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Madya Pradesh

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RELEASE AUTHORIZATION

THIS PRIMARY SAMPLE COLLECTION MANUAL IS ISSUED UNDER THE AUTHORITY OF

Dr.Srilatha

Director (Lab Operations)

SagePath® Excellence In Health Care

SAGEPATH LABS PVT LTD

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AMENDMENT RECORD SHEET

Guideline for using Amendment Record Sheet:

This Departmental Manual belongs to **SagePath Labs**, and any Amendments made to this manual from time to time shall be traced through the below format to show the current revisions made to this Manual. When a revision of a section of this manual is issued, the old Issue will be withdrawn to prevent its inadvertent use. The arrangement of the Amendment details would be such that the latest amendment (decided by Date) will be mentioned last following to the previous amendments made, arranged in chronological order.

AMENDMENT RECORD

Sr. No.	Chapter No.	Section No.	Date of Amendment	Amendment Made	Reason for Amendment	Reviewed by QM	Approved by Director (Lab Ops.)

CONTROL OF THE MANUAL

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable.

The holder of the copy of this Manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

Quality Manager is responsible for issuing the amended copies to the copyholders, the copyholder should acknowledge the same and he /she should return the obsolete copies to the Quality Manager.

The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.

The following personnel of SagePath Labs are holders of controlled copies of this document with the copy number mentioned against their names.

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3	Copy No. 3	All Online Users of SPL	22-12.2021	

MANUAL AWARENESS CERTIFICATE

The following personnel of SagePath Labs are fully aware of the contents in this manual.

Sr. No.	Name	Designation	Signature
1.			
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PREFACE

SagePath Labs Pvt Limited is an emerging Diagnostic Service provider on the horizon with a promise to ensure **PATIENTS & PARTNERS FIRST / QUALITY & COMPLIANCE / RELIABILITY / ACCURACY**. SagePath has ventured into the foray of complete Diagnostic Services by setting up a State of the Art Central Clinical Reference Lab (herein referred to as Medical Laboratory) at Hyderabad, Telangana and plans to grow and acquire bigger dimensions with an aim to become a global network of highly automated and sophisticated diagnostic laboratories synonymous with cutting-edge technology, accuracy, efficiency, dedicated customer service and above all the stringent ethical practices.

The Primary Sample Collection Manual is prepared to detail the process and procedures to be maintained on the basis of provisions of ISO 15189-2012 and NABL-112. The Medical Laboratory complies with NABL and NACO guidelines and meets ever growing needs of customers. The facilities, experience and expertise available with Medical Laboratory would enable to cater exclusively to the wide range of clientele covering Hospitals, Nursing Homes, Pathological Labs and Clinics, which basically serve as Pick up Points (PUPs).

This present Primary Sample Collection Manual is Version-I. The Primary Sample Collection Manual is under document control and only Quality Manager is authorised to revise and change the Primary Sample Collection Manual upon the approval of Director (Lab Ops.).

SagePath Labs (P) Limited would always make every effort for continuous improvement. Whenever necessary, Primary Sample Collection Manual would be revised to bring in new issues. The index of various elements and functions mentioned in this Manual is given in Table of Contents.

The contents of the Primary Sample Collection Manual are confidential as applicable to Sagepath Labs and its pick up points.

I hereby authorize to implement this Primary Sample Collection Manual (SPL-PSC-03, Version No: 1.0) with effective from Date……

Name: -Dr.Srilatha

Director (Lab Operations)

CHAPTER – 1
TEST AVAILABLE WITH CLINICAL REFERENCE LABORATORY

The Comprehensive lists of tests available with Clinical reference lab of **SagePath Labs** are as per the Directory of Services.However it is emphasized that the value of test is only as good as the Quality of sample collected.

Collected samples shall be stored and transported appropriately as per the instructions given in Primary Sample Collection (PSC) Manual, which is available in downloads – Sage Online Software. This will enhance the quality of our services and ensure that correct timely reports are made available to the respective Patients/Clients.

In case of any clarifications please contact Sagepath Labs, via telephone **(040-40125441)** or by email **(info@sagepathlabs.com)**.

CHAPTER – 2
SAMPLE COLLECTION PROCEDURES

1. **Purpose and Scope:** This manual provides the guidelines to the sample collection and technical staff, instructions for preparation of the patient for the test, sample collection techniques, separation if any and transportation of samples to **SagePath Labs (SPL) Private Limited** for testing.

2. **Responsibility:**

2.1. It is the responsibility of all Customers/Clients (Hospitals, Nursing Homes, Diagnostic and Pathological Labs, Clinicians and Clinics) to follow the procedures given in the manual during sample collection and transportation.

2.2. It is the responsibility of the Laboratory staff members to ensure that the samples are received as per the given requirement.

2.3. It is the responsibility of the Director (Lab Ops), HODs, Pathologists, Group Leaders and QAD personnel to verify the compliance of the same at the laboratory.

2.4. It is the responsibility of the Head of Sales and Sales team to implement the same.

3. **General Consideration**

3.1. Laboratory tests results contribute relevant information about a patient's health. Correct diagnosis relies on the accuracy of test results. Correct and adequate patient preparation, specimen collection, and specimen handling are essential prerequisites for accurate test results. The accuracy of test results is dependent on the integrity of specimens.

3.2. Test Interferences: Certain foods, drugs, investigations involving injection/ingestion of dyes, radiological investigations, etc., may interfere in thecorrect evaluation/estimation of some analytes. As a general rule, any such interfering item/s should be discontinued for a period bcorresponding to 2.5 half lives in vivo, or 7–10 days. If for therapeutic concerns the substance/s cannot be withheld, the

treatingphysician should be made aware to either clinically evaluate the necessity of the test or to correlate the results with the limitation.

4. Sample Collection General

4.1. Trained Personnel for Sample Collection:

4.1.1. Ensure that the trained personnel are deputed for Patient Sample collection.

4.1.2. Training should be given on Phlebotomy procedures, personnel safety, handling of emergencies during specimen collection, handling and packing of specimens, handling and cleaning of biological spills.

4.1.3. Periodic training has to be provided to all the personnel involved in the specimen collection.

4.2. Collection and Safety Precautions:

4.2.1. Wear gloves while handling blood or serum.

4.2.2. Do not mouth pipette.

4.2.3. Use 1% sodium hypochlorite solution to clean any spillage of blood or serum.

4.2.4. Report any accidents – however minor.

4.2.5. Haemolysed, chylous and contaminated samples are unsatisfactory for testing.

4.2.6. Avoid 'bubble formation' while diluting.

4.2.7. All blood samples are considered potentially infective – especially for HIV and Hepatitis B & C. Therefore adequate infection control precautions should be taken while handling blood and serum.

4.3. Universal Safety Precautions:

4.3.1. Wash hands before and after handling patients or specimen collection.

4.3.2. Handle the blood and body fluids of all patients as potentially infectious.

4.3.3. Wear gloves for potential contact with blood and body fluids.

4.3.4. Place used needles after destroying immediately in nearby impermeable container (sharps disposal container).

4.3.5. Do not recap or manipulate needle in any way.

4.3.6. Wear protective eye wear and mask if splatter with blood or body fluids is possible.

4.3.7. Wear gowns when splash with blood or body fluids is anticipated.

4.3.8. Handle all linen soiled with blood and/ or body secretions as potentially infectious.

4.3.9. Process all laboratory specimens as potentially infectious.

4.3.10. Wear mask for open tuberculosis cases respiratory and air-borne infections.

4.3.11. Mouth pipetting is prohibited.

4.3.12. Universal precautions are "to protect PATIENTS and STAFF from the spread of blood borne viruses (HIV/Hepatitis) or other harmful microorganisms that may be present in blood or body fluids.

4.3.13. Universal precautions apply to blood, body fluids containing visible blood, semen, vaginal fluid, cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluid needles, scalpels and other sharp instruments.

4.3.14. Universal precautions do not apply to Faces, nasal secretions, sputum, sweat, tears, urine and vomitus.

4.3.15. Consider all blood and certain body fluids of all patients as POTENTIALLY INFECTIOUS for HIV, HBV and other blood borne pathogens.

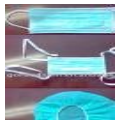
4.3.16. Infectious material must be handled in a manner that minimizes splashing, spraying, splattering, and generation of droplets.

WEAR PERSONAL PROTECTIVE EQUIPMENT

4.3.17.  Gloves are to be worn when hand exposure to blood and/or OPIM (other potentially infectious material) is anticipated, such procedures include phlebotomy, specimen collection, open wound contact and when handling or touching contaminated items or surfaces.

4.3.18.  Cover any existing cuts or lesions with a waterproof dressing/plaster before wearing gloves

4.3.19.  Gowns and disposable plastic aprons are required during procedures when splashing with blood and/or OPIM is anticipated.

4.3.20.  Masks,  face shields, ventilation devices and protective eye wear are required during procedures when splashing, spraying, splatter or droplets of blood and OPIM to the eyes, nose or mouth is anticipated.

4.3.21.  N-95 TB respirator masks are required for protection against tuberculosis. Regular masks are required for protection against other airborne transmitted diseases such as chickenpox

4.3.22. 

Use good HAND HYGIENE. It is required before and after contact with patients and specimens, wearing gloves or other PPE, contact with mucous membranes. Hand hygiene may be accomplished with either waterless disinfectant or soap and water washing.

4.3.23.  Always dispose of SHARPS at the point of use in puncture proof containers. Do not dispose of sharps with other clinical waste.

4.3.24.  Do not RECAP OR MANIPULATE. Needles should not be recapped or manipulated in any way. Don't break, or bend needles. Don't reach your hand into a container that might contain sharps.

4.3.25. Disinfect blood/body fluid SPILLS correctly.

4.3.26. Dispose of waste and excreta carefully.

4.3.27. Disinfect linen heavily contaminated with blood/body fluids by soaking in 5% Sodium hypochlorite solution before sending to laundry.

4.3.28.  Flush eyes, nose, or mouth with water as soon as possible after contact with blood or potentially infectious materials.

4.3.29.  Don't eat, drink, smoke, apply cosmetics, or handle contact lenses in areas that could contain infectious materials.

4.3.30. Hepatitis B vaccination is strongly recommended for all employees who have the potential for occupational exposure to blood and OPIM. This is administered in a series of three injections followed by Anti HBsAg titre to confirm the response to vaccination.

4.4. Patient Preparation:

4.4.1. Many tests require patient preparation under certain specific conditions way to ensure reliable results. The best analytical techniques provide results that are only as good as the specimen that has been submitted for analysis.

4.4.2. Approach thepatient pleasantly, confidently and in a friendly manner. Inform the patient that blood is going to be drawn from him/ her and that it will not hurt and get his/ her confidence and co-operation.

4.5. Instructions to Patient :

4.5.1. Following instructions to be followed prior to diagnostic check-up

4.5.2. Contact our phlebotomist to confirm type of investigation, nature of sample and kindly follow certain prerequisite conditions for diagnosis if specified.

4.5.3. Consume a low fat balanced meal with a min/max of 150 glucose at least 3 days prior to test

4.5.4. Fasting conditions to be observed unless advised otherwise, should be atleast for 10-12 hrs prior test. If non-vegetarian / lipid rich food consumed .a 14 hours fast is recommended.

4.5.5. Refrain from smoking /consumption of alcohol/drugs for atleast 12 hours prior to test is mandatory.

4.5.6. Wear comfortable /loose fitting garments for investigation.

4.6. Fasting Requirements:

4.6.1. For Majority of tests performed on Serum, Whole Blood, Plasma a fasting sample (10-12 Hours) is preferred.

4.6.2. The Fating Sample provides information that reflects the physiological baseline of the Patient.

4.6.3. Information can easily be compared o information from tests obtained at other times and provides a means of reliable monitoring of patient's condition for the duration of care.

4.6.4. Non-fasting samples are lipemic, containing high triglycerides from food which interfere with many analytical procedures.

4.7. Instructions to PSCs /SCFs for Pre-analytical requisites :

4.7.1. Fill PSCs/SCFs pre-printed TRF / Online work order with correct details of Patient name, Age & DOB , Sex refereeing doctor's name and Sample type , Test/s requested along with test code/s ,test/s name ,date & time of sample collection ,sample transit temperature

4.7.2. Fill respective consent form where required/mandatory; refer to Sage online Download section.

4.7.3. Barcoding Instructions

4.7.3.1. Use Appropriate Barcode labels.

4.7.3.2. Place label directly under the tube cap.

4.7.3.3. Place the barcode straight along the length of the tube

4.7.3.4. Leave visible window to see Blood sample

4.7.3.5. Do not modify numbers on the barcode by hand.

4.7.3.6. Do not use ink/marker or write on the barcode label.

4.8. Procedure for Phlebotomy:

4.9. Patient Identification:

4.9.1. Patient identification is extremely important in blood sampling. Identify the patient by name and age. Enter the details in Sage Online Work Order Format in Sage Online Software (SOS-LIMS) or on test request form with the barcode numbers to be applied on blood collection tubes. The patient's identity has to be verified by asking the patient to identify him or her through their name and age.

4.9.2. Ensure all consumables and materials required for vein puncture are available before starting the procedure.

4.9.2.1. Blood collection System (Needle, Tube holder and Vacutainers)

4.9.2.2. Bar code labels

4.9.2.3. Use personal protective equipment (PPE) as applicable

4.9.2.4. Sterile disposable gloves

4.9.2.5. Sterile swabs

4.9.2.6. Disinfectant/Sterilizer

4.9.2.7. Band aid

4.9.2.8. Tourniquet

4.9.3. Verify, before collecting the sample, if the patient has followed the instructions regarding preparation, if any, required for the tests, if not inform the patient/attendant suitably after verifying with the Directory of Services.

4.9.4. Select the vein puncture site first.

4.9.5. Use the median cubital vein at the bend of the elbow or the cephalic or basillic vein in the elbow.

4.9.6. Use of wrist veins acceptable for vein puncture.

4.9.7. Select a vein that looks and feels fullest.

4.9.8. Do not select the following areas for vein puncture.

4.9.8.1. Healed burn areas

4.9.8.2. Areas with hematoma

4.9.8.3. Veins over a scar from surgery or burn

4.9.9. Clean selected site of vein-puncture with 70% isopropyl alcohol/rectified spirit and allow it to air dry. Cleanse vein puncture site in a circular fashion, beginning at the site and working outward.

4.9.10. Apply the tourniquet. Ensure that the patient is not hurt by this procedure.

4.9.11. Do not apply tourniquet within 4 to 6 inches of the vein-puncture site.

4.9.12. Do not apply tourniquet for more than one minute while drawing blood. (As soon as blood enters the syringe release the tourniquet).

4.9.13. Do not ask the patient to pump the fist and do not use tourniquet while drawing blood sample for potassium, calcium or magnesium and lithium estimation.

4.10. Order of Draw:

4.10.1. Always draw blood in the following order to avoid cross-contamination of additives between tubes. The recommended order of draw is:

4.10.1.1. First – Blood Culture

4.10.1.2. Second - coagulation tube (Light Blue Citrate stopper)

4.10.1.3. Third - Non-additive Serum tube (Plain Red stopper)

4.10.1.4. Fourth - Heparin Tube (Green Stopper)

4.10.1.5. Fifth - EDTA Tube (Lavender stopper)

4.10.1.6. Sixth - Oxalate/fluoride (Light Gray stopper)

4.10.2. Blood should be collected only in appropriate vacutainers specified in directory of services for different types of tests and to maintain ratio of anticoagulant to the volume of blood collected. Avoid under filling and over filling of tubes.

4.10.3. Gently but thoroughly mix blood with anti-coagulant by inverting as given in the below table or by using a Hemo mixer.

4.10.4. After blood is drawn cap the needles and dispose in sharps container containing 1% sodium hypochlorite solution and syringes in yellow bags.

4.10.5. For serum, allow the blood to clot for at least 30 min. and separate by centrifugation and transfer the serum to screw capped plastic vials.

4.10.6. For plasma, mix the blood with the anticoagulant by gently inverting the tube 8–10 times and separate by centrifugation. Transfer the plasma to screw capped plastic vials.

Colour Coded Vaccutainer	Anticoagulant	Number of Inversions	Vaccutainer Volume (ml)
Blue Top (Light Blue)	Sodium Citrate	3-4	2.7
Grey Top	Sodium Fluoride	8-10	2.0
Green Top	Sodium Heparin	8-10	4.0
Lavender Top	Potassium EDTA	8-10	3.0
Lemon Yellow Top	Acid citrate dextrose (ACD)/CPDA	5	6.0
Light Green	Lithium Heparin	8-10	4.0
Red Top	No preservative, gel or anticoagulant	No Inversions	4.0
Red/Golden Yellow Top	Gel barrier for serum separation (SST)	5	3.5
White Top	Plasma preparation tube (PPT)	3-4	5.0

5. Centrifugation of SST (Serum Separator Tube):

5.1. After drawing specimen into SST gently invert the tube 5 times and place vertical in test tube rack for 30 minutes till the blood clots completely.

