SAMPLE COLLECTION MANUAL FOR STI/HIV TESTING

NATIONAL REFERENCE LABORATORY FOR STI AND HIV NATIONAL STD/AIDS CONTROL PROGRAMME SRI LANKA







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NATIONAL REFERENCE LABORATORY FOR STI AND HIV NATIONAL STD/AIDS CONTROL PROGRAMME NO:29, DE SARAM PLACE, COLOMBO 10, SRI LANKA. 011-2667163

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Abbreviations

STI Sexually Transmitted Infections
HIV Human Immunodeficiency Virus

NSACP National STD/AIDS Control Programme

GFATM The Global Fund to Fight AIDS, Tuberculosis and

Malaria

EMTCT Elimination of Mother to Child Transmission of HIV

and Syphilis

AIDS Acquired Immunodeficiency Syndrome

NRL National Reference Laboratory
STD Sexually Transmitted Diseases

Ag Antigen Ab Antibody

ELISA Enzyme-linked Immunosorbent Assay

RNA Ribonucleic Acid

PCR Polymerase Chain Reaction

DNA Deoxyribonucleic acid
ART Anti-Retro Viral Therapy

VDRL Venereal Disease Research Laboratory Test

TPPA Treponema pallidum Particle Agglutination Assay

Ig Immunoglobulin

ABST Antibiotic Sensitivity Test
PCR Polymerase Chain Reaction

HSV Herpes Simplex Virus

MRI Medical Research Institute

ESR Erythrocyte Sedimentation Rate

SGOT Serum glutamic oxaloacetic transaminase Test
SGPT Serum glutamic pyruvic transaminase Test

CMV Cytomegalovirus

hCG Human Chorionic Gonadotropin

AFB Acid Fast Bacilli
TB Tuberculosis

DST Drug Sensitivity Test

NPTCCD National Programme for Tuberculosis Control and

Chest Diseases

PLHIV People Living with HIV

PPE Personal Protective Equipment

FPU First Pass Urine

EDTA Ethylenediaminetetraacetic acid

VTM Viral Transport Media
CT Chlamydia trachomatis
NG Neisseria gonorrheae
KOH Potassium Hydroxide
rpm rounds per minute

MSM Men having Sex with Men

GC Gonococci

BHT Bed Head Ticket
CSF Cerebrospinal Fluid
FBC Full Blood Count

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Preface

Receiving a good quality sample at laboratory is a prime requirement in generating an accurate, reliable report. In this sense the importance of obtaining the right sample from the right site from the right person is mandatory in STI and HIV diagnosis.

The necessity of a manual for sample collection, transport and storage was a long felt need in the STI and HIV field. This manual was prepared to fulfill that need and as an initial step of the journey towards accreditation of laboratories for STI and HIV. Streamlining the quality management systems in laboratory sector is very essential in reaching the goals of elimination of mother to child transmission of Syphilis and HIV and in ending AIDS by 2025. It is expected that this manual to be a corner stone in improving the quality of laboratory testing.

It is highly acknowledged the support extended from UNICEF, Global fund for HIV and PEPFAR/CDC – CMAI partnership with NSACP for printing this sample collection manual.

SAMPLE COLLECTION MANUAL FOR STI/HIV TESTING-2019

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1. Introduction

Laboratory diagnosis of an infection is of utmost importance for patient management. Quality of the laboratory result is dependent on the quality of specimens received at the laboratory. The quality of the specimen is achieved with proper collection of an adequate specimen from the proper site of the patient (Right patient, Right test and Right sample). The site of collection of specimens is dependent on the clinical symptoms. Storage and transport of specimens in the required conditions too affect the quality of specimens subjected to testing.

A proper guidance on the collection of specimens and their transportation is a must for obtaining the good quality sample for testing which leads to an accurate diagnosis of sexually transmitted infections. It ensures the sample integrity, prevention of sample mix up and improving the overall quality of the samples sent for testing. It is imperative that the instructions given in the manual are adhered to by all personnel involved with sample collection, storage and transport. The phlebotomy staff too should use this as the guide and the lab staff too should abide by the manual when advising on sample collection and transport for STI/HIV testing.

2. General Information

The NSACP has a network of laboratories comprised of the Reference laboratory and peripheral STI laboratories. The apex body of that laboratory network is the National Reference Laboratory for STI / HIV of NSACP and is located in the National STD /AIDS Control Programme, Colombo 10. Other STI Clinic Laboratories are located in the peripheral STD clinics island wide.

The National Reference Laboratory of NSACP offers testing and reference services on sexually transmitted infections and HIV.

Service hours of the Laboratories

NRL

- Week days from 8.00 am to 4.00 pm
- > Saturday from 8.00 am to 12.00 noon

District Laboratories

- Weekdays from 8.00 am to 4.00 pm
- > Saturdays from 8.00 am to 12.00 noon

Closed on public holidays.

Contact details of NRL

National Reference Laboratory for STI and HIV National Std/Aids Control Programme No:29, De Saram Place, Colombo 10, Sri Lanka.

3. Sample Acceptance Time

Table 1: Sample acceptance times in NRL

lavastiastias	Sample acceptance time		
Investigation	Week days	Saturday	
HIV			
Ag+Ab ELISA Test			
Particle agglutination	8.00 am - 3.30 pm	8.00 am - 11.30 am	
test	6.00 am - 5.30 pm	0.00 aiii - 11.30 aiii	
Western Blot			
Ag/Ab rapid test	8.00am - 4.00 pm	8.00am - 12 noon	
RNA PCR - Viral load			
(VL)			
PCR – GeneXpert for VL	8.00am - 2.30 pm	Not accepted	
PCR for EID			
	Monday-Thursday		
CD4/CD8	8.00 am-3.30 pm	Not accepted	
CD4/CD0	Friday	Not accepted	
	8.00 am-12 noon		
Resistance testing -for	•	Tuesday of the third	
ART	week excluding	public holidays*	
Syphilis			
VDRL			
TPPA	8.00 am - 3.30 pm	8.00 am - 11.30 am	
IgM ELISA			
Total ELISA			
Gonorrhoea			
Culture and ABST	8.00 am - 3.30 pm	8.00 am - 11.30 am	
Gonococcal PCR			
HSV			
PCR for HSV 1 & 2	8.00 am - 3.30 pm	8.00 am - 11.30 am	
IgG & IgM ELISA for HSV			
1 & 2			

Investigation	Sample acceptance time			
_	Week days	Saturday		
Hepatitis				
Hepatitis B-Surface				
antigen				
Hepatitis B core	8.00 am - 3.30 pm	8.00 am - 11.30 am		
antibodies	0.00 um 3.30 pm	0.00 dili 11.50 dili		
Hepatitis B profile				
(Hepatitis B surface Ag,				
Hepatitis B surface Ab				
and Hepatitis B core				
Ab)				
(Done at MRI)				
Hepatitis C-antibodies				
Haematology**	0.00			
Full Blood Count	8.00 am - 3.30 pm	Not accepted		
Haemoglobin				
ESR	8.00 am - 3.30 pm	8.00 am - 10.00 am		
Biochemistry**				
Glucose, Fasting				
Glucose, Post prandial	8.00 am - 3.30 pm	Not accepted		
Glucose, Random				
Blood Urea				
Serum Creatinine				
Renal Profile				
Serum Alkaline				
Phosphatase				
SGPT/SGOT	8.00 am - 3.30 pm	8.00 am - 11.30 am		
Serum Bilirubin (Total,				
Direct & indirect)				
Liver profile				
Total Cholesterol				
Lipid Profile				
Urine hCG	8.00 am - 3.30 pm	8.00 am - 11.30 am		

Investigation	Sample acceptance time		
Investigation	Week days	Saturday	
CMV antibodies (Done			
at MRI)			
Cryptocoocal Antigen	8.00 am - 3.30 pm	8.00 am - 11.30 am	
(Done at MRI)	6.00 am - 5.30 pm	0.00 aiii - 11.30 aiii	
Toxoplasma antibodies			
(Done at MRI)			
Chlamydia			
Chlamydia PCR	8.00 am - 3.30 pm	8.00 am - 11.30 am	
Chlamydia PCR-Urine			
Tuberculosis**			
Sputum for AFB, TB			
culture & DST (Done at	8.00 am - 3.30 pm	8.00 am - 11.30 am	
NPTCCD-Welisara)			
Sputum for Gene Xpert			
Microscopy Slides	8.00 am - 3.15 pm	8.00 am - 11.15 am	

^{*}if the due Tuesday is a public holiday the next date is informed to all peripheral clinics by e mail.

