PRIMARY SAMPLE COLLECTION MANUAL AND CLINICIAN GUIDE

OF

DEPARTMENT OF MICROBIOLOGY

King George`s Medical University, Lucknow (Uttar Pradesh) 226003

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AMENDMENT SHEET

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GENERAL INFORMATION

LABORATORY WORKING HOURS

The working hours, for the various divisions and specimen acceptance timings are provided in the tables below.

S. No.	Working Days	Working Hours
01	Monday- Saturday	09:00 am- 04:00 pm
02	Sundays & Holidays	10:00am- 12:30 pm

SPECIMEN ACCEPTANCE TIMINGS

	Timing	
OPD patients	9.00 a.m. – 2 p.m	OPD counter
Indoor patients	9.00 a.m. – 2. p.m.	IPD counter
	2 p.m to 9.00 a.m on working days & Round the clock on holidays	Urgent specimen will be received in Emergency Laboratory at trauma centre

1.0 Purpose

This manual is designed to provide users of the clinical testing services of the Department of Microbiology, KGMU, with information on the proper collection and handling of primary samples destined for testing in the laboratory.

2.0 Scope: It is intended as a quick reference guide for users of the Department of Microbiology Services both from within the hospital, and those from the community.

3.0 Responsibility

The Laboratory Director (LD), Department of Microbiology decides on the scope of clinical services provided by the department. The final decisions on sample acceptance/rejection are with the laboratory director/designee.

4.0 Abbreviations

LD: lab Director

KGMU: King George's Medical University

HIV: Human Immunodeficiency Virus

TB: Tuberculosis

IPD: In door patient

OPD: Out Door patient

CSF: Cerebral Spinal Fluid

OT: Operation Theatre

5.0 Procedure

General instructions

1. Use standard precautions for collecting and handling all specimens. In case a needle stick injury is sustained while collecting samples, follow standard post-exposure prophylaxis guidelines.

2. All samples sent for testing must be accompanied by a requisition. A separate requisition must accompany each sample/test type

3. Avoid contamination with indigenous flora, while collecting samples. Clean collection site with disinfectant as per standard guidelines.

3. Collect all culture specimens prior to administration of any antimicrobial agents, where possible. If the patient is already on antibiotics, collect samples for culture just before the next dose.

5.1 Information on test requisition form

Requisition for all the tests should be made on e-hospital for digital TRF. For samples where registration on e- hospital cannot be done, manual registration should be done. In such cases samples must be accompanied by test requisitions, which must have the following information at a minimum

- Patient's full name
- Age & sex
- Ward/Bed/Unit
- Sample Type
- Date & time of collection
- Test (s) requested
- The name & signature of the requesting clinician

Desirable details include clinical diagnosis and other relevant information that may be required for interpretation of the laboratory findings.

5.2 Type & amount of Primary samples to be collected

Type of samples needed for various tests is as per table in Annexure 1.

For IPD patients, sample collection should be performed only by trained personnel. Instructions for patient self -collected samples must be given clearly. Sample information sheets for urine, stool and sputum are appended with this manual.

For OPD patients, instructions for self collection of samples like mid-stream urine, sputum and stool, will be provided to patients at the Microbiology OPD counter. Other samples will be collected by trained technicians in the OPD Laboratory section.

5.3 Labeling Samples

The following essential information **must** be documented in a legible manner on the samples sent for testing from the ward/ collected in the OPD

- Patient identifiers- Name, Age, Sex.
- Sample Type
- Date of collection
- Test(s) Requested

It is the responsibility of the person collecting and labeling the samples to match the identity of the patient as per requisition form.

Additional labeling will be made at the sample receiving counters.

5.4 Sample handling & transportation to the Department of Microbiology

Sample from the all Wards/OTs of the hospital must be transported as soon as possible and always within 4 hours of collection to the laboratory. In case unavoidable delays are anticipated, samples should be refrigerated, except for inoculated blood culture bottles and CSF samples, which must be placed an incubator at 37^0C or minimum at room temperature if incubator is not present.

Appropriate bio-safety measures must be implemented while transporting samples from the ward/OTs to the laboratory.

5.5 Sample Receiving:

All samples will be received at the respective microbiology counters as given above, during the timings mentioned. For sample receiving, barcodes are generated at e-hospital, which can be used for sample tracking.

When a sample is received, a reference id is provided to the patient and the patient is informed of the likely time of reporting. The reference id is useful for quickly retrieving reports.

5.6 Sample acceptance and rejection:

Correctly collected, labeled and transported samples will be accepted for testing.

If sample is too little and multiple tests are ordered, possible testing will be done and a request for further sample for remaining tests will be placed while receiving sample.

Sample Rejection Criteria:

General criteria for all samples

(Based on factors which could result in incorrect test results or breach of biosafety protocols)

1. Gross contamination of outer surface of sample
2. Leaking vials/sample containers
3. Incorrect or unclear labeling of sample/requisition i.e., sample identification not clear
4. Samples in incorrect vials (including syringes)/with incorrect anticoagulant for test
5. Incorrectly transported samples likely to result in sample deterioration – too much delay from time of collection, with no clear information on interim storage conditions

Additional criteria for rejection of serum samples

1. Grossly hemolysed samples
2. Excessively lipemic samples
3. Visibly contaminated samples
4. Clots in anticoagulated samples

Additional criteria for rejection of extra-pulmonary samples for CBNAAT

1. Pus samples in cotton swabs
2. Blood samples

Additional Information:

Further questions may be referred to the Microbiology laboratory or Microbiology resident on duty. For tests under government schemes/ programs additional information can be obtained from the respective laboratories. Unresolved queries/complaints/feedback may kindly be referred to faculty members of the department.

6.0 Appendices

Appendix 1: List of available laboratory examination

Appendix 2: HIV Laboratory

Appendix 3: TB Laboratory

Appendix 4: Bacteriology Laboratory

Appendix 5: Bacterial Serology Laboratory and SRC

Appendix 6: Mycology Laboratory

Appendix 7: Parasitology Laboratory

Appendix 8: Virology Laboratory

Appendix 9: Viral Hepatitis Laboratory

Appendix 10: Blood Specimen Collection Order of Draw

7.0 References:

International Standard ISO 15189: 2022 entitled "Medical Laboratories Particular Requirements for Quality and Competency" (current version).

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8.0 Validity Statement

This document is valid for two year from the date of commencement.

9.0 Documents & Records

NA

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Appendix-1

LIST OF AVAILABLE LABORATORY EXAMINATIONS

S.N	Test Name	Preferred Specimen	Specimen collection & Transport	Optimum sample
1	**BACTERIOLOGY**			
1a	**DIRECT MICROSCOPY**			
1.	CSF	CSF	Universal container	1-3 ml
2.	Urine wet mount	Urine	Universal container	3-5 ml
3.	Conjunctival Smear Examination	Conjunctival Smear	sterile swab	1 sterile swab
4.	Corneal scrapings Examination	Corneal scrapings	Sterile spatula, no. 15 blade, or needle	few scrapings from the **active edge of the lesion**
5.	Smear Examination for Diphtheria	Throat Swab	sterile swab in amies transport media	2 sterile swab
6.	Smear examination for Gonococcus	Urethral discharge/ Vaginal discharge Swab/ endocervical swab	sterile swab in amies transport media	1 sterile swab
7.	Smear examination for bacterial vaginosis	Vaginal Swab/ vaginal discharge	sterile swab	1 swab
8.	Wet mount for *Trichomonas vaginalis*	Urine/ vaginal discharge	Universal container/ swab	3-5 ml urine/ sterile swab
1c	**CULTURE & SENSITIVITY**			
1.	Blood Culture & Sensitivity (Automated Aerobic & Anaerobic) With ID (MALDI)/AST (VITEK MIC)-Bacteria	Blood	Inoculated automated blood culture bottles	2 sets; 5-10ml in Adult Blood culture bottles (Aerobic & Anaerobic) 1-5 ml in Paediatric blood culture bottle
2.	Conventional Blood Culture & Sensitivity (Aerobic Bacterial)	Blood	Inoculated conventional blood culture bottles	2 sets; 5-10ml in Adult Blood culture bottles 1-5 ml in Paediatric blood culture bottle
3.	CSF Culture & Sensitivity (Automated	CSF	universal sterile container	1-3 ml

	ID/AST) (Bacterial)			
4.	Conventional CSF Culture & Sensitivity (Aerobic Bacterial) ID and AST	CSF	universal sterile container	1-3 ml
5.	Pus Culture & Sensitivity (Automated ID/AST with MIC) (Bacterial)	Pus/ aspirate/ swab	universal sterile container/ sterile swab	1-5 ml/ sterile swab
6.	Pus Culture & Sensitivity (Aerobic Bacterial) Manual ID & AST	Pus/ aspirate/ swab	universal sterile container	1-5 ml
7.	Pus Culture & Sensitivity (Anaerobic- Bacterial)	Pus aspirate	In syringe	1-5 ml
8.	Urine Culture & Sensitivity (Automated ID/AST) (Bacterial)	Early Morning Urine	universal sterile container	3-5 ml
9.	Conventional Urine Culture & Sensitivity (Aerobic - Bacterial)- ID and AST	Early Morning Urine	universal sterile container	3-5 ml
10.	Sputum Culture & Sensitivity (Automated ID/AST) (Bacterial)	Sputum	universal sterile container	5ml
11.	Conventional Throat swab Culture & Sensitivity (Aerobic - Bacterial)	Throat Swab	sterile swab	1sterile swab
12.	Throat swab Culture & Sensitivity (Automated ID/AST) (Bacterial)	Throat Swab	sterile swab	2 sterile swab
13.	BAL Culture & Sensitivity (Automated ID/AST) (Bacterial))	BAL	universal sterile container	1-5 ml
14.	Conventional BAL Culture & Sensitivity (Aerobic - Bacterial)	BAL	universal sterile container	1-5 ml
15.	Conventional Stool Culture & Sensitivity (Aerobic - Bacterial) ID and AST	Stool	universal sterile container	5 grams or 5 mL (for liquid stool)
16.	Stool Culture & Sensitivity (Automated	Stool	universal sterile container	5 grams or 5 mL (for liquid stool)

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	ID/AST) (Bacterial			
17.	Conventional Vaginal Swab Culture & Sensitivity(ID/AST)	Vaginal Swab	sterile swab	1 sterile swab
18.	Vaginal Swab Culture & Sensitivity(Automated ID/AST) (Bacterial)	Vaginal Swab	sterile swab	1 sterile swab
19.	Trichomonas vaginalis Culture	Urine/ vaginal discharge	Universal container/ swab	3-5 ml urine/ sterile swab
20.	Gonococcus Bacterial Culture & Sensitivity	Urethral discharge/Vaginal discharge Swab	sterile swab	1 sterile swab
21.	Body fluids Culture & Sensitivity(Automated ID/AST) (Bacterial)	Body Fluid	universal sterile container	1-5 ml
22.	Conventional CVP line Culture & Sensitivity (Aerobic ID/AST) (Bacterial)	CVP	tip of venous catheter in universal sterile container	5 cm of length
23.	CVP line Culture & Sensitivity (Automated ID/AST) (Bacterial)	CVP	tip of venous catheter in universal sterile container	5 cm of length
24.	Conventional Tissue Culture & Sensitivity (ID/AST) (Bacterial)	Tissue	universal sterile container	visible tissue
25.	Tissue Culture & Sensitivity (Automated ID/AST) (Bacterial)	Tissue	universal sterile container	visible tissue
1d	**BACTERIAL SEROLOGY**			
1.	Widal Test	Serum	plain vials	1-2 ml
2.	RPR (Rapid Plasma Reagin) Test	Serum	plain vials	1-2 ml
3.	V.D.R.L. Test	Serum	plain vials	1-2 ml
4.	TPHA	Serum	plain vials	1-2 ml
5.	Anti Brucella IgM antibodies	Serum	plain vials	1-2 ml
6.	Anti Brucella IgG antibodies	Serum	plain vials	1-2 ml