5.2. Centrifuge at 3000 rpm for 10 minutes.

5.3. Hold the Specimen at room temperature till separation, don't refrigerate specimen till separation of serum.

5.4. Balance the tubes while placing them in the centrifuge.

5.5. Keep specimens refrigerated till packed and transported to the laboratory at the required temperature as per the Directory of Services.

6. **Precautions to be taken during Centrifugation:**

6.1. Stopper the tubes tightly and balance the weight of buckets, tubes and their contents on opposite side of the rotor should not differ by more than 1%. Tubes filled with water may be used to equalize the weight if required.

6.2. Speed control switch should be set at zero before starting the centrifuge and adjusted to the required speed.

6.3. Do not open the lid while the centrifuge is in operation.

6.4. Do not stop the rotating tubes with your hands. Let them stop on their own.

6.5. In case a tube breaks, the bucket, cushion and chamber should be carefully cleaned with 1% Sodium hypochlorite solution.

6.6. Always wear gloves while handling samples.

7. **Requirements at Pick-Up Points:** SAGEPATH does not have any sample collection centres of its own. The pick-up points constitute Hospitals, Nursing Homes, Diagnostics Labs and Clinics from where the samples are picked up. In line with the company Quality Policies relevant requirements of standards ISO 15189 and NABL 112 have to be adhered by the pick-up points. The minimum guidelines specified as per NABL – 112 are listed below.

7.1. General Requirements:

7.1.1. Adequate size for sample collection with adequately lit and clean.

7.1.2. Temperature-controlled environment for sample collection area.

7.1.3. Hand washing facilities.

7.1.4. Clean toilet facility in the vicinity of sample collection.

7.1.5. Provision of privacy during sample collection.

7.1.6. Reception and waiting area to be away from collection area.

7.1.7. Display hours of operation.

7.2. Equipment:

7.2.1. Refrigerator with temperature monitoring.

7.2.2. Centrifuge, if needed.

7.2.3. Proper storage for supplies.

7.2.4. Suitable chair and/ or couch for collection of blood.

7.2.5. Basic first-aid materials.

7.2.6. Telephone.

7.3. Sample Collection Materials:

7.3.1. Material required for specimen collection e.g. blood collection tubes, syringes, serum tubes, swabs etc have to be available at the sample collection area. Make sure that there is no expired material in the sample collection area.

7.4. Staffing Requirements:

7.4.1. Adequately staffed based on hours of operation.

7.4.2. Initial training to be provided on sample collection, packing and transportation to the staff. Biannual training to be conducted with competency evaluation.

7.4.3. Staff to be trained on first-aid measures to deal with situations they are likely to encounter in the course of specimen collection.

7.4.4. Aprons to be worn by the staff.

7.5. Documentation:

7.5.1. List of services provided – Directory of Services.

7.5.2. Primary Sample Collection manual.

7.5.3. Log Book on Outsourcing of samples.

7.6. Health and Safety:

7.6.1. Collection staff should observe universal precautions (to wear gloves, lab coat, mask protective).

7.6.2. Collection staff should be vaccinated against Hepatitis B.

7.7. Safety and Waste Disposal:

7.7.1. Approved receptacles for sharps and for contaminated waste.

7.7.2. Transport and disposal of waste in accordance with applicable regulatory requirements

7.8. Complaints:

7.8.1. Pick-up Points shall have provision for receiving the complaints.

CHAPTER – 3
SAMPLE COLLECTION SPECIFIC DEPARTMENTS

1. Sample Collection – Biochemistry and Immunoassay

1.1. Sample collection for Therapeutic drugs:

1.1.1. The time of blood collection and drug dosage are an important part of therapeutic drugs monitoring.

1.1.2. When a person takes a doe o drug the amount in the blood rises for a period of time, Peaks and then begins to fall, usually reaching its lowest level or through just before the next dose. To be effective peak levels should be below toxic concentrations and trough levels should remain in the therapeutic range.

1.1.3. Consistent and accurate interpretation of the results depends on the sample collection time.

1.1.4. If someone is unable to take medication or have blood drawn at the appropriate time interval then should consult to clinician before the sample is collected.

1.1.5. Do not use gel barrier tubes for therapeutic drug monitoring or toxicological analysis

1.1.6. Serum separator material extracts lipophilic substances (most drugs), resulting in a falsely low drug concentration result.

1.1.7. Collect the specimen in Red Top (No Additive) tube containing no anticoagulants or preservatives.

1.1.8. Let the tube stand in the test tube rack for 30 minutes till blood clots.

1.1.9. Centrifuge and transfer the serum with a pipette to a screw capped vial. Serum should be clear and free from all red cells.

1.1.10. Enclose clinical history of the patient with quantity of drug dosage and time of drug dosage.

1.1.11. The serum should be clear and free from all red blood cells.

Sr.No	Drug Category	Drugs	Draw Times	Treatment Use
1	Cardiac Drugs	Digoxin, Digitoxin	Determination is needed within 6-24 hrs after the previous dose	Congestive heart failure angina, arrhythmias
2	Antipileptis	Phenobarbital Phenytoin,Valproica cid,Carbamazepine	Trough level-Collect just prior to next dose	Epilepsy prevention of seizures , sometime to stabilize moods
3	Immunosuppressants	Cyclosporine,Tacroli mus,Sirolimus	Trough level-Collect just prior to next dose	Prevent rejection of transplanted organs, autoimmune disorders
4	Psychiatric drugs	Lithium, Valproic acid	Trough level-Collect just prior to next dose	Bipolar disorder , depression

1.2.Sample collection for Glucose Tolerance Testing (GTT):

1.2.1. Collect sample in Sodium Fluoride for glucose testing.

1.2.2. First collect fasting (10-12 hours fasting) sample and then give 75gof glucose dissolved in 250 mL of water orally to the patient

1.2.3. Note the time of dose consumed, collect blood urine sample at ½ hour intervals (½ hr,1 hr, 1 ½ hr,2 hr).

1.2.4. Label all samples correctly with timings transport at appropriate conditions.

1.2.5. For children and the obese, the glucose load is calculated as 1.75 kg of body weight.

1.3.Sample collection for Glucose Challenge Testing (GCT) :

1.3.1. Collect Sodium fluoride plasma sample for glucose challenge test. First collect fasting (12 hrs fasting) sample and then give 50g of glucose dissolved in 250ml-300mL of drinking water orally to the patient. Note the time of dose given, collect the second sample at 1hr interval.

1.4. Sample Collection Lipid Profile and LDL Sub-Fractions:

1.4.1. The Patient should fast overnight for a minimum of 12 hours.

1.4.2. It is recommended to discontinue all drugs for at least 2 weeks prior to test, after seeking consent from Physician.

1.4.3. The patient should maintain a stable weight and normal diet for at least 1 week prior to test.

1.4.4. Avoid test for 4-8 weeks after an episode of Myocardial infarction or similar traumatic episode.

1.4.5. History of hypolipidemic medications, if given, is required for interpretation of results**.**

1.5. Special Handling of Labile Parameters:

1.5.1. All samples bearing labile parameters should be stored 2-8°C prior to transportation to the laboratory.

1.5.2. Specimen containers shall be transported in smooth condition avoiding shaking as much as possible.

1.5.3. Transport should be done at 2-8°C to maintain cold chain.

1.5.4. Depending on the labile parameters special storage conditions, specific temperatures, protecting from light will be required.

1.5.5. If analysis cannot be performed within 4-8 hours it is recommended to store the separated serum at 2-8°C depending on the stability conditions of the parameter.

1.5.6. After 48 hrs if sample stored at 2-8°C is not processed then store the sample at -20°C depending on the stability conditions of the parameter.

1.5.7. Repeatedly freezing and thawing is not recommended.

List of Labile Parameters

Sr.No	Parameters	Sample Type
1	Complement -3	Serum
2	Complement -4	Serum
3	Insulin	Serum
4	C-Peptide	Serum

5	iPTH	Serum
6	ACTH	Plasma EDTA
7	Calcitonin	Serum
8	Human Growth Hormone	Serum
9	Lactate	Serum
10	25-OH Vitamin D	Serum
11	Prothrombin Time	Plasam-Citrated
12	Fibrinogen	Plasam-Citrated
13	Anti Thrombin-III	Plasam-Citrated

1.6. Sample Collection for Double/Triple/Quadruple Marker Tests

1.6.1. Antenatal first & second trimester screening test samples should be collected at appropriate weeks of gestation period & send with dully filled Double/Triple /Quadruple Marker TRF for required clinical data.

1.6.2. Incomplete forms & out gestation samples will not be accepted.

1.6.3. Sample Acceptance Criteria:

1.6.3.1.8-13.6 Weeks for Double Markers

1.6.3.2.4-22 Weeks for Quadruple Markers

1.7. Sample Collection for Urine samples:

1.7.1. Instruct the patient to collect urine in sterile, wide mouthed container.

1.7.2. To prevent contamination by normal vaginal, perineal and anterior urethral flora, patient is instructed to collect a clean-catch midstream urine specimen.

1.7.3. During urination, the first part of the stream is discarded and most of the remaining urine is collected in the sterile container. Discard the last few drops.

1.7.4. To avoid contamination and spillage, the lid has to be replaced immediately and tightly.

1.7.5. Collect a minimum 15 ml of a random sample of mid-stream urine.

1.7.6. Collect Urine samples for Urobilinogen in dark/amber coloured bottles only. Issue amber coloured urine containers to patients.

1.7.7. Container shall be labelled appropriately and transported to the laboratory

1.7.8. 24 Hrs Urine Collection

1.7.8.1. Most urine chemistry tests require 24 hours urine collection, if a preservative is required it is the important that the preservative is added prior to start of the collection.

1.7.8.2. Majority of the tests require Hydrochloric acid (HCL)as preservative. Recommended volume of HCL required is detailed below

Age	**Average Urine Output in mL**	**Concentration of HCL**	**Volume of HCL(mL/24 hour of HCL to be added**
New born (01 Yrs)	50-300	50 %(6 N)	1 mL
Infant(1-2 Yrs)	350-550	50 %(6 N)	1-2 mL
Child(2-9 Yrs)	500-1000	50 %(6 N)	2-5 mL
Adolescent(10-20 Yrs	700-1400	50 %(6 N)	5-8 mL
Adults	800-2500	50 %(6 N)	5-10 mL

Note: Proper collection and preservation of 24 hour urine specimens are essential for accurate test results. Unless the physician indicates otherwise, instruct the patient to maintain the usual amount liquid intake and not to consume alcoholic beverages. During the collection period, place the 24 hours urine container provided by laboratory in a refrigerator or cool place, to prevent growth of microorganisms and possible decomposition of urine constituents.

1.7.8.3. Add Required Preservative suitable for the analyte to be tested to the container.

1.7.8.4. Instruct the patient that the preservative in the 24 hours container should not be discarded.

1.7.8.5. Collect each void in a small container and carefully pour the urine into the 24 hour container to avoid any possible acid burns.

1.7.8.6. On the day of collection, have the patient empty his/her bladder of first morning urine into the toilet (not to be included in the 24 hour collection). Write the date and time of voiding, on the container label (e.g., 0800 hrs on 08 March 2008).

1.7.8.7. Collect the patient's next voiding and add it as soon as possible to the 24 hour container.

1.7.8.8. Add all subsequent voiding to the container. The last sample collected should be the first specimen voided the following morning at the same time as the previous morning's first voiding. (i.e., 0800 hrs on 09 March 2008).

1.7.8.9. Mix the contents of the container gently but thoroughly. Examine to ensure that the contents appear homogeneous.

1.7.8.10. Measure and note the total volume of urine, (unless otherwise specified in the Alphabetical List to Tests) on the Specimen container and the Test Request Form. Do not measure the total volume for Trace Element analysis. Do not send the entire urine volume. Mention the total urine volume on the TRF and send required amount in a container.

1.7.8.11. Transfer, label and ship the required aliquot of urine to the screw-cap plastic containers.

1.8. Dietary Restrictions for 24 hours Urine Collection:

1.8.1. Some of the dietary constituents will interfere in the analysis of 24 hours urine specimen. Hence, a restricted diet for 48 hours prior to the collection should be followed for the following analytes:

1.8.2. VMA: The patient should strictly avoid theophylline, chocolate, vanilla, banana, alcoholic beverages, tea/coffee, tobacco and strenuous exercise at least 72 hrs before and during specimen collection.

1.8.3. Urinary Catecholamines: The patient should strictly avoid alpha-one blockers, aminophylline, amphetamines, ampicillin, beta-blockers, ephedrine,

imipramine, methyldopa, MAO inhibitors, nicotine, phenacetin, phenothiazine, theophylline, vasodilators, aspirin, PAS, alpha-two agonists, bromocriptine, calcium channel blockers (long term use), clofibrate, MAO inhibitors, propranolol, penicillin, reserpine, thyroxine, alpha-methyldopa, isoproterenol, labetalol, mandelamine, paracetamol, cimetidine, metoclopramide, vigorous exercise, alcoholic beverages, tea/coffee and tobacco at least 72 hours before and during specimen collection.

1.8.4. Plasma Catecholamines: The patient should strictly avoid drugs like aldomet (alpha methyldopa), labetalol, isoproterenol, isoetharine, alpha-one blockers, aminophylline, amphetamines, ampicillin, beta-blockers, ephedrine, imipramine, nicotine, phenacetin, theophylline, phenothiazine, vasodilators (minoxidil, nitrates & hydralazine), aspirin, PAS, alpha-two agonists, bromocriptine, calcium channel blockers (long term use), L-dopa, cimetidine, clofibrate, MAO inhibitors, propranolol, penicillin, reserpine, thyroxine, vigorous exercise, severe stress and cigarette smoking at least 72 hrs before and during specimen collection.

1.8.5. Urinary Metanephrines: Patient should strictly avoid alpha-methyldopa, buspirone, codeine, isoproterenol metabolite, mandelamine, L-dopa, parcetamol, metoclopramide, pepper, alcoholic beverages, tea/coffee, tobacco and strenuous exercise at least 72 hours before and during specimen collection.

1.8.6. HVA: The patient should strictly avoid L-dopa at least 72 hrs before and during specimen collection.

1.8.7. 5-HIAA: The patient should strictly avoid banana, kiwis, walnut, avocado, eggplant, pineapple, plum, tomato and drugs including fluorouracil, melphalan, paracetamol, acetaminophen, caffeine, heparin, L-dopa, reserpine, salicylates, chlorpromazine, imipramine, isoniazid, MAO inhibitors, phenothiazines, promethazine, alcoholic beverages, tea/coffee, tobacco and strenuous exercise at least 72 hrs before and during specimen collection.

1.9. Estimation of Metals:

1.9.1. Whole Blood: Collect blood in a Green top (Heparin) or Lavender (EDTA) tube free of the trace elements. Heparin sample is suitable for Lead, Arsenic Cadmium assays and the EDTA sample is suitable for Mercury analysis.

1.9.2. Patient shouldrefrain from eating sea food, antacids, or taking vitamins with mineral supplements prior to sample collection.

1.9.3. Urine: 20 ml aliquot of random or 24 hr urine samples to be collected in special metal free containers using a metal free beaker. Each sample of urine should ideally be passed into a metal free beaker and then transferred to the metal free container. For 24 hour collection, after shaking the can, aliquot 20 mL sample in a metal free transport vial from the kit. Measure remaining volume and document on TRF and vial. Special acid washed metal free container kit is available from PCL. The containers are suitable for Arsenic, Bismuth, Cadmium, Chromium, Cobalt, Copper, Lead, Manganese, Mercury, Thallium and Zinc assays.

1.9.4. Preparation of Metal and Trace Element Free Containers:

1.9.4.1. Rinse the plastic can with distilled water.

1.9.4.2. Take concentrated nitric acid, diluted to a ratio of 1:3 in distilled water (1 part of acid and 3 parts of distilled water).

1.9.4.3. Add acid water in the plastic can. Rotate the can 7-8 times first clockwise and then anticlockwise vigorously.

1.9.4.4. Leave the acid water in the can for a minimum period of 18-24 hrs.

1.9.4.5. Pour out the acid water from the can (This water may be re-used for 8 such procedures).

1.9.4.6. Rinse the can 8 times with distilled water discarding each rinse (Do not re-use).

1.9.4.7. Finally rinse the can with de-ionized/double distilled water 5-6 times (Do not re-use).

1.9.4.8. Air dry container overnight

2. Sample Collection-Clinical Pathology

2.1. Stool sample

2.1.1. Stool has to be collected in a sterile container with a scoop and tight-fitting leak proof lid.

2.1.2. A small quantity has to be collected with the scoop provided.

2.1.3. After collection, the lid has to be replaced tightly.

2.1.4. Container shall be labelled appropriately and transported to the laboratory for processing.

2.1.5. Collect stool samples only in the clean dry sterile containers provided by the laboratory.

3. Sample Collection-Cytopathology

3.1. The success of a laboratory's cytopathology program depends on the combined efforts of the ordering physician and his/her staff and the laboratory, obtaining the patient's medical history and an adequate, properly fixed specimen. A final report, using descriptive cytopathology terminology and an accurate interpretation are required to assure appropriate follow up.