^{**}Perform only for samples of PLHIV

4. General Information on Sample Collection and Dispatch

It is essential to follow Standard precautions at all times during specimen collection, storage, testing, transportation and disposal of bio-hazardous waste. Standard precautions are meant to reduce the risk of transmission of blood borne and other pathogens from both recognized and unrecognized sources. Sexually transmitted pathogens which are fastidious may give falsely negative results if optimal sample collection, storage and transport conditions are not met.

- Only the appropriate investigations should be requested according to the history of the patient, examination findings and previous investigations.
- Wear appropriate personal protective equipment (PPE) and follow only the recommended practices when collecting and handling specimens.
- Collect adequate volume of the specimen in the appropriate collection container(s). Ensure the specimen collection kits are not expired.
- ➤ Take necessary measures to avoid contamination from indigenous commensal flora to ensure a representative sampling of organisms causing the infection.
- ➤ Label each specimen container with the patient's unique identifiers, the source of the specimen, date and time of collection.
- All specimens should accompany a complete and correctly filled request form signed by the medical officer who attend to the patient.

- ➤ Once the sample is collected, it should be delivered to the laboratory in leak proof container. All measures should be taken to avoid the undue delays.
- ➤ All the information pertaining to sample collection and dispatch has to be recorded in a register.
- Disposal of collecting devices and contaminated material should be according to the waste management procedures of the institution.

5. Collection of Specimens for Testing

Table 2: Instructions for containers and volume of specimen

Investigation	Container with colour of the stopper	Volume	Specimen
HIV			
Ag+Ab ELISA Test	Plain tube Size 10 cc	3 cc	Blood/Serum
Particle agglutination test	Plain tube Size 10 cc	3 cc	Blood/Serum
Western Blot	Plain tube Size 10 cc	3 cc	Blood/Serum
Ag/Ab rapid test	Plain tube Size 10 cc	3 cc	Blood/Serum
RNA PCR - Viral load	K3EDTA Tube	3 cc	Blood/Plasma
RNA PCR - GeneXpert	K3EDTA Tube	3 cc	Blood/Plasma
PCR for EID	K3EDTA Tube	3 cc	Blood
CD4/CD8	K3EDTA Tube	3 cc	Blood
Resistance testing for ART	K3EDTA Tube	3 cc	Blood

Investigation	Container with colour of the stopper	Volume	Specimen
Syphilis			
VDRL	Plain tube Size 10 cc	3 cc	Blood /serum/CSF
ТРРА	Plain tube Size 10 cc	3 cc	Blood /serum/CSF
IgM ELISA	Plain tube Size 10 cc	3 cc	Blood /serum
Total ELISA	Plain tube Size 10 cc	3 cc	Blood/serum
Gonnorhoea			
Gonococcal culture and ABST	Modified Thayer Martin agar plate	NA	Cervical& urethral swabs
Gonococcal PCR	Urethral and cervical swabs supplied by the manufacturer	NA	Male – FPU Holding urine for 2-4hrs Female – endocervical swab
HSV IgG & IgM ELISA for HSV 1 & 2	Plain tube	3 cc	Blood/serum
HSV PCR Ulcer	Urethral and cervical swabs supplied by the manufacturer with Viral transport media	NA	Swab from the base of the lesion in viral transport media

Investigation	Container with colour of the stop	Volume	Specimen
Hepatitis			
Hepatitis B-Surface antigen	Plain tube	3 cc	Blood/serum
Hepatitis B core antibodies	Plain tube	3 cc	Blood/serum
Hepatitis B profile (Hepatitis B surface antigen, Hepatitis B surface antibodies and Hepatitis B core antibodies)	Plain tube	4 cc	Blood/serum
Hepatitis C- antibodies	Plain tube	3 cc	Blood/serum
Haematology			
Full Blood Count	K3EDTA Tube	3 cc	Blood
Haemoglobin	K3EDTA Tube	3 cc	Blood
ESR	Sodium Citrate tube 1.6 cc blood and 0.4 cc Sodium citrate makes total volume of 2 cc (Tube has to be filled up to the level which is marked)	1.6 cc	Blood
Biochemistry			
Glucose, Fasting	Sodium fluoride tube	3 cc	Blood
Glucose, Post prandial	Sodium fluoride tube	3 сс	Blood

Investigation	Container with colour of the stopper	Volume	Specimen
Glucose, Random	Sodium fluoride tube	3 cc	Blood
Blood Urea	Plain tube	3 cc	Blood
Serum Creatinine	Plain tube	3 cc	Blood
Renal Profile	Plain tube	3 cc	Blood
Serum Alkaline Phosphatase	Plain tube	3 cc	Blood
SGPT/SGOT	Plain tube	3 cc	Blood
Serum Bilirubin (Total, Direct & indirect)	Plain tube	3 cc	Blood
Liver profile	Plain tube	3 cc	Blood
Total Cholesterol	Plain tube	3 cc	Blood
Lipid Profile	Plain tube	3 cc	Blood
Urine hCG	Wide mouth screw capped bottle	10 cc	Urine
CMV			
CMV antibodies	Plain tube	3 cc	Blood
Cryptococcosis Cryptocoocal Antigen	Plain tube	3 cc	Blood
Toxoplasmosis			
Toxoplasma antibodies	Plain tube	3 сс	Blood

Investigation	Container with colour of the stopper	Volume	Specimen
Chlamydia			
Chlamydia PCR	Urethral and cervical swabs supplied by the manufacturer with VTM	NA	endocervical swab
Chlamydia PCR- Urine	Sterile screw cap wide mouth container	5ml	Urine
Tuberculosis Sputum for AFB, TB culture & DST Sputum for Gene Xpert	Universal bottle	Up to the mark in bottle	Sputum

Figure: 1: Specimen collection containers



Plain tube for serological testing



EDTA Tube for molecular testing



Sodium Fluoride tube for blood sugar



3.8% sodium citrate tube for ESR



Screw capped wide mouth sterile container for urine CT/NG PCR



Universal bottle for sputum for TB culture and ABST



Viral transport medium for HSV, Chlamydia



Amie's transport medium for Gonococcal culture



Modified Thayer martin media for Gonococcal culture

Table 3: Request forms for the investigations

Investigation	Name of the request form	Number of the request form	Annexure Number
HIV			
Ag+Ab ELISA	Request for Special Tests NSACP	Health 407	Annex 01
Test	Request form of Department of Health Services	Health 350	Annex 07
Western Blot	Request for confirmatory HIV testing from the Reference laboratory of the National STD/AIDS Control Programme		Annex 08
Ag/Ab rapid test	Request for Special Tests NSACP	Health 407	Annex 01
RNA PCR - Viral load RNA PCR - GeneXpert	Request form for HIV Viral Load Assay	NRL/RQ/8/HIV/VL	Annex 04
DNA PCR	Request for Early infant diagnosis of HIV DNA	NRL/RQ/6/HIV/GX	Annex 13
CD4/CD8	Request for Enumeration of CD4/CD8 T- Lymphocytes	NRL/RQ/9/HIV/CD4	Annex 05