7.	Anti- Scrub typhus IgM by ELISA	Serum	plain vials	1-2 ml
8.	Pertussis IgG ELISA	Serum	plain vials	1-2 ml
9.	Anti Leptospira IgM by ELISA	Serum	plain vials	1-2 ml
10.	Clostridium difficile stool antigen (GDH & toxin A&B)	Stool	Universal container	5 gms or 5 ml (if liquid stool)
1e	**BACTERIAL IMMUNOLOGY & BIOMARKERS**			
1.	A.S.O. Titre	Serum	plain vials	1-2 ml
2.	C- Reactive Protein (Quantitative)	Serum	plain vials	1-2 ml
3.	C- Reactive Protein (Qualitative)	Serum	plain vials	1-2 ml
4.	Procalcitonin (Quantitative)	Serum	plain vials	1-2 ml
5.	Rheumatoid Factor (Latex Agglutination)	Serum	plain vials	1-2 ml
2	**PARASITOLOGY**			
2a	**MICROSCOPY**			
1.	Microscopy FOR OVA & CYST (Routine)	Stool	universal sterile container	5 grams or 5 mL (for liquid stool)
2.	Microscopy for opportunistic parasite	Stool/Others	universal sterile container	5 grams or 5 mL (for liquid stool)
3.	Microscopy for Malarial Parasite	Blood	EDTA vials	3 ml
4.	Microscopy for Microfilaria	Blood	EDTA vials	3 ml
2b	**PARASITIC SEROLOGY**			
1.	Rapid Malaria Test (HRP-2 based)	Blood/Serum	EDTA vials	1-2 ml
2.	Rapid Malaria Test (p-LDH based)	Blood/Serum	EDTA vials	1-2 ml
3.	Filaria antigen (Rapid)	Blood/Serum	plain vials	1-2 ml
4.	Echinococcus IgG ELISA	Blood/Serum	plain vials	1-2 ml
5.	Entamoeba histolytica antigen ELISA	Blood/Serum	plain vials	1-2 ml

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6.	Entamoeba histolytica IgM ELISA	Blood/Serum	plain vials	1-2 ml
7.	Entamoeba histolytica IgG ELISA	Blood/Serum	plain vials	1-2 ml
8.	Cysticercosis IgG ELISA	Blood/Serum	plain vials	1-2 ml
9.	Cryptosporidium stool antigen ELISA	Blood/Serum	plain vials	1-2 ml
10.	Leishmania antibody (Rapid)	Blood/Serum	plain vials	1-2 ml
11.	Stool Antigen for Giardia (ELISA)	Blood/Serum	plain vials	1-2 ml
12.	Toxoplasma IgM by ELISA	Blood/Serum	plain vials	1-2 ml
13.	Stool for occult blood	Stool	universal sterile container	5 grams or 5 mL (for liquid stool)
3	**MYCOLOGY**			
3a	**FUNGAL MICROSCOPY**			
1.	Smear for Fungal elements (KOH Mount)	Skin/Nail/Hair Scraping/ tissue/ Sputum/BAL/ ET aspirate/ grains	sterile petri plate/black paper/ Universal container	visible sample
2.	Microscopy for *Pneumocystis jiroveci*	Sputum/ Induced sputum	universal sterile container	2-5 ml
3.	Smear examination for Candida	Vaginal Swab/pus/throat swab	sterile swab	1 swab
3b	**FUNGAL CULTURE & SENSTIVITY**			
1. 3	Conventional Skin/Nail/Hair C/S and AFST	Skin/Nail Scraping	sterile petri plate/black paper	visible sample
2.	Skin/Nail/Hair C/S (Automated) With ID/AST (MIC) (Fungal)	Skin/Nail Scraping	sterile petri plate/black paper	visible sample
3.	Conventional Pus C/S	Pus aspirate/ swab	universal sterile container/ sterile swab	1-5 ml/ 1 sterile swab
4.	Pus C/S (Automated) With ID/AST (MIC)-Yeast (Fungal)	Pus aspirate/ swab	universal sterile container/ sterile swab	1-5 ml/ 1 sterile swab

5.	Conventional Sputum C/S	Sputum	universal sterile container	2-5 ml
6.	Sputum C/S (Automated) With ID/AST (MIC)-Yeast (Fungal)	Sputum	universal sterile container	2-5 ml
7.	Throat swab (Automated) With ID/AST (MIC)-Yeast (Fungal)	Throat Swab	sterile swab	1 swab
8.	Conventional Throat swab (With ID/AFST (MIC)- (Fungal)	Throat Swab	sterile swab	1 swab
9.	BAL for Fungal C/S	BAL	universal sterile container	10-20 ml
10.	CSF C/S (Automated) With ID/AST (MIC)-Yeast (Fungal)	CSF	universal sterile container	1-3 ml
11.	Blood/ bone marrow Culture for molds/ dimorphic fungi (Manual)	Blood	biphasic blood culture bottle	1-4 ml pediatrics/ 8-10 ml adults
12.	Blood Culture (Automated) With ID/AST (MIC)-Yeast (Fungal)	Blood	bactec bottle	1-4 ml pediatrics/ 8-10 ml adults
13.	Conventional Body Fluids for fungal C/S	Pleural/Pericardial	universal sterile container	10-20 ml/1-5 ml
14.	Body fluids fungal C/S (Automated ID/AST)	Pleural/Pericardial	universal sterile container	10-20 ml/1-5 ml
15.	Urine fungal C/S (Automated ID)	Early Morning Urine	universal sterile container	10-15 ml
16.	Conventional Urine C/S-ID/AFST	Early Morning Urine	universal sterile container	10-15 ml
3c	**FUNGAL SEROLOGY**			
1.	Cryptococcal antigen	Blood/Serum/CSF	plain vials	1-5 ml
2.	Galactomannan ELISA	BAL/Serum	plain vials	1-5 ml
4	**TB LABORATORY**			
1.	AFB Microscopy (ZN Stain)	Any Sample other than Blood	universal sterile screw caped container	2-5 ml
2.	AFB Microscopy	Any Sample other	universal sterile	2-5 ml

	(Auramin O Stain)	than Blood	screw caped container	
3.	TB Culture – Solid media (Conventional)	Any Sample other than Blood	universal sterile screw caped container	2-5 ml
4.	TB Culture - Liquid media (Automated)	Any Sample	universal sterile screw caped container	2-5 ml
5.	TB Culture and DST-First line drugs (conventional method)	Any Sample	universal sterile screw caped container	2-5 ml
6.	TB Culture and DST-First line drugs (Liquid/Automated)	Any Sample	universal sterile screw caped container	2-5 ml
7.	AFB Culture and DST-Second line drugs (Liquid/Automated)	Any Sample	universal sterile screw caped container	2-5 ml
8.	Line Probe Assay (Identification and susceptibility testing)	AFB Positive Sputum Sample/ TB Culture Isolate	universal sterile screw caped container	2-5 ml
9.	Gene Xpert/ CBNAAT (Identification and susceptibility testing)	Any Sample other than Blood	universal sterile screw caped container	2-5 ml
10.	Drug susceptibility testing (Conventional from Solid culture media)	AFB culture	culture tube/ cryovial	--
11.	Drug susceptibility testing (Automated-Liquid)	AFB culture	Culture tube/ cryovial	--
12.	Smear For Lepra Bacilli	Slit skin smears & Nasal Swabs	sterile slide/ swab	visible sample/1 swab
5	**ICTC**			
1.	Anti-HIV antibodies	Blood/Serum	plain vials	3 ml
2.	CD4 counts	Blood/Serum	plain vials	3 ml
3.	HIV-1 Viral Load	Plasma	K2 EDTA Vials	6 ml
6	**VIROLOGY**			
6a	**VIRAL SEROLOGY**			
1	Anti- Cytomegalovirus IgM Antibodies (Anti-	Blood/Serum	plain vials	3 ml

	CMV IgM)(ELISA)			
2	Anti- Cytomegalovirus IgG Antibodies (Anti-CMV IgG)(ELISA)	Blood/Serum	plain vials	3 ml
3	Anti-Chikungunya Virus IgM Antibodies (Anti-ChikV IgM)(ELISA)	Blood/Serum	plain vials	3 ml
4	Anti-Herpes Simplex IgM Antibodies (Anti-HSV IgM)(ELISA)	Blood/Serum	plain vials	3 ml
5	Anti-Measles Virus IgM Antibodies (Anti-Measles IgM)(ELISA)	Blood/Serum	plain vials	3 ml
6	Anti-Measles Virus IgG Antibodies (Anti-Measles IgG)(ELISA)	Blood/Serum	plain vials	3 ml
7	Anti-Mumps Virus IgM Antibodies (Anti-Mumps IgM)(ELISA)	Blood/Serum	plain vials	3 ml
8	Anti-Varicella Zoster Virus IgM Antibodies (Anti-VZV IgM)(ELISA)	Blood/Serum	plain vials	3 ml
9	Anti-Human Parvovirus B19 IgM Antibodies (Anti- B19V IgM)(ELISA)	Blood/Serum	plain vials	3 ml
10	Anti- Dengue Virus IgM	Blood/Serum	plain vials	3 ml
11	Dengue Virus NS1Ag	Blood/Serum	plain vials	3 ml
12	Anti- Japanese Encephalitis Virus IgM	CSF	Universal sterile container	3 ml
13	Anti- West Nile Virus IgM Antibodies (Anti-WNV IgM)(ELISA)	Blood/Serum	plain vials	3 ml
14	Anti-Epstein Barr Virus IgM Antibodies (Anti-EBV IgM)(ELISA)	Blood/Serum	plain vials	3 ml
15	Anti-Rubella Virus IgM Antibodies (Anti Rubella IgM)(ELISA)	Blood/Serum	plain vials	3 ml
6b	**MOLECULAR BIOLOGY**			
1.	Real Time PCR For Influenza A Virus	Nasal /Throat Swab	VTM	3 ml

2.	Real Time PCR For Influenza A Virus (subtype H1N1)	Nasal /Throat Swab	VTM	3 ml
3.	Real Time PCR For Influenza A Virus (subtype H3N2)	Nasal /Throat Swab	VTM	3 ml
4.	Real Time PCR For Influenza B Virus	Nasal /Throat Swab	VTM	3 ml
5.	Real Time PCR For Respiratory Syncytial Virus	Nasal /Throat Swab	VTM	3 ml
6.	Real Time PCR For Parainfluenza Virus 1,2,3,4	Nasal /Throat Swab	VTM	3 ml
7.	Real Time PCR For Human Metapneumovirus	Nasal /Throat Swab	VTM	3 ml
8.	Real Time PCR For Herpes Simplex 1 Virus	Blood/Serum	plain vials	3 ml
9.	Real Time PCR For Herpes Simplex 2 Virus	Blood/Serum	plain vials	3 ml
10.	Real Time PCR For Varicella Zoster Virus	Blood/Serum	plain vials	3 ml
11.	Real Time PCR For Japanese Encephalitis Virus	Blood/Serum	plain vials	3 ml
12.	Real Time PCR For Dengue Virus	Blood/Serum	plain vials	3 ml
13.	Real Time PCR For Measles Virus	Blood/Serum	plain vials	3 ml
14.	Real Time PCR For Bocavirus	Blood/Serum	plain vials	3 ml
15.	Real Time PCR For Human Adenovirus	Blood/Serum	plain vials	3 ml
16.	Real Time PCR For Human Parvovirus B19	Blood/Serum	plain vials	3 ml
17.	Real Time PCR For Enterovirus	Blood/Serum	plain vials	3 ml
18.	Conventional PCR For Cytomegalovirus	Blood/Serum	plain vials	3 ml
19.	Real Time PCR for Scrub typhus	Blood/Serum	plain vials	3 ml

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7	**HEPATITIS**			
7a	**HEPATITIS SEROLOGY**			
1.	HBsAg ELISA	Blood/Serum	plain vials	3 ml
2.	HBeAg ELISA	Blood/Serum	plain vials	3 ml
3.	Anti- Hepatitis B Core Antigen IgM (Anti-HBc IgM) ELISA	Blood/Serum	plain vials	3 ml
4.	HBeAb ELISA	Blood/Serum	plain vials	3 ml
5.	Anti HBs Antibody ELISA	Blood/Serum	plain vials	3 ml
6.	Anti- Hepatitis A Virus IgM Antibodies (anti-HAV IgM) (ELISA)	Blood/Serum	plain vials	3 ml
7.	Anti- Hepatitis E Virus IgM Antibodies (anti-HEV IgM)(ELISA)	Blood/Serum	plain vials	3 ml
8.	Anti HCV Total antibodies by ELISA	Blood/Serum	plain vials	3 ml
7b	**MOLECULAR BIOLOGY**			
1. 1	Real Time PCR with Viral Load estimation For Hepatitis B Virus (Quantitative) Truenat	Blood/Serum	plain vials	3 ml
2. 2	Real Time PCR with Viral Load estimation For Hepatitis C Virus (Quantitative) Truenat	Blood/Serum	plain vials	3 ml

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Appendix-2

HIV LABORATORY

1. General Information:

- The HIV laboratory is supported and regulated by the National AIDS Control Organization (NACO), which operates under the Ministry of Health and Family Welfare, Government of India.
- The HIV laboratory offers various tests, including rapid HIV card tests, CD4 count tests, and HIV-1 viral load tests.
- The SRL laboratory is a referral laboratory for the HIV program.
- For HIV testing, blood or serum samples are collected from inpatients (wards/hospital), outpatients (OPD), or walk-in clients. To get tested, any individual can visit the counseling centre at OPD.
- For CD4 count and HIV-1 viral load testing, blood and plasma samples respectively are collected from people living with HIV (PLHIV) who are enrolled at the ART center.