3.2. Cyto pathology Test Requisition Form: Use of **Cytopathology Test Request Form**, is mandatory and includes the following information:

3.2.1. Patient's name, age, sex, and telephone number.

3.2.2. Date of specimen collection.

3.2.3. Source of material submitted (cervical, endocervical, vaginal, or other gynaecologic or non-gynaecologic site).

3.2.4. Submitting physician's name and phone number.

3.3. For Gynec Specimens:

3.3.1. Last menstrual period (LMP).

3.3.2. Pertinent clinical information (routine exam, pregnant, postpartum, hormone therapy, oral contraceptives, hysterectomy, postmenopausal, pelvic radiation, etc).

3.4. For Non-Gynec Specimens:

3.4.1. Source and specific site (left, right, quadrant, etc.)

3.4.2. Nature of lesion (solid/cystic, mobile/fixed, functional/non-functional etc).

3.4.3. Any other pertinent history (previous survey, presence of other masses, previous abnormal findings).

3.4.4. Mammography, X-ray or other imaging findings.

3.4.5. Nature of aspirate.

3.5. Conventional PAP Smear:

3.5.1. Complete the test requisition form.

3.5.2. Write the patient's name at one end of the slide (unlabeled slides may not be accepted).

3.5.3. Insert the extended tip of the spatula in the endocervical canal and rotate allowing blunt edge of spatula to scrape the ectocervix.

3.5.4. Insert the cytobrush into the endocervical canal until the bristles are barely visible. Turn 90°–180° and remove. Brush not recommended for use during pregnancy.

3.5.5. Smear the extended tip spatula (cervical) specimen along the entire length of the slide using only half of the surface. Roll the cytobrush (endocervical) specimen along the entire length of the slide using the remaining half of the slide surface. Bending the bristles will help transfer the cells to the slide.

3.5.6. Immediately fix slides in a jar containing 90% ethanol or a mixture of equal volumes of 50% ethanol and ether for a minimum of 30 minutes.

3.5.7. DO NOT use commercial hair spray as a fixative. The variability of ingredients results in poor specimen preservation.

3.6. Liquid Based Cytology:

3.6.1. Use Special Collection Kit available from SagePath only. Collect Endocervical smears with a brush after inserting the speculum.Dip and swirl the brush completely into the container with liquid fixative. Mix thoroughly. Transport at room temperature.

3.6.2. Specimen Collection - Non-Gynaecologic: Appropriate Fixatives for Non-Gynaecological Cytology specimens include:

3.6.2.1. Ethyl alcohol

3.6.2.2. Cytospray

3.6.2.3. Mixture of 50% ethanol + 50% ether

Smear:

3.6.2.4. Complete test requisition form.

3.6.2.5. Write patient's name on one end of slide.

3.6.2.6. Submit slide(s) of material from any source that can be evaluated cytologically

3.6.2.7. Fix slide(s) immediately with Cytospray or immerse in alcohol for 3-5 minutes. Allow fixative to dry thoroughly before packaging slides for transport

3.6.2.8. Submit in a slide container, properly labelled.

Fluid

3.6.2.9. Complete test requisition form.

3.6.2.10. Submit fluid fixed with a minimum of 10 ml of fixative. Specimens greater than 10 ml should be fixed with a volume of fixative equal to the volume of the specimen.

3.6.2.11. Place fluid/fixative mixture in a tightly capped, leak proof, labelled container (label the container wall, not the lid).

3.6.2.12. Syringes are not acceptable specimen containers.

Source	Submission Requirements
Breast Cyst Aspiration	If aspirate is scanty, fluid may be smeared one drop at a time on clean, dry slides and immediately fixed. If aspirate is abundant, mix material with an equal volume of fixative.
Breast Secretion (Nipple discharge)	Drops of fluid from the nipple are smeared directly on clean glass slides and fixed immediately with Cytospray or immersed in alcohol for 3-5 minutes
Bronchial brushings	Swirl brush (es) used to prepare bronchial brushing slides in a

	container of fixative to dislodge additional specimen. Submit liquid specimen together with test requisition.
Bronchial washings	Mix with an equal volume of fixative or put specimen in at least 10 ml of fixative if specimen is less than 10 ml volume
Effusions	Mix material with an equal volume of fixative
Endometrial washings	Mix material with an equal volume of fixative
Esophageal Brushings	Swirl brush (es) used to prepare slides in a container of fixative to dislodge additional specimen. Submit liquid specimen together with test requisition.
Esophageal Washings	Mix material with an equal volume of fixative
Fine Needle Aspiration	Liquid based Fixative Technique
Gastric Brushings	Swirl the brushes in a container of fixative. The container wall should be labelled with the patient's name. Submit liquid specimen together with test requisition.
Gastric Washings	Mix material with an equal volume of fixative
Lymph Node (touch prep)	Fix immediately in alcohol or use Cytospray. Air dried slides should be labelled as such.
Peritoneal fluid	Mix material with an equal volume of fixative
Pericardial fluid	Mix material with an equal volume of fixative
Sputum	Submit early morning deep cough specimen prior to any food ingestion. Have patient rinse mouth with plain water before sputum is collected. Collect separate specimens on 3 consecutive mornings. Do not pool specimens. Mix material with an equal volume of fixative.
Pleural fluid	Mix material with an equal volume of fixative
Urine	Submit all specimens in an equal volume fixative

4. Sample Collection –Flow Cytometry: For various Immune deficiency panels the following procedure is to be adopted:

4.1. Collect 3 ml blood in Lavender Top (EDTA) tube. Specimens should be maintained strictly at 18-22°C and should reach the laboratory as soon as possible (maximum within 24 hours of collection). *Do not store samples in the refrigerator.*

5. Sample Collection-Histopathology

5.1. Instructions for Clinicians on Fixation of Specimens:

5.1.1. Specimens should be immersed in fixative within 1 hour of the biopsy or re-section procedure.

5.1.2. If delivery of a re-section specimen to the pathology department is delayed (ex: specimens from remote sites) the tumor should bisected prior to immersion in fixative. In such cases it is important the clinician ensure that the identity of the re-section margin is retained in the bisected specimen; alternatively, the margins may be separately submitted.

5.1.3. Complete the histopathology test requisition form and send along with the specimen(s). Each container and specimen must be separately identified on the test requisition form.

5.1.4. The test requisition should contain pertinent clinical information including patient's date of birth, sex, clinical information and anatomic location of tissue removed.

5.1.5. Place each specimen in a tightly secured container with 10% neutral buffered formalin. Specimen must be totally immersed in formalin. Do not allow specimens to dry.

5.1.6. Use a separate container for each separately identified specimen.

5.1.7. Do not crush the specimen with forceps, hemostats, or other instruments. Cautery will cause heat artifact. Do not freeze formalin fixed specimens.

5.1.8. Do not force a large specimen into a small container. Formalin must surround the specimen for proper fixation. Formalin volume to specimen ratio should be 10:1.

5.1.9. Label each container wall (not the lid) with patient's name, age/sex, referring clinician, site of specimen, tissue removal date and time, immersion of tissue in fixative data and time and barcode (VAIL ID).

5.2. Immuno Histo Chemistry (IHC):

5.2.1. Formalin fixed paraffin embedded blocks are to be submitted. Preferably submit one routinely stained H&E section of the block with appropriate clinical history and copy of histopathology report.

5.2.2. Alternatively submit specimens with fixed in 10% neutral buffered formalin for at least 6 hours, up to a maximum of 48 hours for HER2 testing and 72 Hours for Estrogen Receptor (ER) and Progesterone receptor (PR) testing. The volume of formalin should be at least 10 times the volume of the specimen. Decalcification solution with strong acids should not be used.

5.2.3. FNA unstained smears are also acceptable. Submit 2 smears for each marker requested. Smears to be fixed in liquid fixative(Absolute Ethanol or 50% Ethanol + 50% Ether) for a minimum of 30 minutes. Allow fixative to dry completely before transporting the slide mailer.

5.2.4. Special Stains: submit specimens as for Routine Histopathology or submit formalin fixed paraffin blocks. Attach Histopathology report, relevant clinical history and one Histology section of the block submitted

6. Sample Collection-Microbiology

6.1. Introduction:

6.1.1. Quality of results in Microbiology depends on the combined efforts of the ordering customer and the laboratory. Factors contributing to the successful isolation of potential pathogens range from sample selection, collection in proper container or transport medium

6.1.2. The Integrity of samples must be maintained during transport.

6.1.3. Pathogen isolation also depends on proper sample handling and pre-analytical fulfilment use of appropriate transport.

6.1.4. As many samples are collected through contaminated pathways, the quality of culture results is directly dependent on collection technique for urine, sputum, samples from the nasopharynx and superficial and deep wound samples.

6.2. Temperature: Appropriate storage and transport temperatures for clinical specimens are essential for successful isolation of organisms. If room temperature is required for a specific test, do not place the specimen in an environment where it would be exposed to extremes of heat or cold, so that fastidious organisms have less chance of survival. Refrigerated temperature can be maintained using a household or commercial refrigerator or cold packs. If refrigeration is requested, do not freeze the specimen

6.3. Test Requisition – Microbiology Specimens:

6.3.1. Ensure that the TRFs/Work Order for all microbiology specimens are accompanied with source of specimen, type of infection or organism expected and antibiotic usage history if any.

6.4. Transport Media: Transport media are required to maintain the viability of organisms during transportation to the laboratory. Certain fastidious organisms will not survive if not transported in required transport media. Transport media available are:

6.4.1. Aerobic Transport Medium: This is Amies media without charcoal used for transportation of swabs for aerobic culture. Store at refrigerated temperature till inoculated.

6.4.2. Stool Culture Transport Medium: CaryBlair Mediumis used for Transportation of stool samples for aerobic cultures and alkaline peptone water – if the sample is liquid and appears rice watery. Store at refrigerated temperature.

6.4.3. Blood Culture Bottles: This includes BACTEC PLUS AEROBIC/F (silver top) and BACTECPEDS PLUS/F (pink top). These bottles are stored at 2-25°C till inoculated.

6.4.4. All the transport media should be checked for expiry before use. Examine

transport media for cracks, contamination, excessive cloudiness and bulging or indented septum (in blood culture bottles). Do not use if any defect is noted.

6.4.5. Transportation of Bio-hazardous Material: When sending an isolate on culture media to the laboratory for identification and/or susceptibility testing, pack the organism in a double tube container and transport at required temperature. Mark the container- "Bio-hazardous".

6.5. Collection of Samples: Following are the considerations to be given while collecting the specimen:

6.5.1. Specimen should be collected from the relevant site with a minimum of contamination from adjacent tissues, organs or secretions e.g., throat swab should be taken from tonsillar areas avoiding contact of swabs with other areas. Similarly adequate cleaning of per urethral area and perineum before urine collection can prevent contamination.

6.5.2. Collection of sterile body fluids (e.g.,: joint, pleural or ascetic fluid) should always be preceded by thorough skin decontamination procedure as outlined below:

6.5.2.1. Prepare the skin by cleaning with 70% Isopropyl or Ethyl alcohol to remove surface dirt and oil

6.5.2.2. Wipe it again with Povidone-Iodine in concentric manner starting from the center and moving outwards. Allow it to dry for 2 minutes. If patient is allergic to Iodine use Savlon.

6.5.2.3. Again wipe the site with 70% Isopropyl or Ethyl alcohol to remove Povidone iodine. Allow the alcohol to evaporate for few seconds before collecting the sample.

6.5.3. Another factor contributing to successful isolation of organisms depends on the stage of disease e.g., enteric pathogens are present during acute or diarrhoeal stage. In Enteric fever blood cultures are usually positive in first week followed by stool and urine culture in 2nd and 3rd week respectively.

6.5.4. Sufficient quantity of specimen should be obtained to perform the requested

culture for adequate recovery of organisms.

6.5.5. Appropriate collection devices and specimen containers must be used for optimal recovery of organisms. Sterile containers must be used for collection of microbiology specimens.

6.5.6. The collection and transportation requirements for different microbiological specimens are presented in the table below:

SPECIMEN COLLECTION AND TRANSPORTATION FOR AEROBIC / FUNGUS / AFB CULTURE

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
1.	***Cerebrospinal fluid (CSF)***	Decontaminate the skin. Perform a sterile lumbar puncture. For micro-biological analysis it is best to submit second or third tube.	For Conventional culture: Submit 1-2 ml of CSF in a sterile screw capped container. Ship at 18–22° C. **Rejection Criteria:** Received Refrigerated/ Frozen.	Submit 1-2 ml of CSF in a sterile screw capped container. Ship at 18–22° C. **Rejection Criteria:** Received Refrigerated/ Frozen.	Submit 1-2 ml of CSF in a sterile screw capped container. Ship refrigerated. **Rejection Criteria:** Received frozen.
2.	***Eye, External Conjunctival Swab***	Remove make up. Cleanse skin around eye with mild antiseptic. Firmly stroke the swab 2-3 times over lower conjunctiva. Avoid eyelid border & lashes. Label carefully whether left or right eye. A swab for conjunctival culture should be taken prior to topical anaesthetic application	Submit swab in Aerobic transport medium. Ship refrigerated. **Rejection Criteria:** Specimen sent without transport media/ Received Frozen.	Submit swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria :** Dry swab. Specimen sent without sterile normal saline/received Frozen.	Submit 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria:** Received frozen.
3.	***Eye, Internal (Aqueous/ vitreous / Lacrimal Fluid***	Surgically collected. Label carefully whether Right or Left Eye.	Submit specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria:** Received frozen.	Submit the specimen as much as possible in a sterile screw capped container. Ship refrigerated. **Rejection Criteria:** Received frozen.	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria:** Received frozen.
4.	***Eye, Corneal scrappings***	Collected by physician. If conjuctival culture will also be submitted, collected	Submit the media at 18-22° C	Submit the media at 18-22° C.	Submit the specimen in 1 ml of sterile normal

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		them first. Instill 1-2 drops of topical anaesthetic. Using a sterile corneal spatula scrape corneal ulcers or lesions gently.	**Rejection Criteria :** Received Refrigerated/ Frozen.	**Rejection Criteria :** Received Refrigerated/ Frozen temperature.	saline. Ship refrigerated. **Rejection Criteria:** Received frozen.
5.	***Ear, External Ear swabs***	Clean the external ear. For cases with otitis externa remove debris, excess earwax and exudate from external canal. Use swab to obtain a specimen from active margin. Specify left or right ear swab	Submit swab in Aerobic transport medium. (Amies media without charcoal). Ship refrigerated. **Rejected Criteria :** Specimen sent without transport media/received Frozen.	Submit swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria :** Dry Swab, Specimen sent without sterile normal saline/Received frozen	Submit the swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria:** Received frozen
6.	***Ear, Internal (Aspirates / Fluid / Swabs)***	Specimen collected by a physician. If eardrum has ruptured, collect exudate using a sterile culture swab, For tympanocentesis use a syringe aspiration technique to obtain a fluid from behind the ear drum. Specify left or right ear.	Submit the fluid/ Aspirates in a sterile container. If swab sent in Aerobic transport medium (Amies media without charcoal). Ship refrigerated. **Rejection Criteria:** Received frozen	Submit the fluid/ Aspirates in a sterile container. If swab sent in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria :** Dry swab. Swab sent without sterile normal saline/Received frozen	Submit fluid/ Aspirates in sterile container. If swab sent in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Swab sent without sterile normal saline/Received frozen.
7.	***Throat Swab***	The patient is instructed to tilt his head back & breathe deeply. The tongue is gently depressed with a tongue blade to visualize tonsillar fossae & posterior pharynx. The swab is extended between the tonsillar pillars & behind uvula. Care should be taken not to touch the lateral walls of the buccal cavity or the tongue to minimize contamination with commensal bacteria. Ask the patient to phonate 'ah' that lifts the uvula & helps prevent gagging. The tonsillar areas & posterior	Submit throat swab in Aerobic transport medium (Amies media without charcoal). Ship refrigerated. **Rejection Criteria :** Received frozen.	Submit the swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria:** Received frozen.	NA