Investigation	Name of the request form	Form Number	Annexure Number
ART resistance testing	Request for Anti- Retroviral Drug Resistance Testing	NRL/RQ/11/HIV/DR	Annex 10
HIV screening in antenatal mothers	Request form for Syphilis/HIV in Antenatal Mothers	NSACP/10/ANC/2	Annex 09
Syphilis			
	Request for Special Tests NSACP	Health 407	Annex 01
VDRL	Request form of Department of Health Services	Health 350	Annex 07
	Request for Examination of Blood for VDRL	Health 406	Annex 06
ТРРА	Request for Special Tests NSACP	Health 407	Annex 01
IFFA	Request form of Department of Health Services	Health 350	Annex 07
IgM ELISA	Request for		
Total ELISA	Special Tests NSACP	Health 407	Annex 01
Syphilis screening in antenatal mothers	Request form for Syphilis/HIV in Antenatal Mothers	HIV/REQ/09	Annex 09

Investigation	Name of the	Form	Annexure		
_	request form	Number	Number		
Gonnorhoea					
GC culture and	Request for				
ABST	Pathological	Medical 408	Annex 02		
GC PCR	Examinations				
HSV					
PCR for HSV 1	Request for				
& 2	Herpes Simplex				
IgG & IgM	Virus Antibody	NRL/RQ/10/HSV	Annex 03		
ELISA for HSV 1	Test				
& 2					
Hepatitis					
Hepatitis B-	Request for				
Surface	Special Tests				
antigen	NSACP	Health 407	Annex 01		
Hepatitis B	NJACE				
core antibodies					
Hepatitis B profile	Request for examination of specimen, Medical research Institute	Health 275a	Annex 11		
Hepatitis C- antibodies	Request for Special Tests NSACP	Health 407	Annex 01		
Haematology &	Haematology & Biochemistry				
Haematology	Request for Pathological				
Biochemistry	Examinations	Medical 408	Ref Annex 02		

r	T	1	1
Investigation	Name of the	Form	Annexure
investigation	request form	Number	Number
Other tests done	e in MRI		
CMV	Poguest for		
antibodies	Request for examination of		
Cryptococcal		Health 275a	Annex 11
Antigen	specimen, Medical research	nealth 275a	Annex 11
Toxoplasma	Institute		
antibodies	institute		
Chlamydia			
Chlamydia PCR	Request for		D.C.A.
Chlamydia	Pathological	Medical 408	Ref Annex
PCR-Urine	Examinations		02
Tuberculosis			
Sputum for	Request Form for		
AFB, TB culture	TB culture, Drug		
& DST	susceptibility and		
	Molecular		
	Testing.	TB 06	Annex 12
Sputum for	National TB		
Gene Xpert	Reference		
	Laboratory,		
	Welisara		

6. Specimen Collection for Microscopy

Table 4: Specimen collection instructions for microscopy

Test	Site of collection	Sampling procedure	Transport
Dark Ground Microscopy for T. pallidum	Lesion	1. Clean the ulcer surface with saline and remove any crusts, if present. 2. Squeeze the base of the ulcer between the thumb and index finger. 3. Wipe away the first few drops of fluid, especially if blood stained. 4. Collect the sample of serous exudates by pressing a clean cover slip on to the lesion. 5. Place the cover slip on a clean slide letting the exudate be present between the cover slip and the slide surface. Note: Dark-field microscopy should NOT be used for the examination of samples from oral lesions as it is difficult to differentiate Treponema pallidum and saprophytic spirochetes in the oral cavity.	Slide should be placed securely on a tray to prevent disturbance to the slide while transportation. This tray should preferably be placed in a box for transportation. Transport the slide immediately in room temperature to the laboratory.

Test	Site of collection	Sampling procedure	Transport
Wet smear for T. vaginalis	Vagina	1. Insert a speculum. (moistened with saline) 2. Insert a dry swab into the posterior fornix and collect vaginal material on to the swab. 3. Press the swab against the vaginal wall and withdraw. 4. Place a large drop of saline on a microscope slide. 5. Emulsify the withdrawn swab in the drop of saline on the slide to make it turbid. 6. Carefully add a coverslip without trapping air bubbles.	Sample should immediately be transported to the laboratory placed on a slide tray in a box.
Urine for T.vaginalis	Urine	Obtain first portion of the void to a sterile container (less than 25 ml) 1 hour after previous void.	Transport immediately to the laboratory in room temperature.

Test	Site of	Sampling procedure	Transport
	collection		
Smear for GC	Endo cervix	1. Instructions for	Place the slide on
	Low Vagina	sample collection are	a tray and keep
	Rectum	described in 8.1.2	the tray in a box.
	Urethra	2. Roll the swab on the	Send to the
	Oropharynx	slide to obtain a thin	laboratory
		homogenous film. (do	without a delay
		not rub it on the slide as	in room
		rubbing may destroy	temperature.
		cellular morphology)	
		3. Smear should cover	
		only the middle of the	
		slide. Do not let the	
		smear spread towards	
		the edges.	
		4. Allow the smear to	
		air dry.	
		Note:	
		The same swab should	
		not be used to	
		inoculate the culture	
		plate.	

Tzanck smear (smear for giant cells) 1. Samples should be taken from a fresh vesicle, rather than a crusted one. (To ensure the yield of a number of virus infected cells) 2. The vesicle should be unroofed or the crust removed, and gently scrape the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)	Test	Site of	Sampling procedure	Transport
(smear for giant cells) from a fresh vesicle, rather than a crusted one. (To ensure the yield of a number of virus infected cells) Transport immediately to the laboratory in room temperature.		collection		
giant cells) than a crusted one. (To ensure the yield of a number of virus infected cells) Transport immediately to the laboratory in room removed, and gently scrape the base with a swab. Transport immediately to the laboratory in room temperature. Transport immediately to the laboratory in room temperature. Transport immediately to the laboratory in room temperature.		Vesicles	•	
ensure the yield of a number of virus infected cells) Transport immediately to the laboratory in room temperature.				•
number of virus infected cells) 2. The vesicle should be unroofed or the crust in room temperature. the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)	giant cells)		1	keep the tray in
cells) 2. The vesicle should be unroofed or the crust in room temperature. the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)			1	
2. The vesicle should be unroofed or the crust removed, and gently scrape the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)				•
unroofed or the crust removed, and gently scrape the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)			1	·
removed, and gently scrape the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)				the laboratory
the base with a swab. 3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)				in room
3. The material obtained is smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)			, , ,	temperature.
smeared onto a clean unused microscopic slide. (cells will not adhere to an unclean slide)				
unused microscopic slide. (cells will not adhere to an unclean slide)				
(cells will not adhere to an unclean slide)				
unclean slide)			•	
· ·			1 -	
			•	
4. Allow to air dry.				
Gram stained Vaginal/ 1. Collect the Place the slide				
smear for Sub vaginal/preputial specimen on a tray and				•
	Candidiasis	preputial		keep the tray in
the middle area of a clean a box.				G. 10 G. 11
dry slide. Transport			1	•
· · · · · · · · · · · · · · · · · · ·			2. Keep to air dry.	immediately to
the laboratory				•
in room				
Wet smear for Vaginal/ 1. Collect the Place the slide	Mot smoor for	\/aginal/	1 Callact the	•
Wet smear for Vaginal/ 1. Collect the Place the slide Vaginal/preputial specimen on a tray and		_		
		0.00		•
KOH preputial to a swab. Roll the swab on keep the tray in the middle of the slide.	KOH	preputial		keep the tray in
2. Add a large drop of 10% Transport				G. 10 G. 11
				immediately to
wooden applicator or swab the laboratory				·
and cover with a cover slip. in room				,
temperature.				
				,