2. Procedure of sample collection:

HIV Testing

1. Before HIV testing, counselors conduct pre-test HIV counseling, obtain informed consent from patients, and collect necessary information such as name, age, sex, Aadhaar number, address, and contact details. After providing a unique PID number, they direct patients to the sample collection counter for blood collection.
2. For samples sent directly for HIV testing from IPD patients, it is expected that the referring clinician has obtained informed consent.
3. The test requisition form is raised on e-hospital using patient UHID, admission no. etc. After registering test orders in e-hospital, a zero bill receipt is generated for HIV tests. A barcode is then printed in 4 copies with UHID, sample number and name of patient (one for sample bill receipt, two for PID card and one for sample vial).
4. For HIV testing, 3-5 ml of blood is collected via venipuncture into a red-capped sterile vacutainer.

5. The samples from the all Wards/OTs of the hospital must be transported in vacutainers/ sample transport vials and NOT IN SYRINGES.
6. Serum is separated by centrifugation of blood samples at 1500 rpm for 15-30 minutes.

CD4 testing

1. Before CD4 testing the ART counselor explains the test to the client.
2. Pre ART/ ART number with patient's name, age/sex, address, contact number etc are mentioned in "Green ART Card"
3. Blood is collected in sterile EDTA vacutainer. The EDTA tubes should be gently inverted 8-10 times to ensure proper mixing of whole blood and EDTA to prevent clotting.
4. All the blood samples are transported in EDTA vacutainer in cold chain along with requisition form to CD4 laboratory.

HIV-1 Viral Load Testing

1. All registered individuals on ART who are scheduled for VL testing are referred by the Medical Officer to the technician at the ARTC for sample collection, with triplicate carbon copies of the Test Requisition and Result Form (TRRF).
2. Unique VL test ID (17 digit) is generated by the laboratory technician at the ART centre at the time of blood collection.
3. For HIV-1 viral load testing, 6 ml blood is collected in a K2 EDTA evacuated tube. The EDTA tubes should be gently inverted 8-10 times to ensure proper mixing of whole blood and EDTA to prevent clotting.
4. All samples are transported to VL lab within 5 hrs. of collection and plasma is separated within 6 hrs. by centrifuging the sample tubes at 2000-2500 rpm for 10-15 minutes. For referred samples plasma is separated onsite and transported in cold chain.
5. Plasma samples are stored in -20°C till the viral load testing.
6. Post testing, the samples are stored at-70° C or lower.

3. **Sample rejection criteria:**

A. Hemolysed samples	B. Grossly lipemic samples
C. Contaminated samples	D. Inadequate volume
E. Leaking tubes	F. Improperly label samples
G. Temperature deviation	H. Samples from HIV-2 infected individuals (For HIV-1 Viral Load)

4. **Critical sample list and conditions where imperfect sample may be accepted:** In case of young children and infants less than 1 year laboratory may accept and report results even if the sample is hemolysed or in smaller quantities, with remark indicating the condition of the sample.
5. **Procedure for informing clinicians/patients in case of sample rejection:** Technicians are informed about sample rejection and need for repeat sampling at the time of sample receiving.
6. **Turnaround Time:**

HIV Testing	24 hours
CD4 Testing	48 hours
HIV-1 Viral Load Testing	14 days

Note: *TAT may exceed in conditions like sample load beyond the routine processing capacity of Lab/ repeat testing requirement /holidays.*

7. **Interpretation of reports:**

HIV Testing

Non Reactive on HIV Rapid Test I	**Negative**
Reactive on HIV rapid tests I, II & III	**Positive**
Reactive on HIV rapid test I but either II/III rapid tests are non-reactive	**Indeterminate**
In all doubtful cases a repeat sample is requested for testing after an interval of 2-6 weeks	

CD4 Testing

Classification of HIV-associated immunodeficiency	Age-related CD4 values			
	CD4%			CD4 Count
	Age <11 months	Age 12-35 months	Age 36-59 months	>5 Years
Normal	>35	>30	>25	>500
Mild	30-35	25-30	20-25	350-499
Advance	25-30	20-25	15-20	200-349
Severe	< 25% or CD4 count <1500 cell/µl	< 20% or CD4 count <750 cell/µl	< 15% or CD4 count <350 cell/µl	<15% or CD4 count <200

HIV-1 Viral Load Testing

Result	Interpretation
Not detected	TND
40 to < 150 copies/ml	< 150 copies/ml
150 to 10000000 copies/ml	Actual no. copies
>10000000 copies/ml	>ULQ

8. **Procedure for report issuance:**

HIV Testing- Manual verified reports are distributed by counselors after post test counseling.

CD4 Testing- Verified reports can be downloaded and printed by ART MO from NACO SOCH portal.

HIV-1 Viral Load Testing- Verified reports can be downloaded and printed by ART MO from NACO SOCH portal.

9. **Sample retention period:**

HIV Testing	72 hours
CD4 Testing	24 hours
HIV-1 Viral Load Testing	4 months

10. **Procedure for complain/ suggestions:** Feedback form and complaint box are available at sample collection sites.

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Appendix-3

TB LABORATORY

1. General Information about the laboratory

The TB Lab also acts as an Intermediate Reference Laboratory (IRL) under the "National Tuberculosis Elimination Program (NTEP)" (formerly known as RNTCP) with the coordination as well as guidance of State TB Cell, Swasthya Bhawan, Uttar Pradesh / Central TB Division (CTD), Nirman Bhawan, New Delhi. It offers a battery of tests to diagnose / treatment follow-up for tuberculosis in compliance to the guidelines provided time to time by CTD (the guidelines on "Programmatic Management of Drug Resistant TB" in force may be referred as available on https://tbcindia.mohfw.gov.in). The samples for TB tests are referred by clinicians of various departments of KGMU. Apart from KGMU, various linked districts (revised time to time by State TB Cell) also refer the TB samples to TB Lab under the NTEP services incompliance to CTD guidelines.

2. Offered Tests and Selection of Right Tests

Test	Purpose	Eligible case (as per revised guideline- PMDT-2017)
AFB Examination (ZN Stain/Auramine O)	Diagnosis/ Treatment follow-up	✓ Presumptive-TB case ✓ Cases on-treatment for anti-tubercular drug
CBNAAT (GeneXpert MTB/RIF)	Diagnosis	✓ Presumptive TB in key population (Extra-pulmonary case, Pediatric, PL-HIV or smear negative pulmonary-TB suspects)
LPA (First Line) (Genotype MTBDR*plus*)	Diagnosis	✓ Smear positive pulmonary TB cases who are suspected for drug resistance
LPA (Second Line) (Genotype MTBDR*sl*)	Diagnosis	✓ Smear positive MDR-TB cases who are suspected for XDR-TB
Culture	Diagnosis/	✓ Cases on-treatment for anti-tubercular

(LJ media/ MGIT 960)	Treatment follow-up	drug
Liquid Culture DST (First Line)- MGIT 960	Diagnosis	✓ Suspected drug resistant TB case (with indeterminate Rifampicin result in CBNAAT/ LPA).
Liquid Culture DST (Second Line)- MGIT 960	Diagnosis	✓ Confirmed MDR-TB case having additional resistance to fluroquinolone and/or second line injectables (in LPA-SL)
Solid Culture DST (First Line) (LJ media)	Diagnosis	✓ Blood Stained samples (that are in-appropriate to be tested by CBNAAT/LPA/ LC-DST).

Note: Please avoid referring multiple/ irrational tests.

3. Sample Collection Procedure

For collection of sputum and other samples, obtain sterile falcon tube and annexure 15A (NTEP request form for examination of biological specimen for TB) from DOTS center at the department of Respiratory Medicine, KGMU. In case it is not available, universal sterile screw capped sample containers may be used.

3.1.*Sputum (Expectorated):* The early morning good quality sputum (muco-purulent, 2-5 ml volume) is preferred. However on-spot collection of sputum is also acceptable but whenever possible efforts should be done to collect a second early morning sputum sample from such patients if the first one is negative.

- Sputum must always be collected at a designate sputum collection area(an open well-ventilated area identified for the purpose). In KGMU it is done at the sample collection center at the department of Respiratory Medicine.
- Label container with a unique patient identifier to match the requisition form. Make sure cap is on container tightly.
- Instruct patient for proper sample collection according to the poster pasted at the sample collection center (poster is as per NTEP guidelines).

E) Sample in wrong container

F) Visually contamination / blood stained

G) Requisition from not received

H) Incomplete requisition form

I) Sample received >72 hours

J) Other (Mislabeled specimen / specimen without test request ID in Nikshay / If the container is full up to the lid with the specimen)

Critical Sample List and conditions where imperfect samples may be collected:

Critical Sample type	Acceptance conditions
Gastric lavage	• Non-neutralized specimen, provided it is received in the laboratory within 4 hours of collection.
Body fluids (spinal, pleural, pericardial, synovial, ascitic, pus, and bone marrow)	• Small volumes (up to 0.5ml) may also be accepted for CBNAAT or liquid culture.
Tissues	• Any amount of tissue may be accepted

6. Informing Clinicians / patients in case of sample rejection:

Sample rejection is updated on the e-Hospital software (if the sample is registered on it). In case it is not registered, sample rejection is communicated to clinicians / patients / sample referring facility via telephonic call (the contact number provided in test request form).

7. Usual turn-around time (TAT):

Sr. No.	Test Name	TAT
1	AFB Microscopy	1 Day
2	CBNAAT	3 Days
3	FL-LPA	5 Days
4	SL-LPA	7 Days
5	Liquid Culture	10-45 Days
6	Liquid Culture DST	50 Days
7	Solid Culture	30-60 Days

Sr. No.	Test Name	TAT
8	Solid Culture DST	85 Days

Note: *TAT may exceed in conditions like sample load beyond the routine processing capacity of Lab, repeat testing requirement.*

8. **Interpretation of possible results of test reports:**

AFB Examination (ZN Stain/Auramine O):-

- POSITIVE: Positive smear indicates a probable mycobacterial infection. The threshold detection limit is 5000 to 10000 AFB per ml of sample. According to the number of acid-fast bacilli seen under the Microscope, the smear can be classified as 3+, 2+, 1+ or scanty. The greater the number, the more infectious is the patient.
- NEGATIVE: Negative AFB smear means Mycobacteria were not present in sufficient number to be seen under the microscope.
- If AFB smears result is negative and there is still strong suspicion of Mycobacteria infection, additional sample may be collected and tested. For pulmonary TB suspects, usually two sputum samples (spot and morning) are recommended for AFB examination.

CBNAAT(GeneXpert MTB/RIF):-

- This test should be used for diagnosis only and is not suitable for treatment follow-up purpose (as DNA might persist following anti-microbial therapy).
- MTB NOT DETECTED: Result does not rule out *M. tuberculosis* infection (as result depends on quality/quantity of specimen and sufficient DNA to be dedicated)(thresh old detection limit: 131 CFU /ml). Investigation for the presence of NON Tubercular Mycobacteria should be explored for known AFB smear Positive Cases.
- MTB DETECTED: means that *M. tuberculosis* DNA is present in the sample. It does not necessarily indicate presence of VIABLE organism.
- RIFAMPICIN RESISTANT indicates that mutation-conferring resistance to rifampicin drug is present in targeted MTB DNA region. Rifampicin resistance is regarded as a surrogate marker for MDR-TB. In this case the sample is tested further by FL-LPA and SL-LPA as reflex testing.