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		pharynx should be firmly rubbed with the swab. Throat specimen should not be collected in patients with epiglottis.			
8.	***Nasal fluid/washings***	Specimen collected by ENT doctor	Submit the specimen in a sterile container. Ship refrigerated. **Rejection Criteria:** Received frozen	Submit the specimen in a sterile container. Ship refrigerated **Rejection Criteria:** Received frozen	Submit the specimen in a sterile container. Ship refrigerated **Rejection Criteria** Received frozen
9.	***Nasal Swab***	Insert a swab through nose. Stay near the septum & floor of the nose. Rotate swab & remove.	Submit Nasal in Aerobic transport medium (Amies media without charcoal). Ship refrigerated. **Rejection Criteria :** Received frozen	Submit Nasal swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria:** Received frozen.	Submit Nasal swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received frozen
10.	***Sputum***	1) The preferred sputum specimen is an early morning expectorated sample obtained after a deep cough. Do not pool multiple specimens together during a 24 hour period. The patient should rinse mouth with water before sputum is collected. Instruct the patient to avoid adding saliva or nasopharyngeal discharges to sputum sample to avoid contamination with commensal micro-organism. 2) Collect the expectorated sputum in a sterile container. Twist the cap securely closed after placing the specimen in the container.	Submit 3-5 ml of Sputum sterile container. Ship refrigerated. **Rejection Criteria** Saliva received instead of sputum/Received Frozen/24 hours Sputum.	Submit 3-5 ml of Sputum in a sterile container. Ship refrigerated. **Rejection Criteria** Saliva received instead of sputum/Received Frozen/24 hours. Sputum.	Submit 3-5 ml of Sputum in a sterile container. Ship refrigerated. As per guidelines of RNTCP India it is mandatory to examine a minimum of two samples for Sputum. 1) Early morning sputum sample before the patient has eaten or taken medication. 2) Spot sample can be taken in lab itself separately in separate container. **Rejection Criteria** Saliva received instead of sputum/ Received Frozen/ 24 hours. Sputum.
11.	***Bronchoalveolar lavage (BAL)***	Specimen collected by a physician. Specimen	Submit 5-10 ml specimen in a sterile	Submit 3-5 ml specimen in a sterile	Submit 3-5 ml of specimen in a

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		collected in sterile container.	screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen.	container. Ship refrigerated. **Rejection Criteria** Received frozen.	sterile container. Ship refrigerated. **Rejection Criteria** Received frozen
12.	***Bronchial brushing***	Specimen collected by a physician. Specimen collected in sterile container.	Submit bronchial brushings in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit bronchial brushings in 1 ml of sterile normal saline. Ship refrigerated . **Rejection Criteria** Received frozen.	Submit bronchial brushings in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received frozen
13.	***Laryngeal Swab***	Specimen collected by E.N.T doctor	Submit Larygeal swab in Aerobic transport medium (Amies media without charcoal). Ship refrigerated. **Rejection Criteria :** Received frozen	Submit Laryngeal swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit Laryngeal swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received frozen
14.	***Transtracheal aspirates***	Specimen collected by physician. Specimen collected in a sterile container.	Submit specimen as much as possible in sterile screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit specimen as much as possible in sterile screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit specimen as much as possible in sterile container. Ship refrigerated. **Rejection Criteria** Received frozen
15.	***Stool***	Precautions: Antibiotics, barium & mineral oil are toxic to bacteria. So stool specimens should obtained prior to their administration Do not contaminate faeces with urine. Collect liquid or semisolid stool where possible. A single negative stool culture does not rule out the absence of bacterial pathogen so three stool samples. Should be taken for diagnosis of infectious diarrhea/Stool cultures cannot be performed on any specimens submitted in formalin or PVA. Culture routinely detects	Submit 3-5 gm of the stool specimen in a clean dry container. Inoculate in stool culture transport medium (Cary Blair Medium). Using a swab provided with stool transport media. Transfer a portion of stool to a stool culture transport medium. Transfer the stools that appear bloody, slimy or watery. If the stool is formed, sample small amount from each end and the middle. Ship at refrigerated temperature	Submit 3-5 gm of the specimen in clean, dry container. Ship refrigerated. **Rejection Criteria** Received frozen.	NA

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		Salmonella &Shigellae. If cholerae is suspected use separate.	**Rejection Criteria** Received frozen/ Specimen not sent in transport media. Not more than 2 samples / patient without prior consultation. Specimen from inpatient after third hospital day admission.		
16.	***Urine (voided urine)***	Thorough cleaning Genitalia is very important prior to Urine collection. Instruct the patient to clean the genital area with soap & water. Males: retract the foreskin. Clean the head of penis with soap & water & Female should clean in between the folds. Dry the area with clean towel or tissue. Discard the first part and then collect midstream in sterile urine container.	Submit Urine in Sterile Urine Container with 3 ml of 1% Boric Acid as preservative. Transport the specimen within 24 hrs in refrigerated condition. **Rejection Criteria** Unpreserved specimens that are of more than 24hrs. Of collection and are transported at room temperature/ Foley's catheter tips/ Sample from Urine collection bag or bedpan /24hr Urine collection.	Submit 20-40 ml urine in sterile screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen / Room temperature & more than 24hrs. Of collection/Foleys catheter tips/ Sample from Urine collection bag or bedpan/24hr Urine collection.	Instruct the patient to collect early morning, voided mid stream urine in sterile wide mouthed container /bottles on three separate days as per instructions of SOP, issued by Central TB Division, Director General of Health Services, Ministry of Health and Family Welfare. And ensure that the samples are transported to the lab at 2-8°C as early as possible. **Rejection Criteria** Received frozen / Foleys catheter tips/ Sample from Urine collection bag or bedpan/24hr Urine collection.
17.	***Indwelling catheter (Foley catheter urine)***	The specimen is obtained by aseptic puncture of the catheter tubing. Select a puncture site 1-2 inches distal to meatus & clamp below the puncture site:	Submit 10-15 ml of specimen in sterile screw capped container. Ship refrigerated. **Rejection Criteria:**	Submit 10-15 ml of specimen in a sterile screw capped container. Ship refrigerated. **Rejection Criteria**	Submit 10-15 ml of specimen in a sterile screw capped container. Ship refrigerated.

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		Clean the puncture site with 70% alcohol. Aspirate & transfer to a sterile container.	Received frozen /Room temperature & more than 2hrs of collection/ Foley's catheter tips/Sample from urine collection bag or bedpan /24hr Urine collection.	Received frozen /Room temperature & more than 2hrs of collection/ Foley's catheter tips/Sample from urine collection bag or bedpan /24hr Urine collection.	**Rejection Criteria** Received frozen / Foley's catheter tips/Sample from urine collection bag or bedpan /24hr Urine collection.
18.	***Suprapubic aspirate***	Specimen is collected with syringe & needle after thorough skin decontamination by a treating physician	Submit 10-15 ml of specimen in a sterile screw cap container. Ship refrigerated. **Rejection Criteria** Received frozen/Room temperature & more than 24hrs of collection.	Submit 10-15 ml of specimen in a sterile screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen/Room temperature & more than 24hrs of collection.	Submit 10-15 ml of specimen in a sterile screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen
19.	***Blood***	Prepare the skin by cleaning with 70% isopropyl or ethyl alcohol to remove surface dirt & oil. 2) Wipe it again with Povidone-Iodine in concentric form starting from the center & moving outwards. Allow it to dry for 2 minutes. 3) Again wipe the site with 70% usioriopyl or ethyl alcohol to remove povidone iodine. Allow the alcohol to evaporate for few seconds. Then collect the blood also prepare the septum of Blood culture bottle by cleaning with 70% isopropyl or ethyl alcohol and then allow the septum to dry. Do not use Iodine on Blood culture bottles.	Collect 8-10 ml of blood in Special Plus Aerobic bottle/BHI Broth. For Paediatric collect 1-5 ml of blood in Special Paeds Plus bottle/BHI Broth. Ship at 18-22°C. **Rejection Criteria** Received Refrigerated/Frozen.	NA	NA
20.	***Endocervical Swab***	Use vaginal speculum with no lubricant. Wipe the cervix clean of vaginal secretions & mucus with a swab. Discard the swab. Use	Insert the swab in Aerobic transport medium (Amies media without charcoal). Ship refrigerated.	Insert the swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria**	NA

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		another swab & insert it into endocervix& rotate for 15-30 seconds. Avoid touching lateral walls with the swab.	**Rejection Criteria** Received frozen.	Received frozen.	
21.	***Semen***	The specimen is collected by masturbation	Submit semen in a sterile container. Ship refrigerated. **Rejection Criteria** Received frozen/Specimen in condoms.	Submit specimen in a sterile container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit specimen in a sterile container. Ship refrigerated. **Rejection Criteria** Received frozen.
22.	***Cul-de-sac (Culdocentesis)***	Surgical procedure Specimens – Fluids/Secretions	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received frozen.
23.	***Endometrium***	Collected by a Gynaecologist Use vaginal speculum with no lubricant. Wipe the cervix clean of vaginal secretions & mucus with a swab. Discard the swab. The endometrial curettings or aspirates are collected in a sterile container.	Submit the specimen in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received frozen/Specimen sent in formalin.	Submit the specimen in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Specimen sent in formalin/Received frozen.	Submit the specimen in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Specimen sent in formalin/Received frozen.
24.	***High vaginal Swab***	Under strict aseptic precautions, open the vaginal orifice with a sterile vaginal speculum with no lubricant. Swab the mucosa high in vaginal canal.	Submit the swab in Aerobic transport medium (Amies media without charcoal). Ship refrigerated. **Rejection Criteria** Specimen sent without transport media / Received frozen.	Submit the swab in 1 ml of sterile normal saline. **Rejection criteria** Dry swab, Swab sent without sterile normal saline / Received frozen.	NA
25.	***Urethral Swab***	Instruct the patient not to urinate 1 hour prior to sampling. Insert the swab 2-4 cm into urethra & rotate the swab for 3-5	Submit the swab in Aerobic transport medium (Amies media without charcoal). Ship refrigerated.	Submit the swab in 1 ml of sterile normal saline. **Rejection Criteria** Dry swab. Swab sent	NA

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		seconds	**Rejection Criteria.** Specimen sent without transport media/Received frozen.	without normal saline/Received frozen.	
26.	***Body fluids from sterile sites (Other than Urine /Blood / Bone marrow***	Collected by a physician after skin decontamination	For Conventional cultures: Submit 2-5 ml of the specimen in a sterile screw capped container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received Frozen	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received Frozen
27.	***PUS/ PUS Swab***	Skin decontamination followed by aspiration from deeper sites.	Aspirated Pus is collected in a sterile container. Ship refrigerated. **Rejection Criteria** Pus Swab sent without transport media/Received frozen.	Submit the Pus aspirate in a sterile container & Pus swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Dry swab. Swab sent without transport media/Received frozen	Submit the Pus aspirate in a sterile container & Pus swab in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Dry swab. Swab sent without transport media/Received frozen
28.	***Bone marrow***	Skin decontamination. Collected by a treating physician.	Submit 1–2 ml of bone marrow in sterile container. Ship at 18-22°C. **Rejection Criteria** Received Refrigerated /Frozen.	Submit 1-2 ml of bone marrow in sterile container. Ship at 18-22°C. **Rejection Criteria** Received Frozen	Submit 1-2 ml of bone marrow in sterile container. Ship at 18-22°C. **Rejection Criteria** Received Refrigerated /Frozen.
29.	***Tissues***	Surgically collected. Do not use formalin.	Submit the tissue in a sterile normal saline. Ship refrigerated. **Rejection Criteria** Tissues sent in formalin/ Specimen received in frozen state.	Submit the tissue in a sterile normal saline. Ship refrigerated. **Rejection Criteria** Tissues sent in formalin/ Received frozen.	Submit the tissue in a sterile normal saline. Ship refrigerated. **Rejection Criteria** Tissues sent in formalin/ Received frozen.

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
30.	***Gastric aspirate***	Patient should be overnight fasting. Procedure performed by a treating physician in a hospital.	Submit 1–2 ml of specimen in sterile container. Ship at 18-22°C.	NA	Submit 3-5 ml of specimen in sterile screw capped container. Ship at 18-22°C.
31.	***Hair***	**Precautions:** Do not submit the specimen if patient is currently undergoing anti-fungal therapy because this may result in negative culture. If anti-fungal treatment has been started discontinue the treatment for 5-30 days (based on topical vs. systemic treatment) If the first culture is negative a repeat culture is recommended if clinical indicated.	NA	Pluck 10-12 infected / luster less hair including root in a sterile container. Ship at 18-22°C. **Rejection Criteria** Received Refrigerated / frozen.	NA
32.	***Skin***	**Precautions:** Do not submit the specimen if patient is currently undergoing anti-fungal therapy because this may result in negative culture. If anti-fungal treatment has been started discontinue the treatment for 5-30 days (based on topical vs. systemic treatment) If the first culture is negative a repeat culture is recommended if clinically indicated. If culture continues to be negative a biopsy may be indicated. The affected area is cleaned with 70% alcohol.	NA	After drying lesion is scraped with a sterile scalpel. Submit 2-3 mm of scrapings from the periphery of active skin lesion in a sterile container. Wrap it in black paper. Ship at 18-22°C. **Rejection Criteria** Received Refrigerated/ Frozen	Submit skin scrapings in 1 ml of sterile normal saline. Ship refrigerated. **Rejection Criteria** Received Frozen.
33.	***Nail specimens***	**Precaution:** Do not submit the specimen if patient is currently undergoing anti-fungal therapy because this may result in negative culture. If anti-fungal treatment has been started discontinue the treatment	NA	Submit clippings and powdery material from friable and discoloured region of affected nail. Submit material from sub fungal debris between the nail plate and bed. Nail clippings	NA

Sr. No.	Specimen	Preparation	Aerobic Culture	Fungus Culture	AFB Culture
		for 5-30 days (based on topical vs. systemic treatment) If the first culture is negative a repeat culture is recommended if clinically indicated. The affected area is cleaned with 70% alcohol.		of at least 3 mm length should be obtained. Do not submit initial nail clippings. Ship at 18-22°C. **Rejection Criteria** Received Refrigerated/ Frozen	
34.	***Vascular cannulae, venous access devices arterial lines.***	Skin decontamination, careful aseptic removal. Segment near skin & tip end should be used; Use sterile scissors to cut.	Collect the device in a sterile container or tube. Ship refrigerated. **Rejection Criteria** Received Frozen.	Collect the device in a sterile container or tube. Ship refrigerated. **Rejection Criteria** Received Frozen.	NA
35.	***Aspirates***	Specimen is collected after thorough skin decontamination in a sterile container.	Submit the specimen as much as possible in sterile container. Ship refrigerated. **Rejection Criteria** Received frozen.	Submit the specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received Frozen.	Submit specimen as much as possible in a sterile container. Ship refrigerated. **Rejection Criteria** Received Frozen

7. Collection Procedure for Parasitology:

7.1. Blood Parasites: Plasmodium (Malaria), Microfilaria (Filarial worms), Babesia, and Trypanosoma (Trypanosomiasis).

7.1.1. Submit one lavender top tube of peripheral blood (EDTA) and minimum of one thick and one thin blood film taken from peripheral blood during the febrile episode and at 6 hourly intervals, for 36 hours.

7.1.2. Obtain patient history as an aid in diagnosis. This should include visits to any endemic area and the date of return.

7.1.3. If Wuchereriabancrofti or Brugiamalayi are suspected, draw blood between 10 PM and 4AM. If diurnal Loa Loa is suspected, draw blood between 10 AM and 2 PM. For Mansonella species, draw anytime.

7.1.4. Specimens collected after the initiation of drug therapy hamper parasite identification.

7.1.5. Preparation of Thick Blood Film

7.1.5.1. Warm the skin area to be punctured. Usually specimens are collected

from the tip of the "ring" finger on the palmar surface in adults and heel prick in infants.

7.1.5.2. Clean and disinfect skin with 70% alcohol.

7.1.5.3. Wipe dry or air dry. Be sure the finger is thoroughly dry prior to pricking.

7.1.5.4. Puncture the finger with a sterile disposable lancet, deep enough to collect a sufficient amount of free-flowing blood for film preparation. Do not squeeze finger to remove the blood.

7.1.5.5. Make a thick film by placing a drop of blood in the centre of a clean glass slide and spreading it out with a corner of anotherslide to cover an area about 4 times the original size of the drop.

7.1.5.6. Allow the film to dry thoroughly for at least 30 minutes at 37°C.

7.1.5.7. After collection, apply pressure to the puncture site until bleeding stops.

7.1.5.8. Label patient's name/identification on one end of the slide.

7.1.5.9. Pack and Transport to the laboratory in a slide mailer.

7.1.6. Preparation of Thin Blood Film:

7.1.6.1. Warm the skin area to be punctured. Usually, specimens are collected from the tip of the "ring" finger on the palmar surface in adults and heel prick in infants.