Test	Site of	Sampling procedure	Transport
	collection		
Wet mount	Vaginal/	<u>Females</u>	Place the slide
for Candidiasis	Sub	1. Obtain the sample from	on a tray and
	preputial	both lateral vaginal walls	keep the tray in
		and posterior fornix with	a box.
		same swab.	Transport
		2. In patients who have	immediately to
		only a slight vaginal	the laboratory
		discharge and extensive	in room
		involvement of the vulva or	temperature.
		labia, it is better to collect a	
		specimen from the irritated mucosa.	
		Males	
		In males with balanitis, use	
		a swab pre-moistened in	
		saline to collect the sample	
		from the glans penis.	
		Preparation of the slide	
		Place a large drop of saline	
		on a microscope slide, roll	
		the swab on to the saline	
		drop. Cover with a cover	
		slip after emulsifying the	
		swab in saline.	
Smear for	Vaginal	1. Place large a drop of	Transport to
Bacterial		saline on a glass slide.	the laboratory.
vaginosis		2. Then take a sample from	Place the slide
		the discharge collected in	on a tray and
		the posterior fornix using a	keep the tray in
		swab	a box.
		3. Mix the vaginal fluid with	
		the saline drop on the glass	
		slide.	
		Place a coverslip over the	
		suspension	

7. Specimen collection for Serology and Molecular Testing

7.1. Materials required for collecting blood

It is recommended to use sterile vacutainer glass/plastic tubes for collecting blood. EDTA tubes should be used for whole blood and plain tubes should be used for serology specimens.

- Syringes and needles / vacutainer needle holder
- Vacutainer tubes (EDTA and plain)
- Well-fitting, latex, non-sterile gloves
- > A tourniquet
- > 70% alcohol
- Alcohol hand rub
- Gauze or cotton-wool
- Laboratory specimen labels
- Writing pen
- Laboratory forms
- Leak-proof transportation containers
- > Ice packs
- Sharps bin and waste bins.

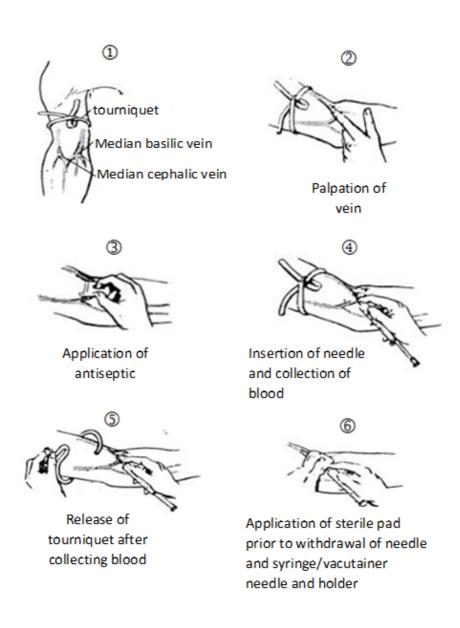
Collect all the materials needed for the procedure and place it within safe and easy reach on a tray or trolley, ensuring that all the items are clearly visible.

7.2. Instructions for Blood Collection

Blood collection should always be done under aseptic conditions

- Identify the patient by checking the patient identification details.
- Select the site
 - Inspect the antecubital fossa or forearm on the extended arm.
 - Select a vein of a good size that is visible, straight and clear (The vein should be visible without applying the tourniquet).
- ➤ Apply the tourniquet about 4–5 finger widths above the venepuncture site and re-examine.
- Clean the entry site with 70% alcohol.
- ➤ If vacutainer is used insert the needle and the holder. Then fix the tube to the holder and draw blood. Blood can be collected to number of tubes in this manner without using a syringe.
- When the bleeding is over, remove the needle and discard it into the sharp bin.
- ➤ If the vacutainer holder is contaminated put it in to the sharp bin.
- ➤ If the syringe is used, use a syringe with appropriate volume according to the number of the samples needed and after collecting discard both syringe and the needle together into the sharp bin. **Do not recap the needle.**

Figure 2: Steps in Drawing Blood



7.3 Collection of Blood specimens for Serological Investigations

7.3.1 Sample Collection

- Collect 3-5ml of blood (adults) in to a dry, sterile plain tube.
- Allow blood to clot at room temperature for a minimum of 20-25 minutes in vertical position before dispatching to laboratory.

7.3.2 Storage and Transportation

- Keep the blood tubes in a rack in refrigerator at 4°C.
 Transport within 24 hours to the laboratory at 4°C.
- If any delay in transport, centrifuge at 2500 rpm for 10-15 minutes.
 - Pipette the supernatant serum into another sterile tube; label it.
- Separated serum should reach the laboratory within 5 days.

7.4 Collection of blood for HIV Viral Load Test

It is essential for the molecular tests to receive a good quality sample to obtain accurate results. Heamolyzed samples are not acceptable. Therefore, one should be very careful in collecting and preparing samples for molecular testing.

7.4.1 Sample collection

 Collect 3ml of venous blood under aseptic conditions into a K3EDTA tube.

Note: Fill the tube exactly up to the marked level.

Excess EDTA, as well as insufficient EDTA will cause coagulation problems in the sample which can affect the accuracy of results.

Mix the tube gently by inverting 10 times.

7.4.2 Storage and Transportation

- Store at room temperature if the sample is dispatched to the laboratory within 6hrs.
- If there is a delay of more than 6 hours to reach the laboratory the blood sample should be centrifuged to separate plasma.

The separated plasma should be pipetted to a sterile container and refrigerate at 4°C.

The container should preferably be a screw capped cryo vial. Separated plasma should reach the laboratory within 5 days.

Transport the specimen in 2-8°C.

7.5 Collection of blood for PCR for EID

7.5.1 Sample collection

 Collect 3ml of venous blood under aseptic conditions into a K3EDTA tube.

Note: Fill the tube exactly up to the marked level of EDTA tube. Excess EDTA, as well as insufficient EDTA will cause coagulation problems in the sample which can affect the accuracy of results.

Mix the tube gently by inverting 10 times.

7.5.2 Storage and Transportation

- Store at room temperature if the sample is dispatched to the laboratory within 8hrs.
- If there is a delay of more than 8 hours to reach the laboratory the blood sample should be stored 2-8°C.
- The blood can be stored at this temperature up to 72 hours.

7.6 Collection of blood for CD4/CD8 Tests

7.6.1 Sample Collection

- Collect 3ml of venous blood in to EDTA tube.
- Mix the tube gently by inverting 10 times.

7.6.2 Storage and Transportation

- Transport the sample immediately to the lab in room temperature within 24 hours.
- **DO NOT** refrigerate the sample.

7.7 Collection of blood for HIV genotypic resistance testing

HIV genotypic resistance tests are done in National AIDS Research Institute, India which is a WHO collaboration center. National Reference Laboratory is coordinating the resistance testing. The samples are sent to India as dried blood spots. As if the viral load is very low the viral amplification for testing is difficult, a recently done (within 2 months) viral load result is essential to decide sending samples for HIV genotypic resistance testing.

7.7.1 Sample Collection

- Collect 3ml of venous blood in to K3EDTA tube.
- Mix the tube gently by inverting 10 times.

7.7.2 Storage and Transportation

- Transport the sample immediately to the lab within the same day of collection.
- Send the samples in 2-8°C.

7.8 Collection of sputum for TB culture

- Sputum is collected to universal bottles issued by the National Reference Laboratory.
- > Samples should be collected in cough area.
- > Samples should be collected up to the mark on the bottle.
- > Transport the sample immediately to the lab in 2-8°C.