- RIFAMPICIN SENSITIVE means but mutation conferring resistance to rifampicin drug is not present in targeted MTB DNA region. In this case the sample is tested further by FL-LPA as reflex testing.
- RIFAMPICIN INDETERMINATE: means the MTB is present in the sample but the test could not conclude the Rifampicin resistance or sensitive status. Test should be repeated on fresh sample to confirm the status of MDR-TB. This may occur due to low mycobacterial load in the sample.
- ERROR / NO RESULT/ INVALID: Some error has been occurred during the testing. The tests with such results should be repeated on fresh sample.

LPA (First Line) (Genotype MTBDR*plus*):-

- **Only smear or culture positive samples are tested by LPA.**
- MTB DETECTED: means the target genes of MTB is present in the sample (the thresh old detection limit: 10000 CFU per ml of sample), however, result does not necessarily indicated presence of VIABLE organism.
- MTB NOT DETECTED result means there is low bacillary load in sample or presence of Non-tubercular Mycobacteria.
- RIFAMPICIN/ISONIAZID (or both) RESISTANT means mutation conferring resistance to respective drug was present in targeted MTB DNA region. Resistance to both Rifampicin and Isoniazid is considered as MDR-TB.
- RIFAMPICIN/ISONIAZID (or both) SENSITIVE means mutation conferring resistance to respective drug was not present in targeted MTB DNA region.
- INVALID: Some error has been occurred during the testing. The tests with such results should be repeated.

LPA (Second Line) (Genotype MTBDRsl):-

- MTB DETECTED: means the target genes of MTB is present in the sample (the thresh old detection limit: 10000 CFU per ml of sample), however, result does not necessarily indicated presence of VIABLE organism.

- MTB NOT DETECTED result means there is low bacillary loads in sample or presence of Non-tubercular Mycobacteria.
- *gyrA* and/or *gyrB* MUTATION DETECTED means mutation conferring resistance to fluroquinolone class of drugs was present in targeted MTB DNA region.
- *rrs/eis* MUTATION DETECTED means mutation conferring resistance to Second line injectable/(s) was present in targeted MTB DNA region. Mutation in *eis* represents low level kanamycin resistance.
- INVALID: Some error has been occurred during the testing. The tests with such results should be repeated.

Culture (LJ media/ MGIT 960):-

- POSITIVE: A tube flagged positive by MGIT 960 instrument or visible growth on LJ medium that has been confirmed by AFB smear microscopy and ICT strip indicating presence of viable Mycobacterial organisms.
- NEGATIVE: A tube flagged negative by MGIT 960 instrument/ no visible growth on LJ medium after incubation for 42 days indicating absence of viable Mycobacterial organisms.
- CONTAMINATION: Visually turbid MGIT tube/ visible contamination on LJ medium confirmed by growth on BHI broth/ AFB smear microscopy indicating presence of micro-organisms other than*M. tuberculosis*.

Liquid/ Solid Culture DST (First Line)- MGIT 960:-

- RESISTANT to 1st line drugs: The resistance to the 1st line drugs viz. Rifampicin (R), Isoniazid (H), Pyrizinamide (Z) and Etambutol (E) means the MTB detected in the sample is resistant phenotypically to the said drugs. The drugs for which resistance has been detected should not be used to treat the patients.
- SENSITIVE to 1st line drugs: The resistant to the 1st line drugs viz. Rifampicin (R), Isoniazid (H), Pyrizinamide (Z) and Etambutol (E) means the MTB detected in the sample is sensitive (not resistant) phenotypically to the said drugs. These drugs may be used to treat the patients.

Liquid/ Solid Culture DST (Second Line)- MGIT 960

- RESISTANT to 2nd line drugs: The resistance to the 2nd line drugs viz. Second Line Injectable (SLI) drugs like Streptomycin (S), Kanamycin (Km), Capreomycin (Cm) and Amikacin (Am); Fluoroquinolones (FQ) like Levofloxacin (Lfx), Moxifloxacin (Mfx); other 2nd line drugs like Linezolid (Lzd)means the MTB detected in the sample is resistant phenotypically to the said drugs. The drugs for which resistance has been detected should not be used to treat the patients.
- SENSITIVE to 2nd line drugs: The resistant to the 2nd line drugs viz. Second Line Injectable (SLI) drugs like Streptomycin (S), Kenamycin (Km), Capriomycin (Cm) and Amikacin (Am); Fluoroquinolones (FQ) like Levofloxacin (Lfx), Moxifloxacin (Mfx); other 2nd line drug like Linezolid (Lzd) means the MTB detected in the sample is sensitive (not resistant) phonetically to the said drugs. These drugs may be used to treat the patients.

9. Report Issuance:

Test reports are issued as following:

- ✓ On e-Hospital portal (https://ehospital.gov.in) (for tests raised on e- Hospital)
- ✓ Nikshay portal (for whom Nikshay ID has been created)
- ✓ Manually in the format "Annexure -15A (as the format prescribed by Central TB Division) as per the request of clinician or patient

10. Sample Retention Period:

Test	Type of Specimen	Retention Period
AFB Microscopy	Clinical Specimen	1 Day (After reporting of result; if sample volume is in excess)
	Stained Slides	2 Days (After reporting / finalization of results)
CBNAAT (Gene Xpert)	Clinical Specimen	1 Day (After reporting of result; if sample volume is in excess)
LPA (First line and	Processed	1 Day (After reporting of result)

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Second line)	sputum pellet	
	DNA Sample	1 Month (After reporting of result)
	Amplicons	1 Day (After reporting of result)
Liquid Culture DST	Processed sputum pellet	7 Days (After sample processing)
	Culture Isolate	1 Month: Primary culture isolate 1 Month: Conclusive DST isolate
Solid Culture DST	Isolate	1 Month (After reporting of result)

11. Complaint / Suggestions Procedure:

Clinicians and patients may lodge their complaints / suggestions in the complaint / suggestion box (locked) placed in Room no 116, New OPD complex and in TB lab. These complaints / suggestions are collected periodically by authorized laboratory person. After analysis, the complaints / suggestions found valid / doable, are used to resolve the issues or further improvement.

13. Contact for any help:

Room No. 116, New OPD Building KGMU, Chowk, Lucknow

Email: irluplno@rntcp.org

Dr. Urmila Singh *(Mob: 9936057067)*

Dr. Vijay Kumar *(Mob: 8126623166)*

Ms. Rashmi Ratnam *(Mob: 8765461628)*

Appendix-4

BACTERIOLOGY LABORATORY

1. General information about the laboratory

This laboratory play a critical role in diagnosing bacterial infections, testing for antibiotic resistance, and researching bacterial strains for public health purposes, food safety, and environmental studies.

The following Techniques Used:

- **Culture Techniques**: Isolating bacteria on growth media to observe colony morphology and growth patterns.
- **Gram Staining**: A method to classify bacteria as Gram-positive or Gram-negative based on cell wall composition.
- **Biochemical Testing**: Identifying bacteria based on their metabolic activities (e.g., catalase test, oxidase test).
- **Antibiotic Susceptibility Testing (AST)**: Determines how effective antibiotics are against a specific bacterial strain.

2. Procedure of sample collection in brief:

- The test requisition form is raised on e-hospital using patient UHID, admission no. etc. After registering test orders in e-hospital, a barcode is printed with UHID, sample number and name of patient (one for sample bill receipt, and one for sample vial).

Blood:

- Site Preparation: Clean the venipuncture site with antiseptic using primary (70% isopropyl alcohol) and secondary disinfection (2% chlohexidine with 70% isopropyl alcohol or 10% betadine) to prevent contamination.
- Blood Volume: Collect 5-10 mL of blood per culture bottle for adults (and 1-5 mL for pediatric patients) to ensure adequate sample volume.
- Bottle Preparation: Use aerobic and anaerobic blood culture bottles and ensure they are pre-labeled and ready. Remove plastic cap and disinfect rubber septum with 70% isopropyl alcohol prior putting blood in bottles.

- Transfer: Immediately transfer the collected blood into the culture bottles, maintaining a 1:10 blood-to-broth ratio.
- Transport: Invert the bottles gently to mix and transport them to the laboratory promptly for incubation and analysis.

CSF: CSF specimens should be attempted to be collected prior to antimicrobial therapy and after using primary (70% isopropyl alcohol) and secondary disinfection (2% chlohexidine with 70% isopropyl alcohol or 10% betadine) of the lumbar area.

- Disinfect the site both with primary and secondary disinfectant as mentioned above when collecting from an Ommaya reservoir,
- Transport all CSF samples promptly to the lab without refrigeration, unless for viral studies.

Sputum (Expectorated): The early morning muco-purulent, 2-5 ml volume is preferred. On-spot collection of sputum is also acceptable.

- Sputum must always be collected at a designate sputum collection area (an open well-ventilated area identified for the purpose). In KGMU it is done at the sample collection center at the department of Respiratory Medicine.
- Label container with a unique patient identifier to match the requisition form. Make sure cap is on container tightly.
- Instruct patient for proper sample collection according to the poster pasted at the sample collection center.
- Transport sample in a sealed and leak-proof box. Form should be kept away from specimen.

ET aspirate: Asceptically collect 5-10 ml in universal container and transport at ambient temperature to the lab.

Brochoalveolar lavage (BAL): Collect asceptically 1-5 ml in universal container and transport at ambient temperature to the lab.

11.1. ***Urine:*** An early morning urine specimen should be collected in an universal container after proper cleansing of the genitalia. Send minimum 1-5 ml of clean catch midstream urine specimen. Suprapubic aspirate, catheterized specimen should also be collected in a sterile container.

11.2. ***Fluids:*** Body fluids (spinal, pleural, pericardial, synovial, ascetic fluids, and bone marrow) must be aseptically collected and submitted in sterile universal containers. A minimum volume of 2 to 5 ml is required.

11.3. ***Pus:*** Pus must be aseptically collected with needle and syringe from undrained abscess following aseptic procedure. Transport to the laboratory either in sterile universal container or syringe.

11.4. ***Tissues:*** Collect aseptically in 2-3 mL of sterile normal saline.

11.5. ***Bone marrow:*** Aseptically collect (i.e. after primary and secondary disinfection of the site) **0.2-0.3 ml** of bone marrow in a **sterile heparinized syringe** to prevent clotting and inoculate pediatric automated blood culture bottle.

11.6. ***Faeces:*** 5gm solid stool or 5ml of liquid stool should be collected aseptically in an universal container.

3. Sample rejection criteria:

Specimen	**Rejection criteria**
Pus	Swab or materials from open wound
Biopsy	Collected in formalin or unsterile container
Cerebrospinal fluid	unsterile container
Body fluids	Swabs
Bone marrow	Clotted bone marrow
Urine	24 hours collection is unacceptable
Sputum	Saliva, nasal secretion, throat swab, 24 hour collection
Bronchial brush/washing/ broncho alveolar lavage	Dried specimen

4. **Critical sample list and conditions where imperfect sample may be accepted**:

   Critical samples like biopsy samples, suprapubic aspirate and all the fluids are to be collected even if in small quantity.

5. **Procedure for informing clinicians/patients in case of sample rejection**:

   Sample rejection is updated on the e-Hospital software (if the sample is registered on it). In case it is not registered, sample rejection is communicated to clinicians/patients/sample referring facility via telephone call (the contact number provided in the test request form).

6. **Turnaround Time**

Sr. No.	Test Name	TAT
1	Direct Microscopy	1 day
2	Blood C/S	5 days
3	Pus C/S	3 days
4	Sputum for C/S	3 days
5	Fluids C/S	3 days
6	Urine C/S	3 days
7	Throat & Vaginal swab for C/S	3 days

7. **Interpretation of reports**:

   Reporting of Blood culture results:

   • Positive cultures:

   - Immediately report Gram stain results to the physician in-charge after the automated bottles beep positive, with as much interpretive information as possible.
   - Blood broth from positive bottles are subcultured on sheep blood agar and Maconkey agar media. Cultures are identified by MALDI-tof after the colonies appear on solid culture media (usually 24 hours) and AST is done.
   - Important Considerations

     For Bottles A & B:

- If same organism is being isolated from bottles A & B. The organism is most likely the causative infective agent.
- If 2 different organisms are isolated from both the blood culture bottles then there is a possibility of contamination.