7.1.6.2. Clean and disinfect skin with 70% alcohol.

7.1.6.3. Wipe dry or air dry. Be sure the finger is thoroughly dry prior to pricking.

7.1.6.4. Puncture the finger with a sterile disposable lancet, deep enough to collect a sufficient amount of free-flowing blood for film preparation. Do not squeeze finger to remove the blood.

7.1.6.5. Place a small drop of blood in the centre of a clean glass slide about 1 cm from one end. Place a spreader in front of the drop at an angle of 30 degrees and move it back to make contact with the drop. With a steady

movement of the hand, spread the drop along the slide for a length of about 3 cm. The blood film should finish at least 1 cm before the end of the slide and air dry the film.

7.1.6.6. After collection, apply pressure to the puncture site until bleeding stops.

7.1.6.7. Label patient's name/identification on one end of the slide.

7.1.6.8. Pack and Transport to the laboratory in a slide mailer.

7.1.7. Duodenal/Gastric Aspirates:

7.1.7.1. Collect the duodenal/gastric aspirates and place the fluids in a sterile transport vial within 30 minutes of collection.

7.1.7.2. Indicate the source of specimen on the vial.

7.1.8. Eye:

7.1.8.1. Corneal scrapings / Contact Lens Fluid can be subjected to direct examination for parasites.

7.2. Parasite Identification (Worm, Tick, Larva, Other Insects):

7.2.1. Submit the entire organism in 70% Isopropyl alcohol in a clean screw-cap container.

7.2.2. Transport at room or refrigerated temperature.

7.2.3. Skin (Microfilaria - Filarial Worms):

7.2.3.1. Epidermal skin snips are the specimen of choice if Onchocerca volvulus or Mansonellastreptocerca infections are suspected.

7.2.3.2. If African onchocerciasis is suspected, multiple skin snips must be taken from the gluteal and calf areas; for American onchocerciasis, the scapular and deltoid areas are the sites of choice.

7.2.3.3. Transport at room temperature as soon as possible and no more than 24-48 hours after collection avoiding extremes of heat and cold.

7.2.4. Scabies (SarcoptesScabiei):

7.2.4.1. Due to the infectious nature of Sarcoptesscabiei, universal precautions must be strictly adhered to when collecting andtransporting specimens

for scabies. Collect skin scrapings from the webbings in between the fingers regardless of the site of therash for the greatest recovery rate. The rash represents sensitization to the bite and does not correspond to the location of theactive adult female mites.

7.2.4.2. Place skin scrapings in a clean dry screw-cap container . Do not submit specimens on glass slides.

7.2.4.3. Transport at room temperature as soon as possible not exceeding 24-48 hours after collection.

7.3. Sputum and Lower Respiratory Tract Specimens:

7.3.1. The patient should rinse mouth with water before sputum is collected.

7.3.2. The induced sputum specimen from an early morning sample obtained after a deep cough, is acceptable.

7.3.3. Do not pool multiple samples collected during a 24-hour period.

7.3.4. Instruct the patient to avoid adding saliva or nasopharyngeal discharges to the sputum sample to avoid contamination withindigenous microorganisms.

7.3.5. Collect the sputum in a sterile screw-capped container.

7.3.6. Collect lower respiratory tract specimens by bronchoscopy or transtracheal aspiration avoiding contaminationby oropharyngeal flora. Tightly secure transtracheal aspirate, bronchial lavage or bronchial alveolar lavage containers beforesubmitting to avoid leakage during transport.

7.3.7. Transport refrigerated within 24–48 hours.

8. Sample Collection –Cytogenetics and FISH

8.1. Cytogenetics helps in identifying genetic defects at the chromosomal level through genetic testing.

8.2. The most common conditions when Karyotyping is opted are bad obstetric history, infertility, recurrent abortions, neonatal deaths, still birth, mentalretardation, menstrual disorders, development problems in children's, congenital anomalies, advanced maternal age etc.

8.3. Patient history is Mandate for a correct and timely report

8.4. Cytogenetics sample collection requirements and rejection criteria

Sample Type	Collection Container	Volume	Storage	Rejection Criteria
Perpheral Blood	Sodium Heparin Green top Vacutainer	Adults- 3-4 mL Neonates-2 mL	Ambient	QNS, Sample more than 72 hours old.
Bone Marrow	Sodium Heparin Green top Vacutainer	Adults- 3-4 mL Neonates-2 mL	Ambient	Sample more than 24 hours old.
Amniotic Fluid	Red Top Vacutainer or Screw cap centrifuge tubes	20-30 mL	Ambient	Should be received within 24 hours of sample collection
Products of Conception(POC)	Normal Saline	Tissues	Ambient	• Should be received within 24 hours of sample collection. • Gross Contamination. • Necrotic Tissue • Sample in fixative

8.5. In case the samples need to be kept at overnight at the collection centre, store at 2-8˚Cand send to the laboratory as soon as possible.

9. Sample Collection-Molecular Biology: Details of collection are mentioned under each test in the Alphabetical Test List. Special instructions for the analytes are given below.

Instructions on Sampling: The type of samples to be collected for all molecular biology tests including sample containers and the environmental conditions to be maintained during transit is presented below:

Sample	Collection	Temperature Conditions
Whole Blood	3 ml in EDTA tube.	2-8˚C
Plasma (EDTA)	3 mL in sterile tube	2-8˚C
Urine	15 ml in sterile screw capped tube.	2-8˚C

Sample	Collection	Temperature Conditions
Tissue	Sterile screw capped tube.	2-8˚C
CSF	0.5 ml fluid in sterile bottle	2-8˚C
Pus/FNAC aspirate	Sterile bottle	2-8˚C
Sputum	Sterile bottle	2-8˚C
Bone Marrow	1-2 ml in citrated/ EDTA bottle.	2-8˚C
Other body fluids	3-5 ml in sterile bottle.	2-8˚C
Bronchial lavage	2-4 ml in sterile screw capped tube.	2-8˚C

9.1. Sars Covid 19 Sample Collection and Transportation: -

9.1.1. It is the responsibility of all Customers/Clients (Hospitals, Nursing Homes, Diagnostic and Pathological Labs, Clinicians and Clinics) to follow the procedures given in the manual during sample collection and transportation.

9.1.2. It is the responsibility of the Laboratory staff members to ensure that the samples are received as per the given requirement.

9.1.3. It is the responsibility of the Head of Sales and Sales team to implement the same.

9.1.4. Laboratory tests results contribute relevant information about a patient's health. Correct diagnosis relies on the accuracy of test results. Correct and adequate patient preparation, specimen collection, and specimen handling are essential prerequisites for accurate test results. The accuracy of test results is dependent on the integrity of specimens.

EQUIPMENT AND PREPARATION

9.1.4.1. Viral transport medium (VTM)
9.1.4.2. Nasopharyngeal Swabs
9.1.4.3. Oropharyngeal Swabs

9.1.4.4. Personal protective equipment (PPE)

9.1.5. Universal Safety Precautions:

9.1.5.1. Before beginning the procedure, the requisition form should be filled properly with patient details, travel history, contact history, and contact number of patient and the doctor.

9.1.5.2. The novel coronavirus testing specimens shall be collected by qualified technicians who have received biosafety training (who have passed the training) and are equipped with the corresponding laboratory skills. Personal protective equipment (PPE) requirements for sampling personnel are: N95 masks or masks with higher filtration efficiency, goggles, protective clothing, double-layer latex gloves and waterproof boot covers; the outer layer of the latex gloves shall be changed in a timely manner should sampling personnel touch patients' blood, body fluids, secretions etc.

9.1.5.3. Specimens of inpatient cases shall be collected by medical staff of the hospital where they are being treated.

9.1.6. Trained Personnel for Sample Collection:

9.1.6.1. Ensure that the trained personnel are deputed for Patient Sample collection.

9.1.6.2. Training should be given on Phlebotomy procedures, personnel safety, handling of emergencies during specimen collection, handling and packing of specimens, handling and cleaning of biological spills.

9.2. Primary Sample Collection-Sars Covid 19

9.2.1. Proper specimen collection is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false or inconclusive test results. The following specimen collection guidelines follow standard recommended procedures.

9.2.2. For initial diagnostic testing for current SARS-CoV-2 infections, CDC recommends collecting and testing an upper respiratory specimen. Contact the testing laboratory to confirm accepted specimen types and follow the manufacturer instructions for specimen collection. Sterile swabs should be used for the collection of upper respiratory specimens. This is important both to

ensure patient safety and preserve specimen integrity. Note that nasopharyngeal and oropharyngeal specimens are not appropriate for self-collection.

9.2.3. Testing lower respiratory tract specimens is also an option. For patients who develop a productive cough, sputum can be collected and tested for SARS-CoV-2 when available. However, the induction of sputum is not recommended due to the possibility of aerosol production during the procedure. Under certain clinical circumstances (e.g., for those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage specimen can be collected and tested as a lower respiratory tract specimen.

9.2.4. Upper respiratory tract

9.2.4.1. Nasopharyngeal specimen (NP) collection /Oropharyngeal (OP) (throat) specimen collection (performed by a trained healthcare provider, only).

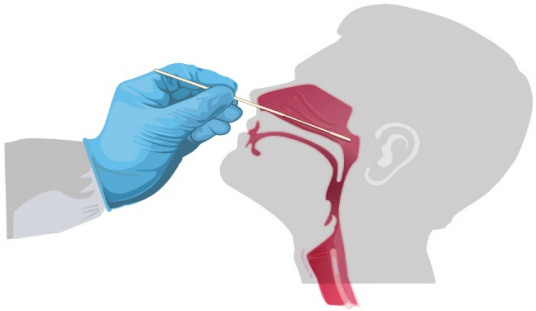
9.2.4.2. Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests.

9.2.4.3. both NP and OP specimens are collected, combine them in a single tube to maximize test sensitivity and limit use of testing resources.

9.2.5. Instructions for collecting an Nasopharyngeal specimen (performed by a trained healthcare provider):

9.2.5.1. Tilt patient's head back 70 degrees.

9.2.5.2. Gently and slowly insert a minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.



9.2.5.3. Gently rub and roll the swab.

9.2.5.4. Leave swab in place for several seconds to absorb secretions.

9.2.5.5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection.

9.2.5.6. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

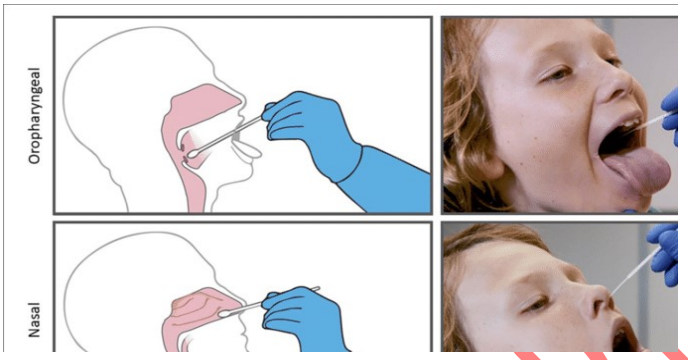
9.2.5.7. Place swab, tip first, into the Viral Transport Medium tube provided.

9.2.6. Instructions for collecting an OP specimen (performed by a trained healthcare provider):

9.2.6.1. Insert swab into the posterior pharynx and tonsillar areas.

9.2.6.2. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

9.2.6.3. Place swab, tip first, into the Viral Transport Medium tube provided.



9.2.7. Lower respiratory tract

9.2.7.1. Bronchoalveolar lavage, tracheal aspirate, pleural fluid, lung biopsy (generally performed by a physician in the hospital setting)

9.2.7.2. Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

9.2.7.3. Due to the increased technical skill and equipment needs, collection of specimens other than sputum from the lower respiratory tract may be limited to patients presenting with more severe disease, including people admitted to the hospital and/or fatal cases.

9.2.8. Sputum (collected under the guidance of a trained healthcare professional)

9.2.8.1. For patients who develop a productive cough, sputum can be collected and tested when available for SARS-CoV-2. However, the induction of sputum is not recommended. Educate the patient about the difference between sputum (deep cough) and oral secretions (saliva/spit). Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container.

9.2.8.2. Note: This is an aerosol-generating procedure and likely to generate higher concentrations of infectious respiratory aerosols. Aerosol-generating procedures potentially put healthcare providers and others at an increased risk for pathogen exposure and infection. Healthcare providers should maintain proper infection control, including standard

precautions, and wear an N95 or equivalent or higher-level respirator, eye protection, gloves, and a gown, when collecting specimens.

10. Specimen packaging

10.1. Collected specimens shall be packaged separately in a biosafety cabinet of a BSL-2 laboratory.

10.2. All specimens should be placed in an airtight freeze-tolerant sample collection tube of appropriate size, with a screw cap and a gasket inside. The sample number, category, name and sampling date should be indicated on the outside of the container.

10.3. The labelled VTM should be placed inside the pouch and sealed with adhesive tape. If the cover is not available, a small-size zip-lock bag should be used. The packed VTM should be placed inside another zip-lock bag which acts as the second layer. Finally, the package should be inserted into a solid, unbreakable, leak-proof outer container which severs as the third layer. The VTM, zip-lock bag and the outer container should be labelled properly.

11. Specimen Transportation:

11.1. Collected specimens should be sent to laboratories as soon as possible.

11.2. The specimen should be transferred to the laboratory maintaining cold chain (2-4°C) throughout. The packed specimen should be placed inside the ice-box; two ice-pads should be placed on both sides of the container. The ice-box should be cleaned thoroughly outside with 1 % sodium hypochlorite and transferred to the laboratory as soon as possible with prior communication. If there is delay of more than 72 hours, sample should be stored at -70°C. Specimen data forms, letters, and other types of information that identify or describe the specimen for testing of SARS-COV-2 should be carried separately.

12. Storing and Shipping Respiratory Specimens

12.1. Store respiratory specimens at 2-8°C for up to 5 Days after collection. If a delay in testing or shipping is expected, store specimens at -70°C.

13. RETENTION OF TESTED SAMPLES

Sr. No.	Department	Sample Retention Period	Storage Temperature
1	Molecular Biology-Viral Transport Medium	48 hrs	2-8°C
2	Molecular Biology-Covid Extracted RNA	30 days	-80 °C

14. Sample Collection-Newborn Screening

14.1. General guidelines for sample collection

14.1.1. The Quality of the sample taken at correct time and in correct manner decides the success of newborn screening.

14.1.2. Newborn screening is complicated by prematurity, infant illness, total parental nutrition

14.1.3. Ideal time of blood collection in newborn is 4th day.

14.1.4. As there is a Thyroid Stimulating Hormone (TSH) surge in normal infants immediately following birth as clinically false positive results will be observed if the sample is collected prior to 48 hours of age.

14.1.5. Premature infants may have persistent abnormalities in newborn screening test results without having any noticeable abnormal condition.

14.1.6. Prematurity may be associated with physiological elevation of 17 OHP and reduction of Thyroxine. Premature or sick infants should have new born screening test performed by 7 days of age.

14.1.7. Premature infants (birth weight under 1500 gms) or sick infants who have congenital hypothyroidism may have delayed raise in TSH. Such infants should be tested for 4 and 6 weeks of age.

14.1.8. If the infant is on Antibiotic the screening id done 24 hours after the last dose.

14.1.9. If blood samples are not collected before blood transfusion, then the sample may be collected between 4-6 weeks after last transfusion.

14.1.10. Screening for galactosemia, amino acids, organic acids and fatty acid

oxidation disorders is must accurate 48 hours or more after the infant has received enteral feedings

14.1.11. Total parental nutrition may cause a false positive test for PKU and several amino acid disorders.

14.1.12. Following situations may increase the risk of false negative or false positive screening test results

14.1.13. Blood Transfusion: The optimum specimen collection time is when the newborn is older than 24 hours of age. However, transfusions may invalidate some screening results by masking the presence of a hemoglobinopathy or galactosemia. If the infant is to receive a transfusion, every effort must be made to collect a specimen prior to transfusion regardless of the infant's age. Infants receiving transfusions with no prior newborn screening test need two specimens collected: one at three days or more after the most recent transfusion and one at four months after the final transfusion.

14.1.14. Total Parenteral Nutrition (TPN) –Hyperalimentation: The optimum collection time is when the newborn is older than 24 hours of age. However, even small amounts of TPN may invalidate some screening results for the acylcarnitines and amino acids. If the infant is to receive TPN, every effort must be made to collect a specimen prior to treatment. Infants receiving TPN with no prior newborn screening test need a collection three days or more after the last administration of TPN.