8. Collection and Transport of Specimens for diagnosis of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*

- 8.1 Specimen Collection for Suspected Gonococcal Infection
- 8.1.1 Sites and Swabs for Gonococcal Culture and Microscopy

Appropriate sites for specimen collection depend on the sex, age and sexual practices of the individual as well as the clinical manifestations of the infection.

Females

- ➤ Endo-cervical canal is the primary collection site. The secondary sites include the urethra, rectum and oropharynx.
- Vaginal discharge and vulval swabs are used in pre-pubertal girls.
- Urethral swab is preferred than the high vaginal swab in women who have had hysterectomy.

Males

- > Primary collection site is urethra in heterosexual men.
- Urethra, rectum and oropharynx are the primary sites in Men having sex with men (MSM)
- o Sterile cotton swabs should be used to collect the specimen.
- o When collecting specimens for PCR use the specimen collection kit provided by the lab.
- o For culture and microscopy use two swabs (one for each)

8.1.2 Collection of Specimens

Collection of Endocervical swabs

- The collection of the specimen should be done by a Medical Officer
- Avoid using antiseptics, analgesics and lubricants before collecting the specimen.
- Use a vaginal speculum, moistened with saline to visualize the cervix.
- After inserting the speculum, clean the ecto-cervix with a cotton swab and discard it.
- After cleaning, insert a sterile cotton swab about 2cm into the cervical canal.
- Rotate the swab gently from side to side for 5-10 seconds to allow absorption of the exudate.
- Take out the swab without touching the sides of the vagina.
- ➤ Either place the swab in transport media / inoculate the culture plates for GC.
- Take another swab for Gonococcal microscopy.

Collection of Urethral specimens

- If discharge is evident collect it directly on to a swab/ container.
- If not, milk the urethra to evacuate exudate.
- ➤ Still if no discharge is evident, collect urethral specimens,4 hours after the patient has passed urine, by inserting a thin swab 2-3 cm in to the urethra and gently rotate the swab for 5-10 seconds to allow absorption of the exudates.
- Collect two swabs, one each for culture and microscopy
- For culture, inoculate the plates/ place the swab in the transport media.

Collection of swabs from Rectum

- Symptomatic patients Rectal specimens should be obtained under direct vision following insertion of a proctoscope.
- Asymptomatic patients Samples may be obtained by blindly inserting a cotton swab 3cm into the anal canal and rotate it for 10 seconds to collect exudates from the crypts just inside the anal ring. Use lateral pressure to avoid fecal contamination.
- If fecal contamination occurs, discard the swab and use another to obtain the specimen.

Collection of swabs from vagina

Vaginal specimens are recommended for prepubertal girls and women who have had a hysterectomy.

- Vaginal discharge of prepubertal girls should be collected with a swab without using a speculum.
- In women who have under gone hysterectomy, use a speculum and swab the posterior fornix for a few seconds and then take out the swab without touching the vaginal walls.

Note: For women who have had a hysterectomy – urethral swab for culture offers a better yield than high vaginal swab

Collection of swabs from Throat

- Instruct the patient to open the mouth widely.
- > Visualize the throat with a good light
- ➤ Using a sterile cotton swab collect the sample from the region of the tonsillar crypts and the posterior pharynx.

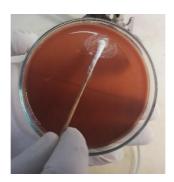
8.1.3 Inoculating the Culture plates for Gonococcal culture

- Label the culture plate with patient identification details.
- ➤ Inoculate directly on the Gonococcal culture medium, in the examination room itself to ensure highest yield of gonococci isolate. (bedside inoculation)
- Roll the swab on agar on a small area of the plate to make a "well". When rolling the swab, care should be taken not to dig into the medium.

Figure 3: Labelling of Gonococcal culture plate



Figure 4: Roll the swab on the plate to make a well



8.1.4 Storage and Transportation

- Inoculated plates should be sent to the laboratory immediately in room temperature for further streaking and incubation.
- ➤ If culture facilities are not available, the swabs should be inserted into a transport medium (Amie's) and transported at room temperature, to reach the laboratory within 24-48 hours.
- **DO NOT** store the specimens/plates in refrigerator.

8.2 Collection of Specimens for PCR in diagnosing *Neisseria* gonorrhoeae and *Chlamydia trachomatis*

8.2.1 Collection of Cervical specimens for PCR

- Label the collecting tube prior to sample collection.
- Use the specimen collection kit and transport medium given by the lab.
- Avoid using antiseptics, analgesics and lubricants before collecting the specimen.
- Collect the swab as described in 8.1.2
- Unscrew and remove the cap from collecting tube making sure not to spill the medium.
- Insert the swab into the tube up to the marked level (be careful not to touch the swab with any surface prior to place in the collection tube).
- Break the swab shaft at the indicated height and discard the top portion of the shaft and insert the bottom portion into the collection tube and seal the tube.
- Once the specimen tube is sealed, mix the specimen to ensure the collected specimen has been thoroughly exposed to the transport media which contains nucleic acid stabilizing agents.

8.2.2 Collection of urine

➤ Collect the urine from the initial part of urination (first pass urine after holding urine for 2-4hrs) to a sterile screw cap container.

8.2.3 Storage and Transportation

- ➤ Cervical swabs/urine in GC/CT transport medium for real time PCR should be transported to the laboratory at ≤4°C within 24 hours of collection.
- ➤ If transport is delayed >24 hours, the transport media containing the specimen should be stored at -70°C until dispatch.

9. Collection of Specimens for PCR for Diagnosis of HSV Infection

The specimen can be collected from vesicular/pustular/crusted lesions to a sterile swab obtained from the lab.

9.1 Collection of swabs from Vesicular or pustular lesions

- 1. Unroof the vesicle with an 18G needle.
- 2. Using the swab, abrade the base of the lesion in order to obtain a good sample of cells.
- 3. Immediately place the swab in viral transport media provided by the laboratory.

9.2 Collection of swabs from Crusted lesions

- 1. Remove the crust.
- 2. Scrape the base of the lesion with a sterile normal saline moistened swab. Avoid making the lesions bleed.
- 3. Immediately place the swab in viral transport media.

9.3 Storage and Transportation

- The specimens should be stored in refrigerator until transported to the laboratory.
- Transport at 4°C within 72 hours and if delivery to the lab is delayed >72 hours, maintain the specimen in dry ice or at -70°C. (Freezer temperature of -20°C will not preserve the virus.

10. Transport of Specimens

10.1 General Instructions

Transport of specimens should always ensure the safety of all individuals handling the specimen and should meet the specific criteria involved in receiving a good sample to perform the test. Therefore, packaging and transportation of specimens should be done appropriately to obtain accurate results.

10.2 Packing of specimens

For Blood and Blood products the International standard of packing identified is the "Three-layer packing".

The three layers involve

- 1. Primary receptacle
- 2. Secondary receptacle
- 3. Outer package

Primary receptacle

- This is a watertight, leak-proof receptacle which is labelled and contains the specimen.
- ➤ The receptacle is sufficiently wrapped in absorbent material to absorb all fluid at instances of breakage.

Secondary receptacle

- The primary receptacle(s) should be placed in a second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s).
- Several wrapped primary receptacles may be placed in one secondary receptacle.
- Sufficient absorbent material must be used to cushion multiple primary receptacles in the secondary container.

Specimen data forms, letters and other types of information that identify or describe the specimen and also identify the sender and receiver should be taped to the outside of the secondary receptacle, preferably in a zip pouch. Ice or dry ice required to maintain temperature should be placed in the secondary receptacle.

Outer package

- ➤ The secondary receptacle should be placed in an outer package which protects contents from outside influences such as physical damage and water while in transport. This is usually made of corrugated cardboard.
- This container must bear the mailing label which identifies the shipper and receiver along with biohazard sign.
- Ziploc plastic bags may also be used as leak-proof containers if suitable boxes are not available. Packed specimens should be sent to the referral laboratory for testing.

