification of the sample

DBS Sample rejection criteria: Procedure steps

- Check the quality of the envelope received; look for any damage in the envelope
- Open the envelope; check the specimen delivery form. Ensure that the form corresponds to the number of the samples received
- **Reject DBS if:**
 - Blood did not completely soak through the filter paper
 - DBS card scratched
 - Specimen is contaminated or discoloured
 - Specimen is caked, clotted or layered on the filter paper
 - Missing or invalid patient demographic information
 - Form serial number does not match that of the blood circles
 - DBS is too old upon receipt (received 14days or more days)
 - No blood on filter paper
 - Specimen submitted on improper collection form
 - Serum separation due to improper drying or collection
 - Specimen torn or damaged on transit
 - Finger prints seen on filter paper circles
 - Haemolysed DBS
 - Insufficiently dried DBS (humidity greater than 60)

Note: The collection devices must be in date through the whole testing process.

6.2 Non-Conforming Specimen Containers, Forms or Specimen Quality Issues

Where the requirements with respect to labelling the request form and specimen container or specimen quality issues are not met the following will apply.

SPECIMEN ISSUES	ACTION	DOCUMENTATION
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<ul style="list-style-type: none"> • No specimen received • Specimen site not identified • Specimen collected at incorrect time or date and time of collection not indicated • Specimens unlabelled • Two of the three mandatory unique identifiers are not correct or absent from the specimen (Full name, DOB, hospital no.) • Addressograph label on blood specimen • Miscellaneous specimen issues 	<ul style="list-style-type: none"> • A second specimen must be collected <i>or</i> the originator accepts responsibility for same in emergency cases or where the specimen cannot be replaced. • If tested the report will show the non-conforming event. 	<ul style="list-style-type: none"> • Originator or nominee signs for the correction of the error on a Specimen Reception form.
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FORM ISSUES	ACTION	DOCUMENTATION
<ul style="list-style-type: none"> • No request form provided with specimen • Inadequate or incorrect patient details:- <ul style="list-style-type: none"> ○ hospital number ○ name ○ address ○ date of birth ○ ward or location ○ gender ○ clinic information • Incorrect test requested • No test requested • No patient details on back copies of form • Ordering Physician not identified • Specimen collected at incorrect time or date and time of collection not indicated • Miscellaneous form issues 	<ul style="list-style-type: none"> • A second specimen is requested if the originator does not correct the error. • If tested or appropriate the report will show the non-conforming event 	<ul style="list-style-type: none"> • Originator or nominee signs for the correction of the error on a Specimen Reception form.



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SPECIMEN APPEARANCE/ QUALITY ISSUES	ACTION	DOCUMENTATION
<ul style="list-style-type: none">Evidence of HaemolysisGross LipemiaPresence of clots in specimens requesting coagulation testsAge of specimenMiscellaneous quality issues	<ul style="list-style-type: none">The NPHL will make a decision on whether or not the specimen is suitable for testing and a second specimen is requested as appropriate.The NPHL may report results within a multi test profile on analytes unaffected by the specimen quality, while not reporting affected analytes in the profile.If tested or appropriate the report will show the non-conforming event	Not applicable

6.3 Further Additional Testing

If on sending a specimen for testing and further additional testing is required, please contact the appropriate section of the NPHL to investigate the feasibility of using the initial specimen for analysis as age of specimen may impact on the validity of test results. Ideally, a request form should accompany such a request but the lack of the request form should not impede the processing of an urgent request.

7. Delivery, Packing, and Transportation of Samples

It is the policy of the NPHL to treat all specimens and samples as potentially infectious or high risk. Therefore, we advise you to take universal precautions in the collection, packaging and the delivery of specimens being sent to the NPHL for analysis.


7.1 Specimen Delivery to NPHL

The requirements stated below apply to all specimens or samples directed to the NPHL. These will be required to be packed and transported in accordance with the WHO and IATA requirements for the transportation of infectious goods.

It is the policy of the NPHL to provide our clients with specimen transport packaging instructions. Please do not hesitate to contact NPHL for more information regarding the packaging of samples.

Packing Procedure for the Transport of Diagnostic Specimens

1. Specimen to be sent should be stored in a secure (preferably plastic) primary container.
2. Wrap the container in tissue or cotton wool which will act as absorbent material in event of any spillages.
3. This will be placed in a biohazard bag.
4. Place the biohazard bag with the sample in a padded (jiffy bag) envelope.
5. Label the envelope with a hazard warning label, "Diagnostic Specimen".
6. Place the name, address and contact number of the NPHL outside of the envelope.
7. Place the name, address and contact number of the originator on the outside of the envelope.