- If one of the bottles has grown Coagulase Negative Staphylococci (CONS) or diphtheroids then it is most likely skin flora contamination. However, CONS are reported with species identification and with AST in pediatric patients and immune compromised patients.

CSF reporting:

Interpretation and reporting of CSF microscopy :

- Gram stain and wet mounts are reported on same day for any bacteria/ fungi/ parasite

Provisional culture report are reported to the clinician after 24 hrs of incubation.

Final Culture reports are given after 72 hours of incubation with or without AST result depending on growth in the culture medium.

Urine reporting:

The significance of a positive urine culture is most reliably assessed in terms of the number of colony forming units (viable bacteria) present in the urine:

- $< 10^3$ CFU/ml : Insignificant colony count
- 10^3 -10^5 CFU/ml: Probable significant
- $>10^5$ CFU /ml: significant

Low colony counts may be considered significant if the history suggests or in cases who are on antibiotics/ diuretics.

Pus Culture reporting:

- Usually reported as Sterile after 48 hours of incubation in case there is no growth in culture media.
- Growth of one or two potentially significant microorganism are reported with species identification by MALDI-tof/ conventional biochemical tests. Growth is reported as Scanty/moderate/heavy with antimicrobial susceptibility testing result.

- If the culture is reported with CONS/ diphtheroids (which are usual skin commensals) then it is always suggested to collect a repeat sample after proper disinfection and aseptic measures.
- CONS are reported with species identification and with AST in post-operative and burn wound infections.

For Catheter tips-

- Semiquantitative results with colony counts >15 CFU are reported with AST as significant organism.

ETA & BAL reporting:

Semi-quantitative cultures for ETA & BAL

- In ETA sample: Colony count 100000/ml (10^5 CFU) are considered significant.
- BAL specimen: Colony count 10000/ml (10^4 colonies) are considered significant.

Sterile Body Fluids reporting:

Cultures are reported as sterile after 72 hours of incubation if there is no growth in culture media

Growth in culture media is reported after species identification and AST.

CONS must be interpreted with caution as they may be skin contaminants. Repeat culture is advised for its relevance.

Anti-Bacterial susceptibility testing(AST) is done by Disc diffusion method. AST with MIC values is available on request.

8. Procedure for report issuance:

Test reports are issued as following:

- ✓ On e-Hospital portal (https://ehospital.gov.in) (for tests raised on e- Hospital)
- ✓ Manual verified reports are distributed if any issues are encountered as per the request of clinician or patient

9. Sample retention period:

All the samples are to be stored for at least 72 hrs.

Retention of isolate: all isolates are retained for 48 hours after final reporting. If any further antibiotic susceptibility is required then it has to be requested within 48 hours only.

10. Procedure for complaint/ suggestions:

Feedback form and complaint box are available at sample collection sites.

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Appendix-5

BACTERIAL SEROLOGY AND SRC LABORATORY

1. General information about the laboratory

Bacterial serology laboratory focuses on detecting and analyzing antibodies or antigens related to bacterial infections. Biomarkers of infections or inflammation are also done in bacterial serology laboratory .The following techniques are used:

1. Serological Tests:
   - Antibody Detection: Identifying antibodies produced by the immune system in response to a bacterial infection (e.g., ELISA, immuochromatograpy based rapid tests). Agglutination and Precipitation assays
   - Antigen Detection: Identifying bacterial antigens (e.g., rapid diagnostic tests, immune fluorescence assays).
   - Biomarkers: Enzyme linked Fluorescent Assay ,Haemagglutination assays
2. Applications:
   - Diagnosis: Confirming infections by detecting antibodies or antigens specific to certain bacteria.
   - Epidemiology: Studying the prevalence of bacterial infections in populations.
   - Biomarkers for the diagnosis of sepsis and autoimmune diseases.
3. Techniques:
   - Enzyme-Linked Immunosorbent Assay (ELISA): A common method for detecting and quantifying antibodies or antigens.
   - VDRL/RPR tests
   - TPHA
   - Procalcitonin
   - Agglutination tests
   - ELFA tests
   - Widal test

2. **Procedure of sample collection in brief:**

   a. **Blood:** Blood is drawn by venipuncture and serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. At least 2-5 ml of whole blood should be collected in a plain tube. Centrifuge, transport, aliquot is used for testing.

   b. CSF specimens should be attempted to be collected prior to antimicrobial therapy, if feasible (unless the patient's condition warrants immediate antimicrobial therapy – in such a case, blood cultures should be collected before administering antibiotics).

   CSF is collected into at least three sterile tubes, with 1 ml recommended for bacterial culture, and ensure the most turbid specimen is sent for Microbiology. Disinfect the site when collecting from an Ommaya reservoir, and transport all CSF samples promptly to the lab without refrigeration, unless for viral studies.

3. **Sample rejection criteria:**

Specimen	**Rejection criteria**
Cerebrospinal fluid	Insufficient quantity
Blood	Hemolysed (red) and visibly hyperlipidemic (milky) samples
Bone marrow	Clotted bone marrow

A. Contaminated samples	B. Inadequate volume
C. Leaking tubes	D. Improperly label samples
E. Temperature deviation	F. Inadequate information about the sample

4. **Critical sample list and conditions where imperfect sample may be accepted**:

   - In case of young children and infants less than 1 year laboratory may accept and report results even if the serum sample is hemolysed or in smaller quantities, with remark indicating the condition of the sample.
   - CSF samples in smaller volume are accepted.

5. **Procedure for informing clinicians/patients in case of sample rejection**:

Sample rejection is updated on the e-Hospital software (if the sample is registered on it). In case it is not registered, sample rejection is communicated to clinicians / patients / sample referring facility via telephonic call (the contact number provided in test request form).

6. **Turn Around Time**

Sr. No.	Test Name	TAT
1	Widal Test	1 day
2	RPR (Rapid Plasma Reagin) Test	1 days
3	V.D.R.L. Test	3 days
4	TPHA	3 days
5	Anti Brucella IgM antibodies	3 days
6	Anti Brucella IgG antibodies	3 days
7	Anti- Scrub typhus IgM by ELISA	3 days
8	Pertussis IgG ELISA	3 days
9	Anti Leptospira IgM by ELISA	3 days
	BACTERIAL IMMUNOLOGY & BIOMARKERS	
10	A.S.O. Titre	1 day
11	C- Reactive Protein (Quantitative)	1 day
11	C- Reactive Protein (Qualitative)	1 day
12	Procalcitonin (Quantitative)	1 day
13	Rheumatoid Factor (Latex Agglutination)	1 day

7. **Interpretation of reports**: According to kit manufacturer

BRUCELLA IgM and IgG ELISA:

Positive	>11 NTU	Antibodies against the pathogen are present. There has been a contact with the antigen.

Equivocal	9-11 NTU	Antibodies against the pathogen could not be detected clearly. It is recommended to repeat the test with a fresh sample in 2 to 4 weeks. If the result is equivocal again the sample is judged as negative.
Negative	<9 NTU	The sample contains no antibodies against the pathogen. A previous contact with the antigen is unlikely.

LEPTOSPIRA IgM ELISA : According to kit manufacturer

Positive	>11 NTU	Antibodies against the pathogen are present. There has been a contact with the antigen.
Equivocal	9-11 NTU	Antibodies against the pathogen could not be detected clearly. It is recommended to repeat the test with a fresh sample in 2 to 4 weeks. If the result is equivocal again the sample is judged as negative.
Negative	<9 NTU	The sample contains no antibodies against the pathogen. A previous contact with the antigen is unlikely.

Serum Procalcitonin (PCT):

S.No	PCT concentration	Analysis/recommendation
1	< 0.10 ng/ml	Indicates absence of bacterial infection
2	0.10-0.25 ng/ml	Bacterial infection unlikely

3	0.26-0.50 ng/ml	Bacterial infection is possible
4	>0.50 ng/ml	Suggestive of presence of bacterial infection

RPR test (Rapid Plasma Reagin test)

- RPR test measures antibodies in the blood that may indicate syphilis
- It's a non-treponemal flocculation assay
- Result is reported as positive with titre.

SCRUB TYPHUS IgM ELISA

- Samples with spectrophotometric readings> Cut-off are considered to be "Reactive" and samples below this criterion are considered to be "Non-Reactive".
- Any "Reactive" sample must be repeated to verify the result. Values near the Cut-off are considered to be doubtful and the assay must be repeated in triplicate or more.

Negative Control (NC) OD <0.200

Positive Control (PC) OD > 0.500

Discrimination Capacity ($R_{PC/NC}$) >/= 5.0

TYPHIDOT:

(Positive control – Positive

Negative control – Negative)

Intensity of sample > PC = Positive

Intensity of sample < PC = Negative

The test is positive for IgM antibodies and is suggestive of Acute Typhoid fever.

WIDAL:

Slide Screen Method: Agglutination is a positive test result and indicates presence of the corresponding antibody in the patient's serum. No agglutination is a negative test result and indicates absence of the corresponding antibody in the patient serum.

Slide Semi-Quantitative Method: Agglutination is a positive test result. The titre of the patient serum corresponds to the visible agglutination in the test circle with the least amount of serum sample.

Quantitative Method: The titre of the patient serum using TYDAL antigen suspensions is the highest dilution of the serum sample that gives a visible agglutination.

TPHA test:

- **Positive Result**: Agglutination of the Test Cells but not the Control Cells indicates the presence of specific antibodies to *T. pallidum*.
- **Negative Result**: Absence of agglutination suggests that the antibody levels are below the detection limit of the test.
- **Equivocal result**: Are to be repeated after 4 weeks.

8. **Procedure for report issuance**:

Test reports are issued as following:

- ✓ On e-Hospital portal (https://ehospital.gov.in) (for tests raised on e- Hospital)
- ✓ Manual verified reports are distributed if any issues are encountered as per the request of clinician or patient

9. **Sample retention period**:

All the samples are to be stored for at least 72 hrs.

10. **Procedure for complaint/ suggestions:**

Feedback form and complaint box are available at sample collection sites. These complaints / suggestions are collected periodically by authorized laboratory person. After analysis, the complaints / suggestions found valid / doable are used to resolve the issues or further improvement.

Appendix-6

MYCOLOGY LABORATORY

1. General information about the laboratory

- Mycology lab also has Advanced Mycology Diagnostic & Research Lab, supported by ICMR, India.
- It provides conventional, serological as well as molecular techniques to diagnose life threatening infections like aspergillosis, candidiasis, mucormycosis, histoplasmosis and pneumocystis pneumonia.

2. Procedure of sample collection in brief:

1. Skin and Interspaces:
   - Wipe skin lesions and interspaces between the toes with 70% alcohol sponge and sterile water.
   - Scrape the entire lesion (from Centre & edges) and both sides of interspaces with a sterile scalpel. The active, peripheral edge of the lesion must be scraped with a scalpel or the end of a microscopic slide.
   - Place scrapings on clean glass slide for direct examination and in sterilized Petri dish for culture.
2. Hair:
   - No cleaning of scalp is needed.
   - Select infected areas, and with forceps, epilate at least 10 hairs.
   - For hairs broken off at the scalp level, use a scalpel on a blade knife. 3.2.4. Place hairs on clean glass slide for direct examination and in sterilized Petri dish for culture.
   - Invaders of the scalp and hair are best isolated by culturing the basal portion of the infected hair.
3. Nail:
   - Clean nail with 70% alcohol.
   - For a specimen of the dorsal plate, scrape the outer surface and discard the scrapings. Then scrape the deeper portion of the specimen.

- Remove a portion of debris from under the nail with a scalpel.
- Collect the whole nail or nail clippings.
- Place material on a clean glass slide and sterilized Petri dish.