Absorbant packing material (Sufficient absorbant material must be placed between the primary and secondary receptacles)

Figure 5: Three-layer packing for transport of Specimens

- 1. Primary receptacle (leakproof, 95kPa)
- 2. Secondary receptacle (leakproof)
- 3. Outer container (w/list of itemized contents)

Figure 6: Biohazard Sign



Figure 7: Cool box in use in NRL-NSACP to transport specimens



11. Sample Reception

All the samples are collected at sample reception counter of NRL. A medical laboratory technologist (MLT) and a lab orderly are available at all times in the sample reception counter.

11.1 Sample reception procedure

- The specimen should correctly be paired with the appropriate request form.
- Check following information on the label.
 - a. Patient number
 - b. Hospital/clinic/institution
 - c. Type of test
 - d. Date and time of collection
- Specimen is registered in the sample reception register.
- Urgent samples should immediately be sent to the relevant section.

Note:

- For HIV screening test, blood sample should come with Health 406 or Health 350 request forms. Incomplete request forms should be brought to the notice of the Medical officers of the laboratory immediately.
- HIV confirmation test samples should come with HIV confirmatory request form. For incomplete request forms instructions should be given to send a complete request form.
- For Private medicals Take documents (Passport size photo and copy of passport) from the person and give specific number(H) and maintain a H Number register.

11.2 Sample rejection

Any specimen not meeting the required conditions are rejected as per policy.

The requests of rejected specimen are be given to medical staff without a delay. The medical officers inform the originating location/collector of the need to re-collect or re-order, if a specimen is rejected. All the rejected samples are entered in a special register.

Reasons for potential specimen rejection may include the following:

- Samples without labels/ Inadequately written labels
- Samples without accompanying request forms
- Incomplete request forms Request forms are incomplete without the following information.
 - BHT number/Clinic number for patient identity
 - Ward /Clinic
 - Type of the sample (Eg: blood, CSF, urine)
 - Tests requested
 - Date &Time of sample collection
 - Short, relevant clinical history of the patient
 - Any relevant detail which specifically requested in request form
- If the details on the label of the sample and the request form are not identical.
- Specimens showing gross evidence of decomposition
- Inadequate/over collected volume of the specimen for the tests requested.
- Samples in inappropriate containers/ wrong container type.
- Specimens which were not transported properly and were not stored properly.
 - Eg. Specimens for N. gonorrhoeae

If collected into transport medium and kept for more than 48 hrs.

If collected in to transport medium and refrigerated.

If discharge is sent on dry swab without transport medium

- Clotted/partially clotted specimens Eg: FBC, ESR, fasting plasma glucose
- Specimens that have leaked or have specimen material on the outside of the container
- Delay in receipt of sample as specified against test (Eg: Sample for CD4 testing should reach the NRL before 12 noon on Friday)
- Duplicate samples
- Visible contamination of sample
- Delayed transport time

Eg: CD4 samples sent at Room temperature after 24 hours of collection

Viral Load samples sent at Room temperature after 6 hours of collection

HSV PCR samples sent at Room temperature after four hours of collection

Chlamydia PCR- urine sent at room delayed more than 24 hours of collection

 Improper Transportation
 Specific testing methodology may require specific handling, such as keeping warm or on ice, during transportation.

12. Reporting of results

Specimens are processed upon receipt. Reporting times vary depending on the nature of the test and the analytical time required for the procedure.

Table 5: Turnaround time

Turna	round time f	or laboratory	testing at N	RL
		Turnaro	und time	
Test	Clinic	NSACP	Out S	tation
	Urgent	Routine	Urgent	Routine
	Requests	Requests	Requests	Requests
VDRL	2 hrs	2-3 days	1 day	4 days
TPPA	1 day	3 days	1 day	5 days
Syphilis IgM	1 day	7 days	1 day	7 days
ELISA-HIV	0-1 days	2-3 days	-	4 days
Western Blot	-	1 week	-	1 week
CD4	0-1 days	1-2 days	-	1-2 days
Viral RNA	-	Once a	-	Once a
		week		week
Hepatitis B	1 day	Once a	1 day	Once a
Surface		week		week
Antigen				
Hepatitis C		Once a		Once a
Antibodies		week		week
GC Culture	NA	3 days	NA	-
Chlamydia	-	-		14 days
PCR				
HSV serology	-	14 days		
HSV PCR	-			
Biochemistry	-	1 day		
Haematology	2 hrs	1 day		

Annexures

Annexures

Annexure 1

H 049265 – 300,000 (2017/03) වූ ලංකා රජයේ මුදුණ දෙපාර්තමේක්තුව H 407

ලිංගික රෝග / ඒඩ්ස් මර්දන වනපාරය STD / AIDS CONTROL PROGRAMME

REQUEST	FOR SPI	ECIAL T	ESTS	
From : M. O				
Signature:			Date	·
To : Bacteriologist				
Particulars of Patient : - Identity :				
Examination	on requested :			
	Results			
Short Clinical History, Probable Diagnosis Results of Relevant tests with	VDRL	FTA	TPHA	HIV ANTIBODY
Diagnosis Results of Relevant tests with dates			<u>1</u> <u>1</u> <u>160</u>	
	COMMENTS	: FOR LAB	ORATORY USE	ONLY

Date	Time of Re	ceipt	Ba	cteriologist Date
M. L. T. :				
				(Perforated Tear)

Annexure 2 Medical 408

A රෝග ති REQUEST FOR	රෝග මර්ධන වනපාරය NTI-V. D. CAMPAIGN ධාන පරීක්පණ අයදුම් පත t PATHOLOGICAL EXAMINATIONS	(2 R 10 Yellow S.& E.) 5/64
emmon Budercylotch නිධාන විශේ To : Bacteriologist / Pathologist වගත/Age : පිරිමි/ගැහැණු/Male/Female : නිදර්ශකය/Specimen :	oddhased අතය :] Patient's No. :] පුතිරල/Results : .	
queල්පය — Smear — මුලු මාර්ගයෙන්] Urethra	eangust අන්තරිගත පේසිව වශයෙන් ඉැම් සුම්පට රකු පැහැය ඇති සොගනුසයන් Intra-Cellular Gram- Negative Diplococci	
 @Cω Cervix • ωαθέω Vagina	මහෙලයන් පිරිත ජෝවු වශයෙන් ඉැම් ඉතිහට රතු පැතැය ඇති කොහඳාපයන් Extra-Cellular Gram- Negative Diplococci	
අතිකුත් ස්ථානවලින් Other	සැරට සෙසලයන් Pus Cells අතිකුත් තීවයන් Other Organisms	
Sp Urine	අපිච්ඡාද හෙසලයන් Epithelial Cells පුණිලියාව Reaction	
	ඇත්මළුම්න් Albumin සිනි Sugar	
ඩාර්ක් ඉටුන්ව පරික්ෂණ <i>යා</i> — Dark Ground Examination—	තිට් Deposits වුපොතිමා පැමරම් Treponema pallidum වුරිකොණේණයේ වැරිපේලිස්	
ලනුදු කටහන්/Notes	Trichomonas vaginalis සැලකිය යුතු කරුණ/Remarks	
కంకర్గం కోల్చమరిద్వారు Medical Officer. శేరున[Date	ගතුවලේ විශේෂදෝශ්රික සිධ Bacteriologis/Patho දිනය[Date	

Annexure 3

NRL/RQ/10/HSV

National STD/HIV Reference Laboratory No.29, De Saram Place, Colombo 10, Sri Lanka