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- The specimen can be transported or posted as appropriate.

Procedure for the Transport of Infectious or Suspected Infectious Specimens

- Specimens or samples suspected or known to contain risk group 3 or 4 Pathogens (refer to attachment 1 of this document) are classified as infectious and are packaged and transported accordingly as outlined below.
- Specimens or samples to be sent should be stored in a secure (preferably plastic) primary container.
- Wrap the container in tissue or cotton wool which will act as absorbent material in event of any spillages.
- Place the wrapped primary specimen or sample container inside of the plastic container of the UN-approved Class 6.2 package type.
- Place the container inside the cardboard box.
- The box should contain a label "Infectious Substance". Write the name of the suspected microbe being transported in brackets.
- Place the name, address and contact number of the destination laboratory on the outside of the box.
- Place the name, address and contact number of the originator on the outside of the box.
- Complete a transport document and provide a copy to the licensed courier.

7.2 Safe Disposal of Waste Material Used in Specimen Collection

All materials used in specimen collection should be treated as potentially hazardous and discarded using sharps containers and other appropriate colour coded bags. Please refer to the National IPC guidelines for Healthcare Services in Tanzania: A pocket Guide.

7.3 Repeat Examination due to Analytical Failure

It is the policy of the NPHL in the event of an analytical failure to:-

- 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.

7.4 Further Examination of the Primary Specimen


Where further testing is relevant to the investigation or diagnosis of the condition or symptoms which gave rise to the original test request then it is the policy of the NPHL to pursue a diagnosis by performance of additional tests using the primary specimen.

7.5 Referral Laboratory Testing

It is the policy of NPHL to refer all samples for testing to referral laboratories for the tests not conducted within NPHL or whereby the tests are not conducted but due to any reason the test is not being offered. In such circumstances, NPHL has the responsibility to refer the test to the laboratory of its choice chosen following the Selection of the Referral laboratory procedure.

7.6 Emergency Out of Hours Service

Generally the NPHL does not operate a standby service or on call service for emergency cases. However in case on national outbreaks or whenever the need arises, the management can organise to arrange members of staff to test samples after normal hours. In case of an emergency, clients are requested to contact the Director or laboratory manager on the telephones numbers available.

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8.0 REPORTING OF TEST RESULTS

8.1 Reporting of Results

All results, once released, shall be sent to the person requesting the test within the same day the results are released. If the results are within the critical limits, the laboratory shall contact the clinician requesting the test on telephone but however following the PR25_Management of Results Procedure. Requests for verbal reports are not entertained. It is the policy of NPHL not to hand results to patients. Patients are required to obtain their test results from their referring physician.

8.2 Reference Ranges (Biological Reference Intervals)

Reference ranges for quantitative tests are described in section 3.3 above.



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AMENDMENT RECORDS

AMMENDMENT SHEET			
<u>Date</u>	<u>Proposed by</u>	<u>Section</u>	<u>Summary of Changes</u>
01/07/2011	QO	Quality	NEW
15/08/2012	Ambele E. Mwafulango	Emerging and Re Emerging	Patient preparation for influenza virus added on section 5.9. Transportation time changed to one week from 72 hours at 2-8°C. All viral Haemorrhagic fevers (VHF) combined together in section 5.9 (Rift Valley fever, Ebola, Yellow fever, Murbug, Dengue and Chikungunya). Two Respiratory viruses (Murbug and Chikungunya) added on section 5.9.
15/02/2013	Ibrahim Y. Ideva	Quality	Definition of TAT added on section 3.3
28/02/2013	Dotto B. Kalovya	Serology and Immunology	TAT for DBS HIV ELISA HIV Test (120 hours) was added on section 3.3 –Serology and Immunology tests. All ELISA Test TAT changed from 72 hours to 24 hours. All TAT for rapid test changed to 6 hours from 48 hours. All Microtitre test TAT changed to 12 hours from 48 hours
01/03/2013	Rukia I. Shani	Clinical chemistry	Changing on transportation time for all clinical chemistry tests page 12 to 18. Deletion of all tests which are not currently processed – page 6 to 8. Additional of critical values column on section 3.3 - Laboratory Tests and Procedures Available.
26/03/2013	Salum K. Nyanga	Microbiology	Note added on section 5.2 (Microbiology) Samples should be taken before antimicrobial treatment has been started. Bacterial Identification added on section 5.2 (microbiology)
27/03/2013	Makune John	Haematology	Storage of samples changed to 16 hours at 15-25°C from 8 hours at 15-25°C (section 3.3). Critical values added
28/03/2013	Joackim M. Nyarigo	Parasitology	TAT for malaria slide changed to 2 hours from 3 hours (Section 3.3)
28/03/2013	Sylvester L. Mattunda	HEID	The word 3 circles changed to 5 circles on section 5.5 (Transport device and/ or minimum volume
24/06/2013	Management	Management	Revised but no changes