4. Pus:
    - Collect aseptically using a needle and syringe from an undrained abscess.
    - If the abscess is opened with a scalpel, express pus and transport it to the laboratory in a sterile container or with the syringe and needle.
5. Biopsy:
    - Place the biopsy sample between two sterile gauze pads or in a sterile petri dish/tube containing 2-3 mL of sterile normal saline or brain heart infusion broth.
    - Tissue should be collected from both the center and edge of the lesion.
6. Grains:
    - Collect by lifting the crust at the opening of a sinus.
    - Grains are commonly found under the pus or can be retrieved from bandages.
    - Aspirate from undrained sinuses if necessary.
7. Body fluids and Cerebrospinal Fluid (CSF):
    - Collect 1-3 mL of cerebrospinal fluid and other body fluids in a sterile tube.
    - Centrifuge at 1000g for 10min
    - Place at least 0.3ml of sediment on each medium
8. Bone Marrow:
    - Collect 0.2-0.3 mL of bone marrow in a sterile heparinized syringe.
    - Place a sterile cap on the syringe and transport immediately.
9. Blood:
    - Collect 5-10 mL of blood using a yellow Vacutainer, syringe, or in biphasic media containing brain heart infusion broth and agar.
    - Maintain a blood-to-broth ratio of 1:10.
    - Collect multiple blood cultures at timed intervals.
    - Techniques such as BACTEC or lysis centrifugation may enhance sensitivity.

10. Urine:
    - Collect 1-5 mL of early morning clean-catch midstream urine, a suprapubic aspirate, or a catheterized specimen in a sterile container.
    - Centrifuge at 2000g for 10min, decant the supernatant and place at least 0.3ml of sediment on each medium

11. Feces:
    - Generally not accepted in a mycology laboratory, though sometimes collected to assess Candida carriage in the gastrointestinal tract.

12. Sputum:
    - The patient should rinse their mouth and brush their teeth prior to collection.
    - Collect 5-10ml of early morning sputum before eating.
    - The patient must be asked to cough the sputum not saliva into the container.
    - Use a sterile wide-mouthed universal container.
    - Sputum decontamination should not be done as NaOH destroys a large no. of Fungi
    - A mucolytic without NaOH may be used for viscous specimens.

13. Bronchial Brush/Washings/Bronchoalveolar Lavage (BAL):
    - Collect the specimen in a sterile container using fiber-optic bronchoscopes.

14. Lung Biopsy:
    - Collect using a bronchoscope, fluoroscope-guided trans-thoracic needle aspiration, or open lung biopsy.
    - While an open lung biopsy yields the best specimen, it is a more hazardous procedure.

15. Tissues:
    - Tissues should be minced with a scalpel or ground with a mortar and pestle or tissue grinder.
    - For recovery of *H.capsulatum* grinding is essential to release the intracellular yeasts and enable their growth by lysis centrifugation.
    - If necessary, add a small amount of sterile saline or broth to facilitate grinding.

- If infection with Zygomycetes is suspected, the tissue should be minced, not ground or homogenized as these may decrease the viability by destroying the hyphae.
- Subcutaneous tissue should be carefully examined for granules. If granules are present, to handle carefully and inform the microbiologist.

16. Serology:

- For serum collection, obtain 1-2 mL.
- For spinal fluid, collect 3-5 mL.

3. Sample rejection criteria:

Specimen	Rejection criteria
Pus	Swab or materials from open wound
Biopsy	Sample in formalin
Cerebrospinal fluid	Non sterile container
Body fluids Swabs	Swabs
Bone marrow	Clotted bone marrow
Urine	24 hours collection is unacceptable
Sputum	Saliva, nasal secretion, throat swab, 24 hour collection
Bronchial brush/washing/ broncho alveolar lavage	Dried specimen
Serology	Specimen collected after skin test with histoplasmin while performing serology for histoplasmosis

4. Critical sample list and conditions where imperfect sample may be accepted:

Critical samples like Grains, Lung biopsy, Blood culture samples are to be collected even if in small quantity.

5. **Procedure for informing clinicians/patients in case of sample rejection:**

Sample rejection is updated on the e-Hospital software (if the sample is registered on it). In case it is not registered, sample rejection is communicated to clinicians / patients / sample referring facility via telephonic call (the contact number provided in test request form).

6. **Turn around Time**

Sr. No.	Test Name	TAT
1	KOH Mount	1 day
2	KOH- Calcoflour white stain	1 day
3	India Ink Stain	1 day
4	Skin/Nail/Hair for C/S	4 weeks
5	Pus for C/S	3 weeks
6	Sputum for C/S	3 weeks
7	Throat swab (Automated) With ID/AST (MIC)-Yeast (Fungal)	3 weeks
8	BAL for Fungal C/S	3 weeks
9	CSF C/S (Automated) With ID/AST (MIC)-Yeast (Fungal)	2 weeks
10	Blood Culture for Filamentous Fungi (Manual)	2 weeks
11	Blood Culture (Automated) With ID/AST (MIC)-Yeast (Fungal)	2weeks
12	Body Fluids for C/S	2 weeks
13	Body fluids C/S (Automated ID/AST) Fungal	2 weeks
14	Urine C/S (Automated ID/AST) Fungal	1 week
15	Urine for C/S	1 week
16	Vaginal swab for C/S	2 weeks
	FUNGAL SEROLOGY	
17	Cryptococcal antigen	1day
18	Cryptococcal Antigen Latex Agglutination	2 days

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Sr. No.	Test Name	TAT
	System (CALAS)	
19	Galactomannan ELISA	3 days

7. **Interpretation of reports:**

KOH mount:

- Negative for fungal elements
- Positive for thin septate branched fungal hyphae resembling Dermatophytes.
- Positive for thin septate branched fungal hyphae resembling *Fusarium* species.
- Positive for pigmented septate branched fungal hyphae resembling Dematiceous fungi (*Alternaria, Curvularia*)
- Positive for broad aseptate branching fungal hyphae resembling Mucorales.
- Positive for yeast and hyphae forms of *Malassezia furfur*.

India ink or Nigrosin preparation for identification of Cryptococcus in CSF:

The India ink procedure is used to detect Cryptococcus species, primarily in cerebrospinal fluid (CSF). A drop of the specimen is mixed with India ink on a glass slide and covered with a coverslip. The preparation is examined under a microscope for the presence of encapsulated yeast cells, which appear as round cells with a clear halo against a dark background. This halo represents the polysaccharide capsule of *Cryptococcus* species.

Results are usually reported as:

- Negative for Capsulated yeast.
- Positive for Capsulated yeast resembling Cryptococcus.

Gram Stain of any pus sample or body fluid is reported as:

- Pus cells are reported as scanty, few, moderate and plenty
- Gram positive budding yeast cells with or without pseudohyphae are reported as Candida species.
- Gram-positive septate filamentous branching hyphae resembling Moulds

Giemsa stain is usually done in sputum/BAL/ tissue samples and is reported as following:

- Histoplasma is reported as "intracellular yeast cells" resembling *Histoplasma capsulatum*"
- Pneumocystis is reported as "Trophozoite form of *Pneumocystis jiroveci*".

Yeast and Mould identification:

Conventional ID/ Vitek AST & Automated ID by MALDI-TOF-MS. AST is also available with MIC by broth microdilution methods for yeast and molds.

Antifungal susceptibility testing: AST is available with MIC by broth microdilution methods for yeast and molds.

Interpretation of AST is done as per CLSI documents (CLSI M27 for yeast and CLSI M38 for molds)

CrAg Lateral Flow Assay:

- Positive result is reported as "positive for Cryptococcal antigen". Titre is also reported on request by CALAS test.
- Negative result is reported as "negative for Cryptococcal antigen

Cryptococcal Antigen Latex Agglutination System (CALAS):

- **Negative**: A negative or 1+ reaction is reported as negative.
- **Positive**: A 2+ or greater reaction indicates a positive result, with CSF titers of 1:4 or less suggesting infection and 1:8 or greater strongly indicative of *Cryptococcus neoformans* infection.

Aspergillus Galactomannan Antigen ELISA: This is done in serum and BAL samples

Gm index < 1.0 is considered to be negative for galactomannan antigen.

Gm index ≥ 1.0 are considered to be positive for galactomannan antigen for both serum and BAL

8. Procedure for report issuance:

Test reports are issued as following:

✓ On e-Hospital portal (https://ehospital.gov.in) (for tests raised on e- Hospital)

- ✓ Manual verified reports are distributed if any issues are encountered as per the request of clinician or patient

9. Sample retention period:

All the samples are to be stored for at least 48hrs

10. Procedure for complaint/ suggestions:

Feedback form and complaint box are available at sample collection sites. These complaints / suggestions are collected periodically by authorized laboratory person. After analysis, the complaints / suggestions found valid / doable, are used to resolve the issues or further improvement.

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Appendix-7

PARASITOLOGY LAB

1. **General information about Parasitology lab:**

   The samples for Parasitology tests are referred by clinicians of various departments of KGMU. Apart from KGMU, various linked districts also refer the samples to the Parasitology Lab.

   - The Parasitology laboratory offers various tests, including Stool Microscopy for cysts, eggs & parasites, Microscopy for opportunistic parasite, Microscopy for Malarial Parasite, Microscopy for Microfilaria, Rapid Malaria Test (HRP-2 and p-LDH based), Filaria antigen (Rapid), Echinococcus IgG ELISA, Entamoeba histolytica antigen ELISA, Entamoeba histolytica IgM ELISA, Entamoeba histolytica IgG ELISA, Cysticercosis IgG ELISA, Cryptosporidium stool antigen ELISA, Rapid test for Faecal Occult blood, Leishmania antibody (Rapid) and Stool Antigen for Giardia (ELISA).
   - Blood or serum samples, Plasma, Stool samples are collected from inpatients (wards/hospital), outpatients (OPD), or walk-in clients.

2. **Procedure of sample collection in brief:**

   Microscopy for Malarial Parasite & Microfilaria, Rapid Malaria Test (HRP-2 and p-LDH based), Filaria antigen (Rapid)

   1. Blood is collected in sterile EDTA vacutainer. The EDTA tubes should be gently inverted 8-10 times to ensure proper mixing of whole blood and EDTA to prevent clotting.
   2. All the blood samples are transported in EDTA vacutainer in cold chain along with requisition form to Parasitology laboratory.

   ELISA tests for Echinococcus IgG, Entamoeba histolytica antigen, Entamoeba histolytica IgM, Entamoeba histolytica IgG, Cysticercosis IgG, Cryptosporidium stool antigen:

1. For ELISA testing, 3-5 ml of blood is collected via venipuncture into a red-capped sterile vacutainer.
2. The samples from the all Wards/OTs of the hospital must be transported in vacutainers/ sample transport vials and NOT IN SYRINGES.
3. Serum is separated by centrifugation of blood samples at 1500 rpm for 15-30 minutes

Stool Microscopy for cysts, eggs & parasites:

- Fresh stool specimens are submitted to the laboratory, it is helpful to determine and report the consistency of the stool (watery, loose, soft, formed).
- Specimens should be collected in clean, wide-mouthed containers (half-pint, waxed cardboard carton, or plastic containers) aseptically.

3. Sample rejection criteria:

- Unlabelled specimen
- Sample Leakage
- Insufficient Specimen
- Sample and Form differ
- Sample in wrong container
- Visually contamination / blood stained
- Requisition from not received
- Incomplete requisition form
- Sample received >72 hours
- Other (Mislabeled specimen / specimen without test request ID / If the container is full up to the lid with the specimen)

4. Critical sample list and conditions where imperfect sample may be accepted:

In case of young children and infants less than 1 year laboratory may accept and report results even if the sample is hemolysed or in smaller quantities, with remark indicating the condition of the sample.

Critical samples like Fluids and Duodenal aspirates are also to be collected.

5. **Procedure for informing clinicians/patients in case of sample rejection**:

Sample rejection is updated on the e-Hospital software (if the sample is registered on it). In case it is not registered, sample rejection is communicated to clinicians / patients / sample referring facility via telephonic call (the contact number provided in test request form).

6. **Turnaround Time** (Please insert a table with the test names and TAT)

Sr. No.	Test Name	TAT
1	Microscopy FOR OVA & CYST (Routine)	1 day
2	Microscopy for opportunistic parasite	1 day
3	Microscopy for Malarial Parasite	1 day
4	Microscopy for Microfilaria	1 day
5	Rapid Malaria Test (HRP-2 based)	1 day
6	Rapid Malaria Test (p-LDH based)	1 day
7	Filaria antigen (Rapid)	1 day
8	Echinococcus IgG ELISA	7 days
9	Entamoeba histolytica antigen ELISA	7 days
10	Entamoeba histolytica IgM ELISA	7 days
11	Entamoeba histolytica IgG ELISA	7 days
12	Toxoplasma IgM by ELISA	7 days
14	Stool for occult blood	1 day

7. **Interpretation of reports**:

Stool Microscopy is reported on following parameters:

GROSS	
Colour	Brown/ yellow/ Black
Consistency	Solid/ liquid/ semi-liquid
MICROSCOPIC	
Ova	Absent/ Present with identification of species
Cyst	Absent/ Present with identification of species
Parasite	Absent/ Present with identification of species

Malaria Parasite Examination (Giemsa Stain):-

Positive smears are reported with microscopic findings such as trophozoite forms, accole forms, gametocyte. Parasite index and parasite count is reported with each positive result to help clinician assess parasite load and response to treatment. Parasite count is reported as parasites/ ul while parasite index is reported in percentage (which is percent of RBC's infected).