Tel: 0112 667163, Tel/Fax: 0112 5336873

REQUEST FOR		
HERPES SIMPLEX VIRU		Lab No:
Patient's File No:		Date of collection:
Age:	••	Time of collection:
Sex:		Time of collection.
Examination Requested:		
	T- 1	\neg
	Ig	
	HSV 1 IgG	
	HSV 2 IgG	
	HSV 1 IgM	
	HSV 2 IgM	_
		<u></u>
Brief Clinical History		
Brief Chinical History		
Results of relevant previous	test(s)	
Requesting Doctor		
Name		
Designation		
Signature		
(For Laboratory use only)		
<u>H</u>	ERPES SYMPLEX VIRUS ANT	IBODY TEST
	RESULTS	
HSV 1 Ab. IgG	HSV 2 Ab. IgG	HSV 1 & 2 IgM
Comments:		
Medical Laboratory Techno	logist Consult	tant Microbiologist
Date:	-	
	Dute	

NRL/RQ/8/HIV/VL

National STD/HIV Reference Laboratory No.29, De Saram Place, Colombo 10, Sri Lanka Tel: 0112 667163, Tel/Fax: 0112 5336873

REOUEST FOR HIV VIRAL LOAD ASSAY

- -	<u> </u>		-
Patient Information		Lab I	No:
Patient's File No:		Date	of collection:
Ward / Clinic / Hospital:		Time	of collection:
Sex:			
JCA:			
Brief Clinical History		Indication for Viral	Load Testing
Previous test Results			
Date	CD4	CD8	Viral Load
Any other relevant inf	ormation:		
Requesting Doctor		Consultant in Charge	
Name		Name	
Designation			
Date		Signature	
Signature			

Annexure 5

National STD/HIV Reference Laboratory No.29, De Saram Place, Colombo 10, Sri Lanka

Tel: 0112 667163, Tel/Fax: 0112 5336873

REQUEST FOR ENUMERATION of CD4/CD8 T – LYMPHOCYTES

pital:		D	ate of collection:	
cory		Indication for	Viral Load Testin	g.
Previous Te	est Re	esults	Brief Histo	ory of ART
CD4		CD8		
nt information:				
		Consultant in Cha	rge	
		Signature		
	Previous Te CD4 nt information:	Previous Test Re CD4 nt information:	Previous Test Results CD4 CD8 nt information: Consultant in Cha Name	Previous Test Results CD4 CD8 Consultant in Charge Name Signature Date of collection: Time of collection: Signature

Annexure 6 Health 406

From : M		equest for E				75/9 L	
Signature	e:		********	Date	:		
Number	VDRL Result	Number	VDRL Result	Number	VDRL Result	Number	VDRL. Result
A							
			V 000 000 000 000 000		52/114/A017/01/		
						1	
Date M.L.T.:		Time	of Receipt		Bacteriologi	st	Date

Annexure 7 Health 350

ම ලංකා ප්රශේ මුදුණ දෙයන්නමෙන්තුව කොට්ටා දෙපාර්තමේන්තුව (F68. & B.) 1/M DEPARTMENT OF HEALTH SERVICES ඉල්ලම් පළාත්/BERQUEST FORM
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(වනාධිවේදඥයන් පුළාගර්ජනය සඳහා / For sthutegist's use)

Annexure 8

Page 1

Date of Portion of Popular Interesting HIV Confirmatory test from the reference laboratory of the National STD/AIDS Control Programme, No. 29, De Saram Place, Colombo 10, Sri Lanka. Patient should be informed that all questions contained in this questionnaire are strictly confidential and will become part of their medical record) PART II — TESTING DETAILS AND DEMOGRAPHIC INFORMATION PATIENT/CLIENT IDENTIFICATION IS TO Clinic Registration Number (For STD Clinic Clients) IS TO Clinic patient REST DETAILS AND DEMOGRAPHIC INFORMATION PATIENT/CLIENT IS TO Clinic Registration Number (For STD Clinic Clients) IS TO Clinic patient REST DETAILS IN DEPARTMENT OF STD Clinic Clients (For STD Clinic Clients) IS TO Clinic Patient (For STD Clinic Clients) IS TO Clinic Registration Number (For STD Clinic Code Sequential No Year Clinic Code Sequent	imple Number in-STD Clinic Clients - Private Lab, TB clinic, Hos r) e of Screening Test:	pital ID
PART II - TESTING DETAILS AND DEMOGRAPHIC INFORMATION PATIENT/CLIENT IA. STD Clinic Registration Number (For STD Clinic Clients) If STD clinic patient Rill A, otherwise fill 2. Type of Screening Test a. ELISA Test b. Particle Agglutination Test c. Rapid Diagnostic Test d. Other 4. Has patient/Client ever been tested for HIV previously HISTORY 5. Name and address of Patient/Client Name 6. Gen	ample Number an-STD Clinic Clients - Private Lab, TB clinic, Hos a) a of Screening Test: y Month Year	
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Continue	e of Screening Test:	
Gender Sequential No Year Clinic Code	y Month Year	vn
HIV SCREENING TEST DETAILS a. ELISA Test b. Particle Agglutination Test c. Rapid Diagnostic Test d. Other 4. Has patient/client ever been tested for HIV previously HISTORY a. If Yes (date of last negative test) Day Month Year 5. Name and address of Patient/Client Name 6. Gen	y Month Year	vn
HIV SCREENING TEST DETAILS b. Particle Agglutination Test c. Rapid Diagnostic Test d. Other 4. Has patient/client ever been tested for HIV previously HISTORY a. If Yes (date of last negative test) Day Month Year 5. Name and address of Patient/Client Name 6. Gen		VR.
TEST DETAILS D. Particle Agglutnation Test c. Rapid Diagnostic Test d. Other 4. Has patient/client ever been tested for HIV previously HISTORY 4. Has patient/client ever been tested for HIV previously Day Month Year 5. Name and address of Patient/Client Name : 6. Gen		vn
d. Other	□ □ b. No □ c. Not Know	vn
4. Has patient/client ever been tested for HIV previously IIV TESTING a. If Yes (date of last negative test) Day Month Year 5. Name and address of Patient/Client Name : 6. Gen	□ □ b. No	vn
AIV TESTING a. If Yes (date of last negative test) Day Month Year 5. Name and address of Patient/Client 6. Gen	□ b. No ☑ c. Not Know	VΠ
Name : 6. Gen		
Address : Oth	DF COACO	
DEMOGRAPHIC INFORMATION 8. Marital status	ied/Living Together	Divorced .
9. Occupation 🔲 a. Unemployed 🗎 b. Student 🗎 c	:. Employed as:	d. NA
10. District of Residence: 11 Nat	tionality 🖸 a. Sri Lanka 🔲 b. Other (sp	ecify)
12. Ethnicity	er (specify) e. Not Sri Lank	an
13. Reason for HIV Testing (More than one option possible)	1	
a. Voluntary Testing e. Partner/spouse or family member diagnosed	isa Screening Screening of a Survey	g as part
□ b. Provider Initiated Testing asymptomatic) □ f. STD Screening □ j. For Streening	oreign Job Screening	
☐ c. Clinical symptoms suggestive ☐ g. Blood Donor Screening ☐ k. S purpos	screening for Legal/Insurance	
	creening before	pecify):

Page 2

PART III:INFORMATION ON EXPOSURE TO HIV	16. Ever sold sex to client
15. Sexual Exposure (Multiple Responses Possible	7 1
a. Sexual Contact with Regular Partner of Opposite Sex	a. Yes
☐ b. Sexual Contact with Non-Regular Partner of Opposite Sex	□ b. No
☐ c. Sexual Contact with Person of Same Sex	
d. Sexual Contact with Both Sexes	
e. No Sexual Contact	
17. Ever bought sex from sex worker	18. Ever gone abroad?
a. Yes	a. Yes, countries:
n. No	☐ b. No
19. History of Blood Exposure ☐ a. No	20. Ever had sex with a foreigner? (In Sri Lanka or abroad)
☐ b. Injecting Drug Use	☐ a. Yes
☐ c. Receipt of Blood/Tissue/Organ/Sperm Specify year:	
	□ b. No
d. Needle stick injury/mucosal splash Specify year:	c. Not Applicable (Foreign Nationality)
21. Acquired from mother to child transmission	
Ej a. No	
□ b. Yes	
□ c. Not Known	
INFORMATION ABOUT SPOUSE/LIVE-IN PARTNER EXPOSURE	TO HIV
22. HIV status of spouse	23. Has spouse ever gone abroad?
a. Positive	a. Yes, countries
☐ b. Negative	□ b. No
☐ c. Not Known	C. Not Known
☐ d. Not Applicable	
	d. Not Applicable
24. Risk factors for HIV spouse	
a. None b. MSM c. Sex Worker (now or former) d. Mu	Iltiple Sex Partners
a. Injecting drug user (now or former) f. Not Known g. Not Appli	cable
DETAILS OF THE REFEREING DOCTOR/HEALTHCARE WORKER	
A. Name :	D. Institution
B. Signature :	E. Telephone No. :
C. Designation :	F. Date :

MLT:

Date:

National STD/HIV Reference Laboratory No.29, De Saram Place, Colombo 10, Sri Lanka Tel: 0112 667163, Tel/Fax: 0112 5336873

REQUEST FOR SYPHILIS / HIV TESTING IN ANTENATAL MOTHERS Institution / Clinic **MOH Area Date of Sample Collection** Patient No (ANC) Age Parity POA **HIV Results VDRL Results** Name of Collecting Officer Designation Signature Name of Medical Officer Designation Signature REPORT (Laboratory use only) Date/Time of Receipt of Samples :.....am/pm

Consultant Microbiologist:

Date:

National STD/HIV Reference Laboratory No.29, De Saram Place, Colombo 10, Sri Lanka Tel: 0112 667163, Tel/Fax: 0112 5336873

REQUEST FOR ANTI-RETROVIRAL DRUG RESISTANCE TESTING

The result of a viral load test done within $\bf 2$ months should be available to accept the specimens. If not sample will be rejected.

Patient Information	
Patient's File No:	Lab No: Date of collection: Time of collection:
Brief Clinical History	History of ART
Indication for Testing	
Previous Test Results of Viral Load Testing	
Date	Viral Load
Any other relevant information:	
Requesting Poster	Consultant in Charge
Requesting Doctor Name	Consultant in Charge Name
Designation	Signature

Annexure 11

Page 1

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Annexure 12

Page 1

National P	rogramme (oi Tubero	ulesis Cont	rol and	Chest Disc	eases				TB	76
	1			USCEPT	REQUEST FORM SCEPTIBILITY AND MOLECULAR TESTING Reference Laboratory, Welisara						
Sr	pecimen		Date of Coll	ection	7	Lab Use 0	Only	Serial	No		1
Sputum	Other (Speci	fy) dd	mm	Yy		Dat dd	e of Red	and the second second	Cultur	ab No.	-51
Last Name o	f the Patient	(In Black L	ettersl	1]
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First Name/	initials of the	Patient (In	Block Lette	ers)	-		L				
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If Previously Treated	First Relapse	>1 Re	lapse	Rx A	fter	Rx Afte Loss to Follow		Other (Specif			
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Past ATT (Indicate pe	riods of treat	ment)		Cat II/Cat							
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Positive	Ne	gative						Yes		No	

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Other Relevant Cl	inical Details	(e.g. HIV	/ Other Cau	ises of Imir	une Suppres	sion/X R	ay/Mant	ouxj			
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Please Refer to Lis	its Given to Dis	trict Ches	st Clinic for th	e Following							
indications for	Culture - List 1										
	Xpert MTB/RI	F - List 2									
Procumption 5	ADD Groups -I										
Presumptive A	ADR Groups -L	E 981									
Presumptive N	ADR Groups -L	ist 3		AND DESCRIPTION OF THE PERSON						-	
Presumptive A	ADR Groups -L	ist 3		Laborat	ory Use Only					-	
Presumptive N	ADR Groups -L		en della dictation di la constanti	Laborat	ory Use Only					-	
Presumptive N	ADR Groups -L			Laborat	ory Use Only						
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Presumptive N	Positive 3+		2+	Pos	sitive 1+	Posit scan	nty	Negativ	e		
Presumptive A Lab Serial No: Smear Culture	Positive 3+		2+ Negative	Po	sitive 1+	Posit scan	nty	Negativ	e		
Presumptive A	Positive 3+		2+	Po	sitive 1+ taminated	Posit scan	nty	Negativ	e		
Lab Serial No: Smear Culture	Positive 3+ Positive MTB		2+ Negative	Po	sitive 1+ taminated	Posit scan	nty	Negativ	e		
Lab Serial No: Smear Culture Identification Results of Sensit	Positive 3+ Positive MTB		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other	Negativ			
A Presumptive A Lab Serial No: Sinear Culture Identification Results of Sensit Result	Positive 3+ Positive MTB		2+ Negative	Po	sitive 1+ taminated	Posit scan	Other			l de la constant de l	
Presumptive A Lab Serial No: Smear Culture Identification Results of Sensit Result Sensitive	Positive 3+ Positive MTB		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other			31	
A Presumptive A Lab Serial No: Sinear Culture Identification Results of Sensit Result	Positive 3+ Positive MTB		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other			21	
Presumptive A Lab Serial No: Smear Culture Identification Results of Sensit Result Sensitive	Positive 3+ Positive MTB		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other				
Presumptive A Lab Serial No: Smear Culture Identification Results of Sensit Result Sensitive	Positive 3+ Positive Strepto		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other	Ethai	nbuto		
Lab Serial No: Smear Culture Identification Results of Sensit Results of Result Sensitive Resistant	Positive 3+ Positive Strepto		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other		nbuto		
Presumptive A Lab Serial No: Smear Culture Identification Results of Sensit Result Sensitive Resistant MLT/NTRL	Positive 3+ Positive Strepto		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other	Ethai	nbuto		
Lab Serial No: Sinear Culture Identification Results of Sensit Result Sensitive Resistant	Positive 3+ Positive Strepto		2+ Negative	Con	sitive 1+ taminated	Posit scan	Other licin	Ethai	nbuto		

To be filled by blood drawing officer

National STD/HIV Reference Laboratory No.29, De Saram Place, Colombo 10, Sri Lanka

Tel: 0112 667163, Fax: 0112 5336873

NRL/RQ/6/HIV/GX

Lab use only

Request for Early Infant Diagnosis

Da	te of Sam	ple Colle	ction:		Sam	ple Re	te:				
Time of Sample Collection: Sample Received Time:											,
ati	ent Inforn	nation:									
nfaı	nt File Nu	mber :			. Date o	of birth	:	Se	x:		
Иot	hers File N	Number :									
Var	d/Clinic	:									
los	oital/Instit	tution	:								
	At 4 – 6										
Mother's Previous Test Results in Patient's Previous Test Results in											ts in
_		1	gical Orde					Chronolog	ical Ord	er	
	Date	CD4	CD8	Viral load (RNA	1	Date		CD4 %	HIV DN		Viral load
				copies/m	nl)				PCR Tes Results		(RNA copies/ml)
					•				resures		copics/iiii/
Δ	t Delivery					At Del	ivery				
	Current F	eeding P	ractice:								
						_			_		
	Formu	ıla feedii	ng E	Breast fe	eeding	Mix feeding					
Α	ny other r	elevant in	formation	:							
R	Requesting Doctor Consultant in charge of patient										
	lame:	-				Name	e:				
	esignatio					Signa	ture: -				
	Date:										
<u> </u>											