14.2. Blood Collection Procedure :

14.2.1. Required Materials

14.2.1.1. Sterile, disposable lancet or automated lancet devises

14.2.1.2. 70 % alcohol swab

14.2.1.3. Disposable gloves

14.2.1.4. Blood collection card

14.2.1.5. Baby's detailed medical history

14.2.2. Method :

14.2.2.1. Use Universal precautions for blood collection.

14.2.2.2. Ask the mother to cuddle the baby on her knee to help and comfort the baby.

14.2.2.3. Place a Paper towel on the lap of the person holding the baby to protect from any blood spill.

14.2.2.4. Ensure that the heel is warm. Hold the heel in warm hands for 3 mins or dip the heel in warm water and not hot water.

14.2.2.5. Warming of the heel will enhance the blood flow and positioning the foot in a downward position from the heart will help to collect a good sample.

14.2.2.6. Wash hands and put on gloves. Cleanse the puncture site with a sterile alcohol pad. Wipe dry with a sterile gauze pad. Residual alcohol may cause hemolysis of the blood specimen resulting in an invalid specimen.

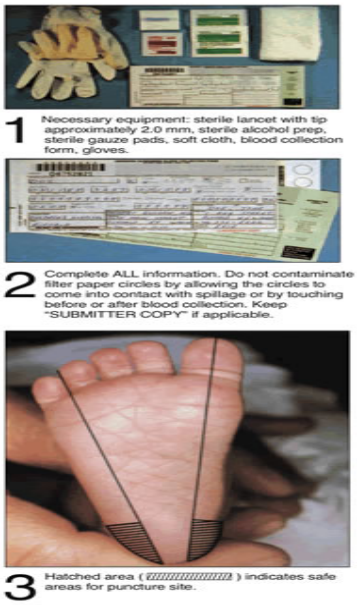
14.2.2.7. With a lancet or specialty device, puncture the heel skin with one continuous, deliberate motion at a slight angle (a little less than 90o). Wipe away the first drop of blood with a dry sterile gauze pad, as it is likely to contain tissue fluids that will contaminate the specimen.

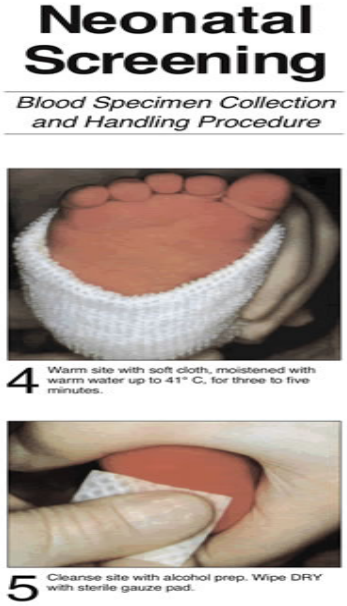
14.2.2.8. Allow a second, large drop of blood to form.

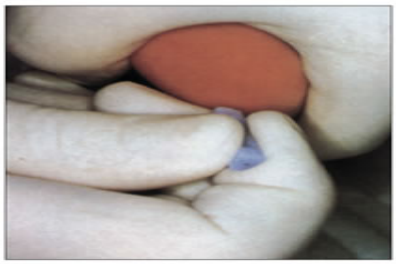
14.2.2.9. Lightly touch the filter paper to this large drop of blood. Allow the blood to soak through and completely fill the preprinted circle. To enhance blood flow, very gentle intermittent pressure may be applied to the area surrounding the puncture site. Do not "milk" the area surrounding the puncture site. Milking may cause an admixture of tissue fluids with blood specimen, resulting in an invalid specimen. Apply blood to one side of filter paper only. Either side may be chosen for this procedure. Do not use capillary tubes or other devices (syringes etc.).

14.2.2.10. Fill remaining circles in same manner as steps 6 and 7 with successive

drops of blood. **Note**: If the first drop of blood does not fill the circle or most of the circle immediately, express another blood drop and continue to fill the circle. This must be done within a few seconds of the placement of the first drop. Alternatively, allow a larger drop to form and move on to the next four circles. If more than two drops are required to fill a single circle, or there is more than 10 seconds of time between drops, follow the steps above to repuncture a different site with a sterile lancet. This time, ensure that the baby's heel has been properly warmed and that you firmly press the lancet against the skin prior to activating the device. Most often, these steps will allow blood to flow more freely for sampling. Multiple contacts to the same circle, over a period of greater than 10 seconds, can result in layering which renders the circle unsuitable for testing.

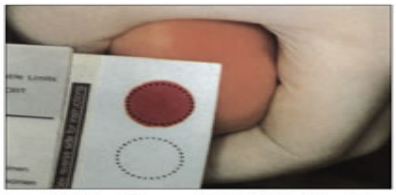






6 Puncture heel. Wipe away first blood drop with sterile gauze pad. Allow another LARGE blood drop to form.

8 Fill remaining circles in the same manner as step 7, with successive blood drops. If blood flow is diminished, repeat steps 5 through 7. Care of skin puncture site should be consistent with your institution's procedures.



7 Lightly touch filter paper to LARGE blood drop. Allow blood to soak through and completely fill circle with SINGLE application of LARGE blood drop. (To enhance blood flow, VERY GENTLE intermittent pressure may be applied to the area surrounding the puncture site). Apply blood to one side of filter paper only.

9 Dry blood spots on a dry, clean, flat, non-absorbent surface for a minimum of four hours.

10 Mail completed form to testing laboratory within 24 hours of collection.

Information provided by The New York State Department of Health.

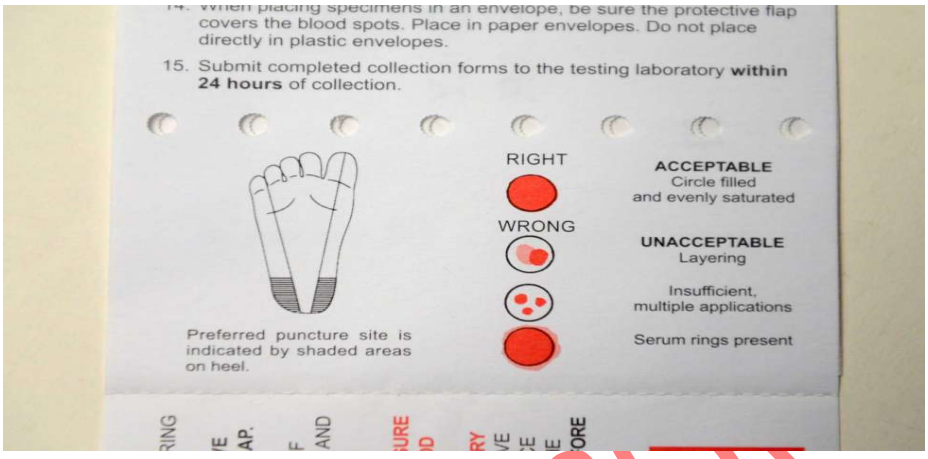
14.3. Post Collection

14.3.1. Do not place the protective flap over the blood spots until the blood is completely dry.

14.3.2. Allow blood spots to air-dry thoroughly for at least four hours in a horizontal position on a clean flat, non-absorbent surface away from direct heat and sunlight.

14.3.3. Do not refrigerate specimens after collection. Both sides of the dried specimen should be inspected to ensure suitability.

14.3.4. If the specimen is deemed unsuitable by the hospital staff, and the newborn is still in-house, another specimen should be collected



CHAPTER – 4
SAMPLE ACCEPTANCE AND REJECTION CRITERIA AT LABORATORY

1. **Purpose:** The purpose of this procedure is to provide information to the customers/clients on the specimen acceptance and rejection criteria adopted for accepting the specimens at the laboratory.

2. **Authorized Requestor (Clients/Customers):**

The procedure adopted by SPL for appointment of pick-up points (Hospitals/Nursing Homes/Diagnostic Labs/Clinics) is through a customer contract form and the same is approved and the client is allotted a code with password based on the location of the client/customers. The clients/customers are appointed based on their requirements of outsourcing of their samples and facilities available for sample collection. The pick-up points receive test requisitions from registered clinicians. Specimens are accepted by the laboratory only from the authorised clients/customers. Client/Customers are identified by their allotted designated codes and the same are identified in the Sage Online Software (SOS-LIMS). The laboratory performs tests only when the written or electronic request for testing from an authorized client/customer is received.

3. **Sample Labelling:**

3.1. All primary specimen containers must be labelled with **2 identifiers** at the time of collection viz., **Patient Name and Barcode Number.** All the specimens have to be labelled in the presence of the patient with:

3.1.1. Patient Name and Age

3.1.2. Barcode Number

3.1.3. Date and Time of Collection

3.1.4. Name of the Sample Collector (phlebotomist)

3.2. **Barcode Labels** consists of 6 digit numbers starting with "20" where "20" refers to the current year. Numeric "20" will change to "21" and so on and so forth on yearly basis.

3.3. Affix barcode label to the specimen transport container. Each submitted specimen in the tubes or containers have to be bar-coded.

3.4. The following precautions needs to be taken while affixing the barcode labels.

3.4.1. Affix sticker on centre of the tube.

3.4.2. Do not change the numbers on the barcode by hand.

3.4.3. Do not soil the barcode.

3.4.4. Affix barcodes without any folds.

4. Sample Registrations:

4.1. Test Requisition Form (TRF)/Work Order Format is provided for all clients/customers in the Sage Online Software (SOS-LIMS). All patient details have to be filled in the TRF/Work Order Format required for testing of patient samples.

4.2. Non-receipt of fully completed TRF/Online Work order would result in samples kept pending for want of information.

4.3. Register the sample in the work order format in SOS-LIMS with the following details:

4.3.1. Patient Name, Age and Sex.

4.3.2. Name of the Customer and Referring Physician.

4.3.3. Sample Collection Date and Time.

4.3.4. Test Code and Test Name.

4.3.5. Specimen Type.

4.3.6. Barcode Number - Sample ID (Vial ID).

4.3.7. Clinical History

4.3.8. All clinical history formats can be scanned and attached to the work order, which would be reviewed by the Head of the Department (HOD) of the laboratory while authorizing the test reports.

4.3.9. Ensure that the TRFs/Work Order for all microbiology specimens are accompanied with source of specimen, type of infection or organism expected.

4.4. Upload the registrations details and click the "Submit" button which completes the registration process and a temporary registration number is generated automatically.

4.5. Dispatch the sample along with patient name and the barcode to the laboratory.

5. Status of Work Order (Select "Work Order Status" option from "SPP" Menu):

5.1.1. Here the sample status can be filtered using a combo box provided corresponding dates of samples sent and the status of work order submitted by the SPP is known.

5.1.2. If the status of the report says "Approved", it means that the analysis is completed. If the status is as 'Collected then it means that the samples have been accepted by the accession department. If the status is as 'Received' then it means that the respective testing department has received the samples for testing. If the status is "Tested" then it means that the analysis is completed and pending for HOD Verification and Authorization.

5.1.3. If the sample is Rejected the reason is mentioned based on which the follow-up action needs to be taken by the SPP.

5.1.4. In the same SPP menu the Adding of Doctors or Customers can also be done for that respective SPP.

5.2. Work Order Acceptance at the Laboratory (Select "Worksheet" Option for Accession Menu):

5.2.1. Once the specimens are received at the laboratory, the samples are arranged serially in racks and the name of the patient and barcode number on the sample are checked for matching patient name and barcode code entered by the client/customers in the Sage Online Work Order/TRF– all this process is done in "Accession Window of SOS-LIMS".

5.2.2. Once the samples are identified– the samples are verified for acceptance or rejection criteria as per the checklist given **under chapter-3.**

5.2.3. If the samples pass the acceptance criteria the samples are accepted then status of the sample is accepted for testing in the Sage Online Work Order (SOS-LIMS) and the sample status changes to registered mode and the patient is

assigned a unique registration number with sample receipt date and time by the Sage Online Software (SOS-LIMS).

5.2.4. Once samples are accepted for testing the Departmental Work Sheet is generated and the samples are routed to the concerned department by accession.

5.2.5. In the department the samples are accepted by verifying the sample Barcode in the SOS-LIMS to generate the final sample receiving list at the departmental level.

5.2.6. In case any samples are found not suitable for analysis such samples are rejected at departmental level and the same is entered in the SOS-LIMS.

5.3. Accession Work Sheet (Select "Result Entry" Option under "Departmental Work Sheet"):

5.3.1. Departmental work sheet – contains the following Combo Box viz., departmental sample acceptance or rejection, results entry and authorisation of the test reports.

5.3.2. Once the registered specimens are received at the department the samples are verified as per the departmental rejection criteria and the samples are either accepted or rejected.

5.3.3. All the samples which are found to be fit for testing are accepted in the SOS-LIMS by the department technicians – once accepted the sample receipt, date and time is generated by the SOS-LIMS.

5.3.4. In case of any rejections – the reasons for rejection is recorded in the SOS-LIMS under Departmental Rejected Samples.

5.3.5. Once the date and the department is mentioned in the SOS-LIMS the list of samples for a particular department are displayed.

5.3.6. Once you get the list of sample registrations, you can select to view the **Results** or **Patient Registration Details** by selecting the corresponding LINK under Registration Number column. (Please note that the registration number allotted by SPL is the actual registration number for the sample).

5.3.7. The Test result entry or Authorization options will not get activated until the sample is accepted in the departmental worksheet.

5.3.8. In the same sheet the Technicians can enter the results after the testing of samples is done.

5.3.9. If the status of the report says **"Approved"**, it means that the analysis is completed. If the status is as **'Collected** then it means that the samples have been accepted by the accession department. If the status is as **'Received'** then it means that the respective testing department has received the samples for testing. If the status is **"Tested"** then it means that the analysis is completed and pending for HOD Verification and Authorization.

5.4. Printing of Reports:

5.4.1. Click on Reports under SPP menu.

5.4.2. Select the dates and click list for the reports to be filtered and shown.

5.4.3. Click on Report to view the report or if it is a graph click on download graph.

5.4.4. Print Report: Opens the report in PDF format which can be saved on to your desktop or directly printed.

5.4.5. Back: Gets you back to the Reports page where you can print another report.

6. Specimen Container Tracking:

6.1. All specimens originating from the remote areas have to send in their dispatch details (name of the courier and docket number) for the specimens sent through couriers via email or telecom to the customer care centre.

6.2. Dispatch details of the specimens transported would help the laboratory to track the consignment and to pick up the same from the courier offices, without any delay.

6.3. Specimens transported to the laboratory should contain the patient name and the barcode numbers and the work order registrations (SOS-LIMS) done for each specimen.

6.4. The patient name and barcode numbers are used for tracking in SOS-LIMS on receipt of the specimens at the laboratory.

7. **Verbal Test Authorization:** As a policy verbal test authorizations are not entertained by the laboratory. Any request for tests on the specimens received by the laboratory will be through the registration in the Sage Online Software (SOS-LIMS).
8. **Test order Read Back:** At SPL, all samples are accepted for testing only if accompanied with a work order or test request form. In the event of a referring physician or customers/clients ordering the test either orally or over telephone, the lab staff who attends call reads back the entire order to verify the accuracy of transcription and also confirms whenever any test orders are unclear (e.g., using non-standard or non-specific terms). SPL ensures a test request form is generated later for the same.
9. **Un-clear Test Orders:** All specimens with un-clear test orders are kept pending at the accession department and the specimens are stored in the Refrigerator at 2-8˚C. After receipt of necessary information through the customer care department in writing – the specimens are registered in the Sage Online Software (SOS-LIMS).
10. **Unlabeled/Mislabelled Specimens:** SPL will make every attempt to correctly identify specimens. However, if it is found that an improperly labelled specimen is received at the Laboratory then the customers would be notified via, an email or telephone. On receipt of the correct information on the patient sample the samples would be taken for testing. Non-receipt of correct information - may lead to the samples kept pending for want of information. If the laboratory receives two unlabeled specimens of the same type (both serum), both specimens will be rejected and the customers would be advised to recollect the fresh samples. Samples found to be unacceptable for testing will be rejected.

10.1. Samples that are rejected will NOT be tested and will be informed to the concerned Customer/Doctor as soon as possible via Sage Online Software or email or telephone and request for a fresh sample immediately.

10.2. Samples that leak in transit will contaminate other samples contained within that ziplock bag. The possibility that the leaked sample may contain any blood borne pathogen prevents us from:

10.2.1. Opening the package and putting our laboratory personnel at risk for exposure.

10.2.2. Testing samples that have even a remote possibility of being contaminated.

10.3. SPL understands that it is not always easy (and in some cases impossible) to recollect samples. Therefore, atmost care must be taken to examine all samples collected so that immediately correction can be made or redraw an inappropriate sample. If you have questions as to the quality of a sample or the specific rejection criteria – contact the SPL customer care department.

11. Quantity Not Sufficient (QNS): One of the most common and expensive errors in specimen collection is the submission of an insufficient sample for testing. This means that the laboratory has to send out a report marked QNS and the patient has to be called back for a repeat collection at additional expense and inconvenience to the patient and to the physician. To ensure an adequate quantity of the specimen, please refer to the Alphabetical List of Tests (Directory of Services).

12. Turnaround Time (TAT):

12.1. The most meaningful and quantifiable measures in healthcare are accuracy and speed of diagnosis. SPL is committed to providing the fastest turnaround time possible to improve patient management. The lab monitors the TAT stringently and evaluates areas for improvement on a daily basis.

12.2. For urgent samples – the clients should inform the customer care department via email or telephone giving the details of the urgent specimens. The laboratory will take up the requests on priority basis.

13. Request for Addition of Tests:

13.1. Samples are routinely retained as per the Lab Retention Policy at appropriate temperatures to maintain stability during storage.

13.2. Addition of tests on retained samples beyond the parameter stability would require fresh samples.

13.3. Test Additions are entertained when the requests are given by the clients/customers via email only to the customer care department.

13.4. On receipt of the request for additional tests the department inspects the status of the retained sample with respect to quantity and quality and suitable action is taken.

13.5. All addition of tests requires authorization from the concerned department HOD and the customer care department.

14. HIV Counselling and Reporting:

14.1. As per NACO guidelines, all clients/customers are informed about Pre and Post test counselling by the attending physician to all the patients registered for an HIV test. Being a clinical referral centre SPL does not take the responsibility for counselling of patients. All samples for HIV testing should be accompanied by completely filled pre test consent form duly filled. (Pre-test counselling form available in Sage-Online Software - Downloads).

14.2. Whenever the laboratory observes positive cases for HIV (1 & 2 Antibody), the results are re-confirmed with two different methods as per NACO guidelines.

14.3. All HIV positive test reports will be handed over to the attending physician by the local SPL representative (in stations and out stations) in an envelope labelled confidential and records will be maintained by the laboratory.

15. Amendments To Test Reports:

15.1. Any alteration of the test reports is carried out only by the Head of the Department (HOD)/Authorized signatory of the laboratory on approval from the Quality Manager. No other staff is authorized to alter test reports under any circumstances.

15.2. If the final report has already been released and printed and if the report requires alteration for any reason, the report is recalled after informing the referring physician or client/customer and required alterations are made and amended report is issued.

15.3. If there are multiple revisions in the single report, all corrections/revisions will be referenced in a sequential order on subsequent report indicating the corrections/ revision to allow the clinicians to take appropriate clinical decisions.

15.4. In case of any alterations in the final test report, the amended report will indicate "This report super cedes the report issued earlier and previous report is considered as nullified" at the time issuing to the clients/customers.

15.5. If the final report has not been released but the report requires alteration for any

reason, the report is released only after making required alterations and approval by the HOD and Quality Manager.

16. **Inoperable Tests:** In case of any tests which become inoperable due to continuous failure in PT performance, lack of supplies of kits or reagents, tests suspended by the suppliers due to any statutory regulations or manufacturing defects – the information on the suspended tests would be communicated to all the clients/customers via bulletin board option available in the Sage Online Software (SOS-LIMS).

17. **Customer Complaints:**

17.1. The laboratory has put in place specific personnel (Customer Care Department-CCD) to provide services to the clients. All the incoming calls and emails with respect to reports not co-relating, TAT delay, sample not registered, demographic changes add test etc., are recorded in the customer compliant record available with the CCD along with the time of resolution of complaints.

17.2. For any clarification or co-operation, the clients are free to contact the Customer Care Department (CCD), who will help the clients. CCD will direct them to the concerned HOD and Director (Lab Ops.).

18. **Client/Customers Satisfaction:** In order to assess the client/customer satisfaction on the services provided by SPL, "Customer Satisfaction Form" would be circulated by SPL twice a year to receive the feedback on the quality of testing, service. TAT, Critical Alert notification etc. The process would be initiated through the SPL sales field staff/Online – hence all the clients/customers are required to be in touch with the team to facilitate this process. Your suggestions and recommendation would be considered in the Management Review Meetings to improve the services provided by SPL.In case of any complaints kindly send an email with the sample ID and the details of the compliant to info@sagepathlabs.com.

19. **Sample Receipt:**

19.1. Once the specimens are received at the accession department the laboratory staff performs the following activities:

19.2. Sample boxes are opened in the Bio-safety cabinet/LAF under aseptic condition. Follow the instructions provided on use of bio-safety cabinets/LAF. Proper care is taken while opening the sample boxes like wearing gloves, lab coats, face masks etc.

19.3. Temperature displayed on the data logger kept in the sample transport boxes is recorded after opening the boxes, acceptable temperature is 2-8 °C.

19.4. Samples are verified for acceptance or rejection criteria as per the checklist.

19.5. All samples are arranged serially in racks and the barcode number on the samples is checked for matching barcode number entered by the client/customers in the Sage Online Work Order/TRF.

19.6. If the samples pass the acceptance criteria the samples are accepted then status of the sample in the Sage Online Work Order (SOS-LIMS) is changed to registered mode and patient is assigned a unique registration number with sample receipt date and time by the Sage Online Software (SOS-LIMS).

19.7. **For Urgent Samples** – the clients/customers inform the customer care department via email or telephone giving the details of the urgent samples and the information is communicated to the accession department. The laboratory will take up the requests on priority basis. All urgent samples are pasted with Fluorescent Red Colour Sticker – which denotes the urgent samples.

19.8. **Combination Specimens**– are received mostly for bio-chemistry and immunology tests. All specimen vials/containers having combination tests are identified with a Fluorescent Green Sticker – which denote the combination specimens. The combination specimens are first routed to the main testing department and after testing the required parameters – the specimens are routed to the second department for completion of the tests. All technicians are trained to handle the combination specimens with care and NOT to aliquot or dilute the specimens.

20. Criteria for Sample Rejection:

20.1. The laboratory will not process specimens with the following criteria. Depending on the specific problem, the specimen may be rejected/cancelled or held at the accession department until the appropriate requirements are met:

20.1.1. Unlabeled specimens.

20.1.2. Mislabelled / not matching with Patient's name on TRF /Online Work order.

20.1.3. Insufficient patient information /demographics.

20.1.4. Specimens not accompanied by a valid requisition.

20.1.5. Broken/Leaking tube or container.

20.1.6. Specimens collected in wrong tube (ex: anti coagulant)/container.

20.1.7. Specimens collected in wrong preservative.

20.1.8. Specimens collected in un-sterile container.

20.1.9. Inadequate volume of preservative.

20.1.10. Haemolysed specimens depending on test requested.

20.1.11. Specimens showing visible signs of contamination.

20.1.12. Exposure to light / extreme temperature.

20.1.13. Inconsistent information between the specimen container and the requisition.

20.1.14. Specimens with inadequate volume for the test ordered.

20.1.15. Prolonged transport time.

20.1.16. Urine specimens received after 24hours.

20.1.17. Urine for Urobilinogen specimens not received in Dark/Amber coloured containers.

20.1.18. Grossly contaminated, broken or leaking transport device (VTM)

20.1.19. Specimens received without swabs

20.1.20. Specimens received Single Swab

21. Rejected Specimens (Storage and Disposal):

21.1. Pending/Rejected samples are stored in the refrigerator maintained at 2ºC-8ºC temperature.

21.2. Information on pending/rejected samples is given to the customer care department.

21.3. Customer care department informs the Client/Customer through email or phone and procures the necessary information and transfers the information to accession.

21.4. After receiving the necessary information – the samples are taken up for registration.

21.5. Most of the samples are cleared on the same day and dispatched to concerned department for analysis.

21.6. If information is kept pending beyond 24 hrs, the samples viz., whole blood and urine are discarded after providing the information to the client/customers.

21.7. Samples of body fluids, microbiology samples are retained only for 48 hrs and biopsies are retained till the information is received by the laboratory.

21.8. All rejected samples are discarded as per the bio-medical waste disposal practices adopted by the laboratory after receiving confirmation from the client/customers.

21.9. The details are recorded in the rejection record available in the Sage Online Software (SOS-LIMS).

22. Sample Dispatch from Accession Department: Once the specimens are registered at the accession department the distribution of specimens from accession department to the respective testing department is done.

23. Policy on Repeat Samples and Additional Tests:

23.1. SPL does not usually accede to requests for repeat sample analysis;

23.2. However to cater for repeat analysis and additional tests, the samples are retained as detailed in the table given below in appropriate environmental conditions except for urine samples;

23.3. In case a request for re-analysis is forwarded, the sample will be retrieved from the retained samples (refer to table below) and retested at free of cost after complete review by the Director (Lab Ops.).

23.4. Fresh sample would be required only if quantity of the retained sample is insufficient to repeat the tests;

23.5. Request for repeat analysis is only accepted if the results are not correlating with the patient clinical condition and after brief exchange of views on the test report by the Director (Lab Ops.)/HOD and the physician ordering the test;

23.6. Written request for additional tests via email to the customer care department needs to be received by the laboratory;

23.7. Lab will evaluate the nature of specimen and its suitability for additional testing based on the retention policy of the laboratory; and

23.8. If found suitable additional tests would be carried out and reported.

RETENTION OF TESTED SAMPLES

Sr. No.	Department	Sample Retention Period	Storage Temperature
1	Clinical Biochemistry	24 hrs	2-8°C
2	Clinical Pathology	24hrs	2-8°C
4	Clinical Microbiology	48 hrs	2-8°C
5	Haematology (Blood)	24hrs	2-8°C
6	Haematology (Body Fluids)	48hrs	2-8°C
7	Immunology / Serology (General Parameters)	3 days	2-8°C
8	Immunology / Serology (HIV)	7 days	2-8°C
9	Immuno Genetics – DNA	5 years	-20°C
10	Immuno Genetics – Plasma	7 days	2-8°C
11	Molecular Biology – RNA	2 years	-80°C
12	Molecular Biology – DNA	2 years	-20°C
13	Molecular Biology-Viral Transport Medium	48 hrs	2-8°C

14	Molecular Biology-Covid Extracted RNA	30 days	-80 °C
15	Molecular Biology –Plasma	7 days	2-8°C
16	Haematology& Microbiology Slides	7 days	RT

CHAPTER – 5
CRITICAL ALERT NOTIFICATION

1. Critical Alert Notification:

A critical value is defined as a value that presents a patho-physiological state at such variance with normal or expected values that it is considered life threatening unless a corrective action is undertaken. Critical values do not necessarily correspond with normal reference ranges, toxic range or therapeutic ranges but are based on a level at which medical actionis considered necessary. All possible critical value limits will be informed within 60 minutes to the concerned client/customers representative.

SPL will document all informed critical values and verification of the "read back" of these values. The documentation includes the name of the laboratory individual placing the call, the first initial, last name and professional title of the clinical individual who was notified, the date and time at which the notified individual read back the critical values. Any problems, including refusal to accept the values, that may be encountered in making the call in a timely manner is recorded in the comments field.

Upon completion of the critical value notification, the doctor or the listener **must** verbally read back **ALL** of the reported critical values(s) and properly identify themselves (at minimum with the first initial of their name and their entire last name), **including their professional title (MD, LVN, RN, NP, PharmD).**

"Request the doctor or the listener to **"**Please read back the critical value and Patient name/age/sex/barcode + registration number that I just reported to you, and please provide me with your name and professional title**."**

All clients/customers nominated representatives are requested to comply with the critical alert notification and the read back policy of the laboratory. Critical values for all the departments are listed below and the same are decided in consultation with the prescribing physicians.

CRITICAL VALUES - CLINICAL BIOCHEMISTRY

Sr. No.	Parameter		Critical Low (Less than)	Reference Range		Critical High (Greater than)	Units
				Low	High		
1.	Amylase		---	28	100	200	U/L
2.	Bicarbonate		10	22	32	40	mmol/L
3.	Bilirubin- Total (New Born)		---	0.4	2	15.0	mg/dL
4.	Calcium		6.0	8.9	10.3	13	mg/dL
5.	Chloride		80	101	111	120	mmol/L
6.	CK	Male	---	49	397	400	IU/L
		Female	---	38	234	240	IU/L
7.	Glucose	New born 0-2 days	30	80	140	325	mg/dL
		Three days to one year	40	80	140	400	mg/dL
		above one year	46	80	140	445	mg/dL
8.	Iron		---	45	182	200	µg/dL
9.	Lipase		---	22	51	200	U/L
10.	Magnesium		1.0	1.8	2.5	4.7	mg/dL
11.	Phosphorus		1.0	2.5	4.6	8.9	mg/dL
12.	Potassium	Below one year	2.8	3.6	5.1	7.8	mmol/L
		Above one year	2.8	---	---	6.2	mmol/L
13.	PSA		---	---	4.0	6.0	ng/mL
14.	Sodium	Below one year	125	136	144	150	mmol/L
		Above one year	120	136	144	160	mmol/L
15.	Urea		---	15	40	80	mg/dL
16.	Uric acid	Male	---	4.8	8.7	13	mg/dL
		Female	---	2.6	8	9.5	mg/dL

CRITICAL VALUES FOR NEONATES

Sr. No.	Parameter	Critical Low (Less Than)
1.	Calcium	< 7mg/100 ml
2.	Creatinine	>0.9mg/100 ml
3.	Glucose	< 40mg/100 ml
4.	Lactate	>2.6 mmol/L
5.	Magnesium	<0.6 mmol/L
6.	Potassium	< 3 mmol/L, > 6 mmol/L
7.	Sodium	<130mmol/L
		>150 mmol/L
8.	Urea	>80mg/100ml

CRITICAL VALUES FOR TOXICOLOGY

Parameter Name	Low Critical Value	High Critical Value	Units
Digoxin, Serum	-	> 4.0	ng/ml
Phenobarbital	-	> 60	µg/ml
Phenytoin, Total	-	> 30	µg/ml
Theophylline, Plasma	-	> 30	µg/ml
Valproic Acid	-	> 120	µg/ml

CRITICAL VALUES FOR CLINICAL PATHOLOGY

Sr. No.	Parameter	Critical Alert Values	When to Call
1.	Urine Routine	**Microscopic:** Presence of pathological crystals (Urate, cysteine, Leucine, or tyrosine). **Chemical:** Strongly positive glucose and ketones abnormality.	1st time same day

CRITICAL VALUES FOR HAEMATOLOGY

Parameter Name	Age	Low Critical Value	High Critical Value	Units
Platelets	Any	< 10	> 1000	X 10^3 /µL
Hemoglobin	Adults	< 4.0	> 20.0	g/dl
Hemoglobin	New Born	< 10.0	> 20.0	g/dl

Parameter Name	Age	Low Critical Value	High Critical Value	Units
WBC	Children	< 2.0	> 43.0	X 10^3 /µL
Smear	Immature cells/toxic granules, abnormal peripheral smear			
Red Cell Morphology	Any	Sickle cells		1 st time
Hemoparasites (eg. Malaria)	Any	Positive		1 st time
CRITICAL VALUES - FLUID EXAMINATION				
Cerebrospinal Fluid(CSF)-TNC (Total Nucleated Cells)	Adult	-	> 5	Cells / µL
CSF TNC	0-1	-	30	Cells / µL
CSF TNC	1-4	-	20	Cells / µL
CSF TNC	5-17	-	10	Cells / µL

Any type of fluid	Malignant cells, Blasts

CRITICAL VALUES FOR IMMUNOLOGY

Parameter	Critical Alert Values
Cryptococcus Antigen	Positive
Dengue NS1 Antigen	Positive
Dengue IgM Antibody	Positive

CRITICAL VALUES FOR MICROBIOLOGY

Parameter	Critical Alert Values
Blood Culture	Positive
Cerebro Spinal fluid gram stain or culture	Positive
Sreptococcus pyogenes (Group A Streptococcus) in surgical wound	Positive
Gram stain suggestive of gas gangrene	Positive

Parameter	Critical Alert Values
Detection of a significant pathogen	Positive
Negative Stain in CSF	Positive

CRITICAL VALUES FOR HISTOPATHOLOGY

Parameter	Critical Alert Values	When to call
Biopsy Specimens	• Fat in colonic Endoscopic Polypectomies. • Uterine contents in pregnancy women without villi/trophoblastic tissue • Fat in endometrial curettage • Leucocytoclastic vasculitis • Suspected Pemphigus. • Specimen for transplant rejection. • Neoplasm causing paralysis. • Crescents in greater than 50% glomeruli in renal biopsy. • Unexpected or discrepant findings. • Unexpected malignancy. • Significant disagreement and/or change between primary and outside Pathologist consultation. • Presence of secondaries in bone marrow biopsy *(At either at original or consulting institution)*	1st time same day
Cytopathology Specimens	• Known primary malignancy, new diagnosis of metastasis.	1st time same day

	• Malignancy (suspected or not) in critical places (eg, superior vena cava syndrome, risk of spinal cord injury) • New diagnosis of high-grade squamous intraepithelial lesion • The finding of organisms (bacteria and fungi) in non-gynecologic specimens. • Bacteria or fungi in CSF Cytology in immuno comprised patient. • Pneumocystis, fungi, or viral cytopathic changes in BAL, wash, or brush specimen inimmuno comprised patient. • Disagreement between the immediate and final interpretations in FNA specimens.	

CHAPTER – 6
SAMPLE COLLECTION, PACKING AND TRASPORTATION

1. **Specimen Collection, Packing and Transportation:** The purpose of this procedure is to give instructions to the collection staff for preparation of the patient for the test, sample collection techniques, separation if any and transportation of samples to the referral laboratory.
2. **Responsibility:** All sample collection technicians are responsible for the activities detailed in this procedure. Collect specimen(s) in proper containers supplied by the company. Refer to the List of Tests **(Directory of Services)** for detailed instructions for Specimen collection and transport.
3. **Packing Instructions for Samples:**
   - **3.1.** Ensure all container lids are tightly secured before packaging.
   - **3.2.** Samples and TRFs to be packed individually in different plastic covers, preconditioned gel packs.
   - **3.3.** Hand writing TRFs should be legible, Upper case is recommended for easing registration process.
   - **3.4.** Specimens must be packed and shipped properly for accurate testing, which helps ensure that patients receive optimal treatment. All medical specimens have to arrive at the testing facility:
     - **3.4.1.** At the correct temperature for testing.
     - **3.4.2.** Containers shall be tightly sealed to prevent leakage and external spillage.
     - **3.4.3.** Containers shall be intact without breakage or leakage.
     - **3.4.4.** In the shortest possible time.
     - **3.4.5.** In compliance with all applicable regulations.
     - **3.4.6.** Styrofoam boxes shall not over loaded with samples.

4. **Packing Instructions for Blood Samples:**
   - **4.1.1.** All primary containers have to be reinforced with Adsorbent pad in a Zip lock bag.

4.1.2. The primary containers along with the Zip Lock bag have to be re-packed in the second Zip Lock bag which acts the secondary container.

4.1.3. Remove all contents of transport box.

4.1.4. Seal the Zip Lock bags (primary and secondary). This will prevent the sample from contaminating the Test Request Form (if enclosed) in cases of accidental leakage.

4.1.5. Place a pre-frozen gel pack on the bottom of the Styrofoam box (gel packs must be pre-frozen at 0oC for 24 hours prior to use).

4.1.6. Place samples sealed in zip lock bag over the gel packs.

4.1.7. Place the data logger for temperature monitoring.

4.1.8. Cover specimens with second layer of gel packs and close the Styrofoam box lid.

4.1.9. Place the Styrofoam box in the ice box and transport to laboratory immediately.

5. **Packing Instructions for Urine and Stool:** Use polypropylene sterile containers supplied by the laboratory for the collection of urine and fecal specimens. Any substitute containers must have a screw cap and should be leak proof. A special small Styrofoam box is used for shipping one or two stool or urine containers. Large-volume of stool and urine containers must **NOT** be mixed with other specimens. They must be shipped in a separate small Styrofoam box.

5.1.1. Use only sterile containers supplied by the laboratory for the collection of urine and stool specimens.

5.1.2. Ensure that Urine/Stool and other samples are packed separately.

5.1.3. All urine and stool containers have to be reinforced with Adsorbent pad in a Zip lock bag.

5.1.4. The primary containers along with the Zip Lock bag have to be re-packed in the second Zip Lock bag which acts the secondary container.

5.1.5. Remove all contents of transport box.

5.1.6. Seal the Zip Lock bags (primary and secondary). This will prevent the sample from contaminating the Test Request Form (if enclosed) in cases of accidental leakage.

5.1.7. Place a pre-frozen gel pack on the bottom of the Styrofoam box (gel packs must be pre-frozen at 0oC for 24 hours prior to use).

5.1.8. Place specimens sealed in zip lock bag over the gel packs.

5.1.9. Place the data logger for temperature monitoring.

5.1.10. Cover specimens with second layer of gel packs and close the Styrofoam box lid.

5.1.11. Place the Styrofoam box in the ice box and transport to laboratory immediately.

5.1.12. Transport requirements are of three types: Refrigerated, Room Temperature and Frozen. Use of sterile containers supplied by the laboratory is recommended.

5.1.13. Remember, no other type of specimens can be packed in the Styrofoam box containing urine and stool containers. Please refer to the transport conditions and minimum volumes required for each analyte in the Directory of Services before using appropriate mode of transport to laboratory**.**

6. Transport Containers:

6.1. Transport boxes supplied by the laboratory will have to be used.

6.2. The transport boxes have to be labelled with the complete address and telephone numbers of the laboratory, bio hazard symbols pasted or printed on the boxes indicating the boxes containing infectious materials.

6.3. All the transport boxes should have primary and secondary containers, styrofoam boxes for packing urine and stool samples, adsorbent pads, data logger and ice packs for maintaining cold chain.

7. Transport of Samples to the Laboratory:

7.1. SPL – Customer Care Department works closely with couriers, air carriers and clients to make sure that specimens arrive at the Laboratory in the most expedient,

efficient and safe manner possible. Local area samples are provided with Lab-provided courier service (SPL-Collection Representatives).

7.2. Different routes are prepared within the twin cities of Hyderabad originating from the regional office of SagePath Labs and with the final destination at Central Laboratory at Boduppal. Each route comprising about 8-10 clients are serviced by independent SPL-collection representative. All the SPL collection representatives are equipped with Specimen Collection & transport Boxes with proper packing materials and the data loggers.

7.3. Within a specified route at some designated collection points (hospitals, nursing homes, diagnostic labs) ice gel packs are stored in the freezer for making use by the SPL representative in case of temperature goes beyond +6°C.

7.4. At each of the collection point the temperature is seen by the SPL collection representative before putting the samples pertaining to the collection point and if the temperature is going beyond +6°C the ice gel packs available at the collection point are taken and placed in the sample collection boxes for maintaining the temperature. Unfrozen ice gel packs taken from the sample collection containers are again freezed at the collection point for future use. Proper training is provided to all the SPL-collection representatives in monitoring the temperature, handling and placing of ice packs.

7.5. It is advised to all the SPL-collection points to transport all samples collected as early as possible of collection to laboratory along with online test request form with all the patient details.

CHAPTER – 7
FIRST AID, ADVERSE EFFECTS IN SAMPLE COLLECTION AND TRANSPORTATION

1. **First Aid:** First Aid is a simple emergency medical care procedure intended for lay rescuers to perform before emergency medical professionals are available.
   - **1.1.** Accidents in the laboratory and sample collection areas may have various causes.
   - **1.2.** Acids and alkalis splashes on the skin or in the eyes, swallowing of Toxic substances.
   - **1.3.** Heat naked flames, hot liquids, flammable liquids and explosions.
   - **1.4.** Injuries involving infectious material, electric shocks, etc.
   - **1.5.** To handle these situations a first aid box has to be in place and at least one health care personnel with extensive first aid training should be available onsite.
2. **Contents of First Aid Box:**
   - **2.1.** An instruction sheet giving general guidance.
   - **2.2.** Individually wrapped sterile adhesive dressings in a variety of sizes.
   - **2.3.** Gauze for wiping the wound.
   - **2.4.** Sterile eye-pads with bandages for attachment.
   - **2.5.** Sterile dressing pads for serious wounds.
   - **2.6.** A selection of sterile small dressing pads for minor wounds and safety pins.
   - **2.7.** A bottle containing eye drops and Antiseptic solution or ointments.
   - **2.8.** Stock first aid kits with Band-Aids, 4x4 inches gauze, roller bandages and ace bandages (creams, ointments, etc.) report to physician after first aid has been administered.
3. **First Aid Measures:**
   - **3.1. Bleeding and Wound Care**: Wear clean gloves, cover area with gauze (or clean paper towels). Apply pressure to bleeding area -- have person sit or lie down. If wound is large or person is dizzy or weak, shift to Casualty Room of the hospital**.**
   - **3.2. Burns -- Heat/Chemical (Heat burns)**: Run cool water over area for 5 minutes if burn area is large, cover with a cool, wet cloth and contact physician.

3.3. Chemical Burns (acid or alkaline) - Flush with large amounts of cool running water for 15 minutes. For larger area or if person is weak or dizzy, contact physician.

3.4. Eye Splash Chemical: Flush with lukewarm (body temperature) running water; turn head side to side and have water run across both eyes. Flush eyes for at least 15 minutes before going for further treatment.

3.5. Eye - Foreign Body (dust or metal, paint, wood chips): Cover or close eye. Report to ophthalmologist.

4. **Adverse Effects during Phlebotomy:** Adverse reactions include fainting seizures and injuries. Immediate assistance should be available to care for patients who experience adverse reactions from phlebotomy. The following measures have to be taken during the occurrence of adverse effects:

4.1. Nausea:

4.1.1. Make the patient as comfortable as possible.

4.1.2. Instruct the patient to breath slowly and deeply.

4.1.3. Apply cold compressors to the patient's forehead.

4.2. Vomiting:

4.2.1. Give the patient the emesis basin or other container and keep tissues ready.

4.2.2. Give the patient water to rinse his/her mouth.

4.2.3. Notify the designated personnel.

4.3. Convulsions:

4.3.1. Prevent the patient from injuring him/herself not to re-strain the movements of the patient extremities completely.

4.4. Hematoma:

4.4.1. Injuries to the patient, remove the tourniquet and the needle from the arm.

4.4.2. Place 3-4 gauze squares to the hematoma and apply firm pressure for 7-10 minutes with patient arms held above the heart level.

4.5. Fainting or Unexpected Non responsiveness:

4.5.1. Lay the patient flat or lower his/her head and arms if patient is sitting and loosen tight clothing.

4.6. Needle Stick injury:

4.6.1. A needle stick injury is a percutaneous piercing wound typically set by a needle point, but possibly also by other sharp instruments or objects.

4.6.2. Commonly encountered by people handling needles in the medical setting, such injuries are an occupational hazard in the medical community.

4.6.3. Occupational needle stick injuries are mainly focused on the healthcare environment. These events are of concern because of the risk to transmit blood born disease through the passage of the Hepatitis B virus (HBV), the Hepatitis C virus (HCV), and the Human Immunodeficiency Virus (HIV), the virus that causes AIDS and other pathogens.

4.6.4. These injuries also commonly occur during needle recapping and as a result of failure to place used needles in approved sharp containers.

4.6.5. When Needle Stick Injury Occurs:

- Do not Panic
- Wash hands immediately in running water for 10 minutes (don't squeeze)
- Report to the Concerned HOD

4.6.6. Generally needle stick injuries cause only minor bleeding or visible trauma, however, even in the absence of bleeding the risk of viral infection remains. Needle stick injuries are less frequent but precautions have to be taken before collecting samples.

5. Adverse Effects during Transportation of Samples: An adverse effect is an unwanted or harmful effect. Adverse effect during transportation of samples can be due to leakage of samples and unexpected accidents, the following measures have to be taken to handle such situations.

5.1. To be safe, treat every spill as if it were infectious. If any specimen container in the sample collection/laboratory appears to be leaking, don't touch it. Bring it to the attention of lab personnel for repackaging. Do this even if the leaking container is inside another bag.

5.2. To avoid such leakages samples have to be collected in a screw tight primary containers and placed in biohazard marked zip lock bag with adsorbent pads.

5.3. The primary containers shall be placed in the second zip lock bag which acts as the secondary container.

5.4. The zip lock bags are placed in the Styrofoam box which are kept inside the transport box along with cool packs and data logger.

5.5. All collection boys are instructed to carry their identity cards while transportation of samples from pick up centres to the laboratory.

5.6. All collection boxes have the lab address and helpline numbers with instructions to reach the lab support team in case of any adverse effect during transportation of samples.

5.7. After information reaches to the laboratory, lab personnel will rush to the spot for the necessary action such as transporting the samples to the lab.

5.8. Sample transportation box will be shifted immediately to the lab for checking of any leakage of samples. If any leakage occurs it will be discarded in 1% Sodium hypochlorite solution.

5.9. In case of any leakage of samples information will be given to the customer.

6. **Handling of Adverse Incidents - Lab-provided Courier Service:** If a leak or spill occurs away from a laboratory, the courier will have to clean it up, using either a commercial clean-up kit or bleach.

6.1. Make sure no one touches or walks through the spill.

6.2. Always wear latex gloves when dealing with a spill.

6.3. If a spill is large, blot up as much as possible with a paper towel.

6.4. Any materials used to clean up a spill, including paper towels and gloves, should be sent to the SagePath Labs in a separate Styrofoam box.

6.5. Put a large note on top of the Styrofoam box headed: "LEAKING SPECIMEN."

6.6. If the specimen was infectious, put all of the contents into a container/box with the infectious substance label and write "INFECTIOUS LEAKING SPECIMEN" on top of the Styrofoam.

6.7. On the note, include the courier's name, whose specimen it was, where the leak or spill occurred, and any other relevant details.

6.8. Be sure to note on the appropriate specimen control document that the specimen from that box has been shipped in a separate Styrofoam box.

6.9. If a container is leaking inside a bag, immediately secure it inside another zip lock bag and ship it in a separate Styrofoam box.

6.10. Be sure to communicate if the courier or anyone else came in contact with the specimen.

7. **Procedure for Notifying Adverse Events:** Any leak or spill should be reported immediately to SagePath Labs or the courier's employer. Don't wait for the end of the run; call SagPath Labs immediately at **040-40125441** and ask for the Customer Care Department. On receiving the information the customer care department will inform the local State Pollution Control Board and send the authorized bio-medical waste agency to the incident site for clean-up. All incidents will be reported to State Pollution Control Board in prescribed form-III as per bio-medical waste (management and handling) rules 1998.

CHAPTER – 8
BIO-MEDICAL WASTE HANDLING AND DISPOSAL

1. **Purpose:** The purpose of this procedure is to give instructions to the collection staff on of handling and segregation of general and biomedical waste generated from the phlebotomy areas.
2. **Responsibility:** The housekeeping staffs available at the collection points are responsible for this process.
3. **Procedure:**

3.1 Decontamination of Collection Waste:

3.1.1 If open type vacutainer system (disposal syringes and needles) are used – then the used needles should be destroyed in a needle cutter and disposed offin Sharps Container containing 1% Sodium Hypochlorite solution.

3.1.2 All plastic ware should be disposed of in Red bio-hazard bags.

3.1.3 Avoid manual manipulation of needles viz., recapping, bending, breaking, removing from disposal syringes.

3.2 Collection and Segregation of Solid Waste:

3.2.1 The segregation of waste generated in the sample collection area has to be done based on the disposal options listed in the table below.

3.2.2 All scalpels, blades, to be disposed in SHARPS container mentioned below.

3.2.3 The waste needs to be disposed through the authorized bio-medical collection agency approved by State Pollution Control Board for treatment and disposal.

Sr. No.	Colour/Type of Bag for Disposal	Biomedical Waste to be Disposed
1.	Black	Paper, food waste, paper waste, disposable cups, cardboards and water bottles.
2.	White Jar (Puncture Proof Container)	Needles, scalpels, slides, nails, blades, sharp items and other broken glass items.

3.	Red	Gloves, plastic disposables, disposable tips, syringes, urine bags, catheter stents, ELISA plate and vials not containing blood samples.
4.	Yellow	Body parts, placenta, human tissue specimens, surgical waste, cotton bandages and gauzes, dressings, solid plastics and infectious waste, waste blood bags (containing date expired or contaminated blood).
5.	Blue	Broken Glass ware, Metallic body implants, Slides.

4. **Management of Blood/Body Fluid Spills:**

4.1 Place caution board and call for help.

4.2 Bring the spill kit.

4.3 Wear appropriate Personal Protective Equipment's (PPEs) – Face mask, gloves, and Apron available before handling the spills.

4.4 Place the absorbent pad or tissue paper over the spill.

4.5 Pour adequate amount of 1% sodium hypochlorite over the pad depending on the amount of spill. (1% sodium hypochlorite solution is prepared by dissolving 25 ml of 4% sodium hypochlorite solution in 75 ml of distilled water and a contact period between the chemicals of 30 minutes is allowed).

4.6 Wait for 10-30 minutes (Depending on minor or major spill).

4.7 Remove the absorbent material using dust pan and brush from outwards to inwards and discard in the red bag.

4.8 Mop the area with disinfect solution.

4.9 Used gloves discard in the Red bag.

4.10 If broken pieces of glasses are present discard in puncture proof container (SHARPS CONTAINER) which is half filled with 1% sodium hypochlorite solution.

5. **References:** NACO And ICMR guidelines