RDT for Occult blood results: Results are reported as positive and negative.

MICROSCOPY FOR MICROFILARIA IN BLOOD:

- Positive Result: The presence of microfilariae, with specific morphological characteristics, confirms filarial infection; species identification is crucial for treatment.
- Negative Result: Absence of microfilariae may indicate no infection, low parasitemia, or incorrect timing of sample collection, warranting repeat testing if nocturnal periodicity is suspected.
- Inconclusive Sample: Contamination or poor preparation of the sample can hinder accurate identification, necessitating a new blood sample for reliable results.
- Clinical Relevance: Positive microscopy for microfilariae confirms filariasis, guiding appropriate management based on the identified species.

Reporting of parasite serology by ELISA tests:

Echinococcus IgG ELISA:

Cut-Off	**10 Novatech units (NTU)**	
Positive	>11 NTU	Antibodies against the pathogen are present. There has been a contact with the antigen.
Equivocal	9-11 NTU	Antibodies against the

		pathogen could not be detected clearly. It is recommended to repeat the test with a fresh sample in 2 to 4 weeks. If the result is equivocal again the sample is judged as negative.
Negative	<9 NTU	The sample contains no antibodies against the pathogen. A previous contact with the antigen is unlikely.
Diagnosis of an infectious disease should not be established on the basis of a single test. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.		

Entamoeba IgG ELISA:

Cut-Off	10 Novatech units (NTU)	
Positive	>11 NTU	Antibodies against the pathogen are present. There has been a contact with the antigen. ,
Equivocal	9-11 NTU	Antibodies against the pathogen could not be

		detected clearly. It is recommended to repeat the test with a fresh sample in 2 to 4 weeks. If the result is equivocal again the sample is judged as negative.
Negative	<9 NTU	The sample contains no antibodies against the pathogen. A previous contact with the antigen is unlikely.
Diagnosis of an infectious disease should not be established on the basis of a single test. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.		

Toxoplasma IgM ELISA:

Cut-Off	**0.2**	
Positive	Ratio ≥ 1.2	Antibodies against the pathogen are present. There has been a contact with the antigen. ,
Equivocal	Ratio 0.8-1.2	Antibodies against the pathogen could not be detected clearly. It is recommended to

		repeat the test with a fresh sample in 2 to 4 weeks. If the result is equivocal again the sample is judged as negative.
Negative	Ratio < 0.8	The sample contains no antibodies against the pathogen. A previous contact with the antigen is unlikely.

8. Procedure for report issuance:

Test reports are issued as following:

- ✓ On e-Hospital portal (https://ehospital.gov.in) (for tests raised on e- Hospital)
- ✓ Manual verified reports are distributed if any issues are encountered as per the request of clinician or patient

9. Sample retention period:

ELISA testing	72 hours
Microscopy for parasites Testing, RDTs	24 hours
Stool microscopy	24 hrs

10. Procedure for complaint/ suggestions: Feedback form and complaint box are available at sample collection sites. These complaints / suggestions are collected periodically by authorized laboratory person. After analysis, the complaints / suggestions found valid / doable, are used to resolve the issues or further improvement.

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Appendix-8

VIROLOGY LABORATORY

1. **General information about the laboratory:**
   - The Virology laboratory is supported by the PM ABHIM (Department of Health & Research) Scheme.
   - The Virology laboratory offers various tests for diagnosis of viral infections like RT PCR for Respiratory viruses (eg. H1N1, H3N2, RSV A/B etc), Arboviruses (Dengue, Chikungunya, Japanese Encephalitis), HSV1/2 and serology tests for various viruses (eg. Anti Dengue IgM antibody, Dengue Virus NS1 antigen etc).
   - The virology laboratory is a state referral Virology Research & Diagnostic laboratory (VRDL).
   - For testing various samples (as per requisition) such as blood/serum/nasal swab/nasopharyngeal swab/throat swab/CSF etc. are collected. Samples from inpatients (wards/hospital), outpatients (OPD), or walk-in clients are accepted. To get tested, any individual can visit virology laboratory.
2. **Procedure of sample collection in brief:**
   - Before collecting sample, a written informed consent is taken from every patient or his/her attendant/ guardian.
   - Whole procedure of sample collection is explained to the patient
   - A case report form is filled for every patient and test requisition is raised on Virology lab in-house software.
   - For virology serology testing, 3-5 ml of blood is collected via venipuncture into a red-capped sterile vacutainer. CSF is accepted in a sterile leak proof container from cases presenting with neurological manifestations.
   - For molecular testing, various samples are collected as per requirement.
     a. NS/TS is collected in VTM for respiratory virus.
     b. Blood/serum is collected via venipuncture in a red-capped sterile vacutainer.
     c. CSF is accepted in a sterile leak proof container.

d. 3-5 ml urine in a sterile leak proof container is acceptable.
e. For buffy coat 3-5 ml blood is collected in EDTA vial
f. Blister fluid/body fluids are collected in a sterile container.
g. Blister swabs are not encouraged, if unavoidable are collected in VTM.

- Serum is separated by centrifugation of blood samples at 1500 rpm for 15-30 minutes.
- Serum samples are stored at 4°C after collection and samples are tested within 2 working days, if more time is required for sample processing, they are stored at -20 °C
- Post testing, the samples are stored at -70^0 C .

3. Sample rejection criteria:

Hemolysed samples	Grossly lipemic samples
Contaminated samples	Inadequate volume
Leaking tubes	Improperly label samples
Temperature deviation	

4. Critical sample list and conditions where imperfect sample may be accepted:

- In case of young children and infants less than 1 year laboratory may accept and report results even if the serum sample is hemolysed or in smaller quantities, with remark indicating the condition of the sample.
- CSF samples in smaller volume are accepted.

5. Procedure for informing clinicians/patients in case of sample rejection: Clinicians/patients are informed telephonically and are requested to deposit a repeat sample as soon as possible.

6. Turnaround Time

	VIROLOGY	
8a	**VIRAL SEROLOGY**	
1	Anti- Dengue Virus IgM Antibodies (ELISA)	Within 3 working days
2	Dengue Virus NS1Ag ELISA	Within 3 working days
3	Anti- Japanese Encephalitis Virus IgM Antibodies	Within 3 working days

	ELISA	
4	Anti-Chikungunya Virus IgM Antibodies (Anti-ChikV IgM)(ELISA)	Within 3 working days
5	Anti-Scrub typhus IgM Antibodies (Anti Scrub typhus IgM)(ELISA)	Within 3 working days
6	Anti- Cytomegalovirus IgM Antibodies (Anti- CMV IgM)(ELISA)	Within 5 working days
7	Anti- Cytomegalovirus IgG Antibodies (Anti- CMV IgG)(ELISA)	Within 5 working days
8	Anti-Herpes Simplex IgM Antibodies (Anti-HSV IgM)(ELISA)	Within 5 working days
9	Anti-Measles Virus IgM Antibodies (Anti-Measles IgM)(ELISA)	Within 5 working days
10	Anti-Measles Virus IgG Antibodies (Anti-Measles IgG)(ELISA)	Within 5 working days
11	Anti-Mumps Virus IgM Antibodies (Anti-Mumps IgM)(ELISA)	Within 5 working days
12	Anti-Varicella Zoster Virus IgM Antibodies (Anti-VZV IgM)(ELISA)	Within 5 working days
1	Anti-Human Parvovirus B19 IgM Antibodies (Anti-B19V IgM)(ELISA)	Within 5 working days
14	Anti- West Nile Virus IgM Antibodies (Anti-WNV IgM)(ELISA)	Within 5 working days
15	Anti-Epstein Barr Virus IgM Antibodies (Anti- EBV IgM)(ELISA)	Within 5 working days
16	Anti-Rubella Virus IgM Antibodies (Anti Rubella IgM)(ELISA)	Within 5 working days
8b	**MOLECULAR BIOLOGY**	

1	Real Time PCR For Influenza A Virus	Within 3 working days
2	Real Time PCR For Influenza A Virus (subtype H1N1)	Within 3 working days
3	Real Time PCR For Influenza A Virus (subtype H3N2)	Within 3 working days
4	Real Time PCR For Influenza B Virus	Within 3 working days
5	Real Time PCR For Respiratory Syncytial Virus	Within 3 working days
6	Real Time PCR For Parainfluenza Virus 1,2,3,4	Within 3 working days
7	Real Time PCR For Human Metapneumovirus	Within 3 working days
8	Real Time PCR For Herpes Simplex 1 Virus	Within 3 working days
9	Real Time PCR For Herpes Simplex 2 Virus	Within 3 working days
10	Real Time PCR For Varicella Zoster Virus	Within 3 working days
11	Real Time PCR For Japanese Encephalitis Virus	Within 3 working days
12	Real Time PCR For Dengue Virus	Within 3 working days
13	Real Time PCR For Measles Virus	Within 3 working days
14	Real Time PCR For Bocavirus	Within 3 working days
15	Real Time PCR For Human Adenovirus	Within 3 working days
16	Real Time PCR For Human Parvovirus B19	Within 3 working days
17	Real Time PCR For Enterovirus	Within 3 working days
18	Conventional PCR For Cytomegalovirus	Within 3 working days
19	Real Time PCR for Scrub typhus	Within 3 working days

Note: *TAT may exceed in conditions like sample load beyond the routine processing capacity of Lab/ repeat testing requirement /holidays.*

7. **Interpretation of reports**:

	VIROLOGY	
8a	**VIRAL SEROLOGY**	
1	Anti- Dengue Virus IgM Antibodies (ELISA)	Positive/negative/equivocal
2	Dengue Virus NS1Ag ELISA	Positive/negative
3	Anti- Japanese Encephalitis Virus IgM Antibodies ELISA	Positive/negative/equivocal

4	Anti-Chikungunya Virus IgM Antibodies (Anti-ChikV IgM)(ELISA)	Positive/negative/equivocal
5	Anti-Scrub typhus IgM Antibodies (Anti Scrub typhus IgM)(ELISA)	Positive/negative/equivocal
6	Anti- Cytomegalovirus IgM Antibodies (Anti- CMV IgM)(ELISA)	Positive/negative/equivocal
7	Anti- Cytomegalovirus IgG Antibodies (Anti- CMV IgG)(ELISA)	Positive/negative/equivocal
8	Anti-Herpes Simplex IgM Antibodies (Anti-HSV IgM)(ELISA)	Positive/negative/equivocal
9	Anti-Measles Virus IgM Antibodies (Anti-Measles IgM)(ELISA)	Positive/negative/equivocal
10	Anti-Measles Virus IgG Antibodies (Anti-Measles IgG)(ELISA)	Positive/negative/equivocal
11	Anti-Mumps Virus IgM Antibodies (Anti-Mumps IgM)(ELISA)	Positive/negative/equivocal
12	Anti-Varicella Zoster Virus IgM Antibodies (Anti-VZV IgM)(ELISA)	Positive/negative/equivocal
13	Anti-Human Parvovirus B19 IgM Antibodies (Anti-B19V IgM)(ELISA)	Positive/negative/equivocal
14	Anti- West Nile Virus IgM Antibodies (Anti-WNV IgM)(ELISA)	Positive/negative/equivocal
15	Anti-Epstein Barr Virus IgM Antibodies (Anti- EBV IgM)(ELISA)	Positive/negative/equivocal
16	Anti-Rubella Virus IgM Antibodies (Anti Rubella IgM)(ELISA)	Positive/negative/equivocal
8b	**MOLECULAR BIOLOGY**	
1	Real Time PCR For Influenza A Virus	Detected/Not Detected

4	Anti-Chikungunya Virus IgM Antibodies (Anti-ChikV IgM)(ELISA)	Positive/negative/equivocal
5	Anti-Scrub typhus IgM Antibodies (Anti Scrub typhus IgM)(ELISA)	Positive/negative/equivocal
6	Anti- Cytomegalovirus IgM Antibodies (Anti- CMV IgM)(ELISA)	Positive/negative/equivocal
7	Anti- Cytomegalovirus IgG Antibodies (Anti- CMV IgG)(ELISA)	Positive/negative/equivocal
8	Anti-Herpes Simplex IgM Antibodies (Anti-HSV IgM)(ELISA)	Positive/negative/equivocal
9	Anti-Measles Virus IgM Antibodies (Anti-Measles IgM)(ELISA)	Positive/negative/equivocal
10	Anti-Measles Virus IgG Antibodies (Anti-Measles IgG)(ELISA)	Positive/negative/equivocal
11	Anti-Mumps Virus IgM Antibodies (Anti-Mumps IgM)(ELISA)	Positive/negative/equivocal
12	Anti-Varicella Zoster Virus IgM Antibodies (Anti-VZV IgM)(ELISA)	Positive/negative/equivocal
13	Anti-Human Parvovirus B19 IgM Antibodies (Anti-B19V IgM)(ELISA)	Positive/negative/equivocal
14	Anti- West Nile Virus IgM Antibodies (Anti-WNV IgM)(ELISA)	Positive/negative/equivocal
15	Anti-Epstein Barr Virus IgM Antibodies (Anti- EBV IgM)(ELISA)	Positive/negative/equivocal
16	Anti-Rubella Virus IgM Antibodies (Anti Rubella IgM)(ELISA)	Positive/negative/equivocal
8b	**MOLECULAR BIOLOGY**	
1	Real Time PCR For Influenza A Virus	Detected/Not Detected

2	Real Time PCR For Influenza A Virus (subtype H1N1)	Detected/Not Detected
3	Real Time PCR For Influenza A Virus (subtype H3N2)	Detected/Not Detected
4	Real Time PCR For Influenza B Virus	Detected/Not Detected
5	Real Time PCR For Respiratory Syncytial Virus	Detected/Not Detected
6	Real Time PCR For Parainfluenza Virus 1,2,3,4	Detected/Not Detected
7	Real Time PCR For Human Metapneumovirus	Detected/Not Detected
8	Real Time PCR For Herpes Simplex 1 Virus	Detected/Not Detected
9	Real Time PCR For Herpes Simplex 2 Virus	Detected/Not Detected
10	Real Time PCR For Varicella Zoster Virus	Detected/Not Detected
11	Real Time PCR For Japanese Encephalitis Virus	Detected/Not Detected
12	Real Time PCR For Dengue Virus	Detected/Not Detected
13	Real Time PCR For Measles Virus	Detected/Not Detected
14	Real Time PCR For Bocavirus	Detected/Not Detected
15	Real Time PCR For Human Adenovirus	Detected/Not Detected
16	Real Time PCR For Human Parvovirus B19	Detected/Not Detected
17	Real Time PCR For Enterovirus	Detected/Not Detected
18	Conventional PCR For Cytomegalovirus	Detected/Not Detected
19	Real Time PCR for Scrub typhus	Detected/Not Detected

8. **Procedure for report issuance:**

Manual verified reports are distributed from reception of virology laboratory for every test.

9. **Sample retention period**:

Each sample is retained for 3 days after reporting.

10. **Procedure for complaint/ suggestions:**

Feedback form and complaint box are available at sample collection sites.

Appendix-9

VIRAL HEPATITIS LABORATORY

1. General Information:

- The Viral Hepatitis laboratory is partly covered under National Viral Hepatitis Control Program (NVHCP) for providing patient services
- The Viral Hepatitis laboratory offers various tests, including HBsAg, Anti HCV antibody, HBeAg, HBcAg, Hepatitis B viral load, Hepatitis C viral load etc
- For testing, blood or serum samples are collected from inpatients (wards/hospital), outpatients (OPD), or walk-in clients.

2. Procedure of sample collection:

Viral Hepatitis Serology testing

- The test requisition form is raised on e-hospital using patient UHID, admission no. After registering test orders in e-hospital, a barcode is printed with UHID, sample number and name of patient (one for sample bill receipt, and one for sample vial).
- For Hepatitis serology testing, 3-5 ml of blood is collected via venipuncture into a red-capped sterile vacutainer.
- The samples from all Wards/OTs of the hospital must be transported in vacutainers/ sample transport vials.
- Serum is separated by centrifugation of blood samples at 1500 rpm for 15-30 minutes.

For Hepatitis Viral load testing

- Viral load testing is done only in the patients found positive for HBsAg or anti HCV.
- 3-5 ml of blood is collected via venipuncture into a red-capped sterile vacutainer.
- Serum is separated by centrifugation of blood samples at 1500 rpm for 15-30 minutes.
- Serum samples are stored at -20oC for viral load testing.

3. Sample rejection criteria:

Hemolysed samples	Grossly lipemic samples
Contaminated samples	Inadequate volume
Leaking tubes	Improperly label samples

Temperature deviation	

4. Critical sample list and conditions where imperfect sample may be accepted:

In case of young children and infants less than 1 year, laboratory may accept and report results even if the sample is hemolysed or in smaller quantities, with remark indicating the condition of the sample.

5. Procedure for informing clinicians/patients in case of sample rejection:

Technicians are informed about sample rejection and need for repeat sampling at the time of sample receiving. Patients/clinicians are informed about this and requested to submit a fresh sample.

6. Turnaround Time:

9	**VIRAL HEPATITIS**	
9a.	**HEPATITIS SEROLOGY**	
1	HBsAg ELISA	Within 3 working days
2	HBeAg ELISA	Within 21 working days
3	Anti- Hepatitis B Core Antigen IgM (Anti-HBc IgM) ELISA	Within 21 working days
4	HBeAb ELISA	Within 21 working days
5	Anti HBs Antibody ELISA	Within 21 working days
6	Anti- Hepatitis A Virus IgM Antibodies (anti-HAV IgM) (ELISA)	Within 5 working days
7	Anti- Hepatitis E Virus IgM Antibodies (anti-HEV IgM)(ELISA)	Within 5 working days
8	Anti HCV Total antibodies by ELISA	Within 3 working days
9b.	**MOLECULAR BIOLOGY**	
1	Real Time PCR with Viral Load estimation For Hepatitis B Virus (Quantitative) Truenat	Within 21 working days
2	Real Time PCR with Viral Load estimation For Hepatitis C Virus (Quantitative) Truenat	Within 21 working days

Note: *TAT may exceed in conditions like sample load beyond the routine processing capacity of Lab/ repeat testing requirement /holidays.*

7. **Interpretation of reports:**

9	**VIRAL HEPATITIS**	
9a.	**HEPATITIS SEROLOGY**	
1	HBsAg ELISA	Initially Reactive/Non reactive
2	HBeAg ELISA	Positive/ Negative
3	Anti- Hepatitis B Core Antigen IgM (Anti-HBc IgM) ELISA	Positive/ Negative
4	HBeAb ELISA	Positive/ Negative
5	Anti HBs Antibody ELISA	Positive/ Negative
6	Anti- Hepatitis A Virus IgM Antibodies (anti-HAV IgM) (ELISA)	Positive/ Negative
7	Anti- Hepatitis E Virus IgM Antibodies (anti-HEV IgM)(ELISA)	Positive/ Negative
8	Anti HCV Total antibodies by ELISA	Initially Reactive/Non reactive
9b.	**MOLECULAR BIOLOGY**	
1	Real Time PCR with Viral Load estimation For Hepatitis B Virus (Quantitative) Truenat	Detected/Not detected (If detected viral load in IU/ml)
2	Real Time PCR with Viral Load estimation For Hepatitis C Virus (Quantitative) Truenat	Detected/Not detected (If detected viral load in IU/ml)

8. **Procedure for report issuance:**

Hepatitis Virus serology:

Reports (except for Anti- Hepatitis A Virus IgM Antibodies (anti-HAV IgM) ELISA and Anti- Hepatitis E Virus IgM Antibodies (anti-HEV IgM) ELISA) are entered on e-hospital and verified electronically. Verified reports can be downloaded and printed at OPD.

Reports for Anti- Hepatitis A Virus IgM Antibodies (anti-HAV IgM) ELISA and Anti-Hepatitis E Virus IgM Antibodies (anti-HEV IgM) ELISA are entered on virology laboratory in-house database. Printouts of report are verified manually by authorized signatory.

Hepatitis Viral Load Testing-

Data is entered in virology laboratory in-house database and printouts of report are verified manually by authorized signatory

9. **Sample retention period:**

Hepatitis serology (Serum)	72 hours after release of reports
Hepatitis viral load and RNA/DNA	72 hours after release of reports

10. **Procedure for complain/ suggestions**: Feedback form and complaint box are available at sample collection sites.

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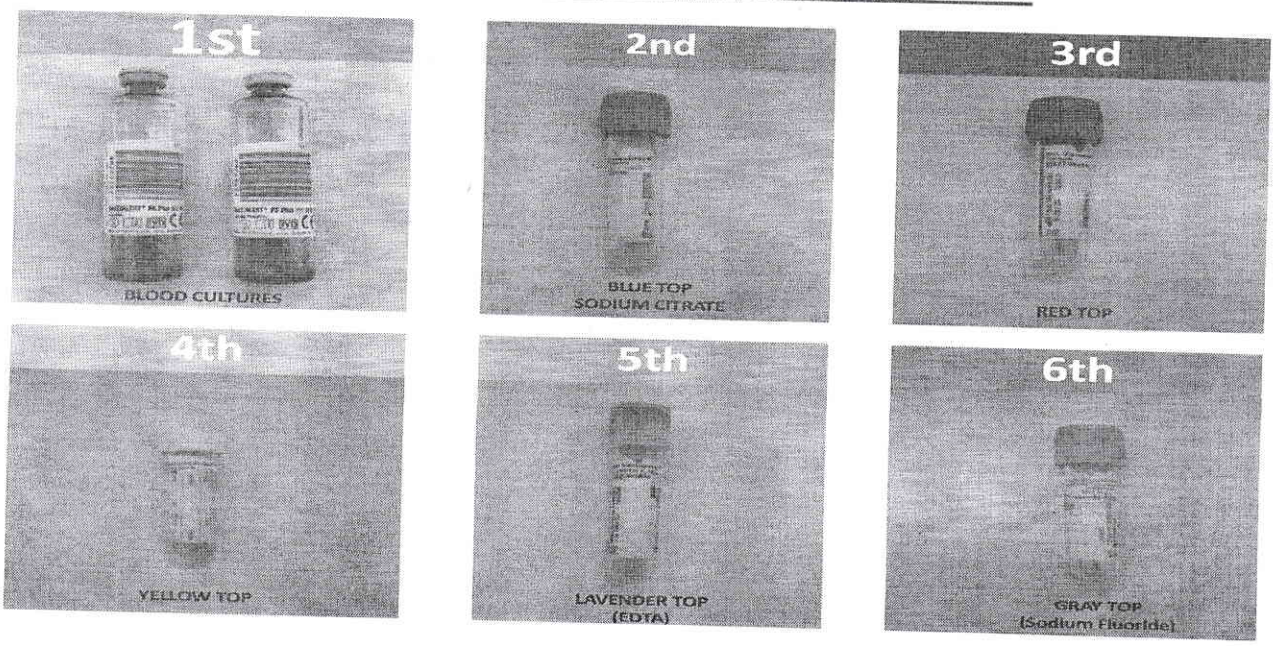
Appendix-10

BLOOD SPECIMEN COLLECTION ORDER OF DRAW



Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes. The recommended order of draw is:

1. **First-** blood culture bottle (**BD BacT/ALERT**)
2. ***Second-** coagulation tube (**light blue top**).
3. ***Third** – clot activator serum tube (**red top**)
4. **Last draw** - additive tubes in this order:
    1. SST (**gold top**). Contains a gel separator and clot activator.
    2. EDTA (**lavender top**)
    3. Oxalate/fluoride (**light gray top**)

Examine list of tests ordered.

Decide on tubes to be used for appropriate sample collection.

Lineup tubes using chart above for order of draw. Proceed with sample collection after skin cleaning as per SOP.

Note: *Order 2nd and 3rd to be interchanged if non additive serum collection tube used.

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Revision Summary

Issue No	Effective date	Revised By	Revision Summary
03	05.07.2024	NA	NA