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30/08/2014	QO	Quality	Reviewed to cover new changes of ISO 15189:2012
12/11/2014	QO	Quality	On section five in column number six was changed to Time frame
25/06/2015	Ester Mwavika	HEID	Changing the unit of the results for heid from copies per ml to Not Applicable since it is a qualitative test.
23/07/2015	Joseph Mziray	Viral Load	Time frame for viral load samples and storage conditions have been reviewed considering transportation logistics and scientific bases
31/07/2015	Peter Mburah	Microbiology	Time frame for enteric samples and special consideration of processing of these samples have changed
24/08/2015	Carolyn Riwa	Genotyping and Sequencing	Changes on ARV Drug resistance and Dengue sequencing testing on TAT, Patient preparation, Transportation, Storage and Special sample handling conditions
24/08/2015	Regnald Julius and Ebiezel Samson	Clinical Chemistry	Changes made on TATs and Urgent TATs for Clinical Chemistry tests
04/12/2015	Joseph Mziray, Ester Mwavika and Mura Ngoi	HEID and Quality	Changes made in page 42 in EID section to clearly describe on sample collection, storage time, storage condition, time frame, packaging, transportation time, devices used, temperature, amount of primary sample and special consideration instruction according to MoHCDGEC guideline
01/03/2018	Carolyn Riwa	Genotyping and Sequencing	Changes made on page 13 and 48 (added "a Rotavirus genotyping test"
01/03/2018	Jacob Lusekelo	Quality Office	Changes made on page 65, where MOHSW has been changed to MoHCDGEC
08/06/2018	Jacob Lusekelo	Quality Office	Changes made throughout section 5.0, where column which was headed " storage time and temp" was changed to " Transport and storage temp and time" and added specific transporting temperature ranges Added "Annexes" on table of contents (page 2) and on page 68. Changes on document approval authority name
25/02/2019	Regnald Julius	Clinical Chemistry	Added a note on TAT (<i>guidance on TAT for testing study or project samples as per PR 02</i>) at section 3.3; Types of clinical services offered by NHL-QATC for Clinical Chemistry .



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12/02/2021	QO	Quality	Change on the name of the ministry and document ID number



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ANNEXES

Annex 1: Laboratory Request form

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN
National Public Health Laboratory
Laboratory Request form
 Address:9083 Dar Es Salaam.

A. Clinician Information		
Name.....	Position.....	Signature.....
Contact details.....	Tel(Bus).....	Cell.....
Health Facility.....	District.....	Region.....

B. Patient information		
Patient identification number.....		
Name.....	Age..... (Years)	Sex <input type="radio"/> : Male - Female
Address.....		
Occupation of patient.....		Nationality.....
Clinical Information/History		
.....		
.....		
Regional Laboratory Technologist Phone number.....		

C. Sample Information		
Anatomical Site	Nature of specimen.....	
Transport medium.....	Conditions for transportation.....	
Collection Date	Time.....	Collected By.....
Transportation date.....	Time.....	
Examination requested		
.....		
.....		

NPHL-Laboratory Use only

Specimen laboratory number..... Date Received (dd/mm/yy)

Time.....

Name of receiving officer..... Signature.....

Condition upon receipt..... Transportation temperature.....

Comments:



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Annex 2: Complaints form
NPHL/M/FM 013
Effective Date: 01.08.2021
Version No: 1 Complaints form



Date (DD /MM/ YYYY): / /

Time: :

Complaint No: _____

Staff Member recording occurred

Source of complaint:

Contact Person:

Contact Number


Email address:

Description of complaint:

.....
 Related Document

Documents are (tick appropriate) attached or Located

Investigation assigned to

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Date (YYYY/MM/DD): / /

Description of Investigation (include impact assessment):

Is corrective action needed: Yes (Describe Below) No

Briefly Describe the Corrective action taken

Follow-up contact with person or organization that initiated complaint:

Date (DD/MM/YYYY): / /

By:

Feedback Status

Feedback given by: Mode of Feedback:

