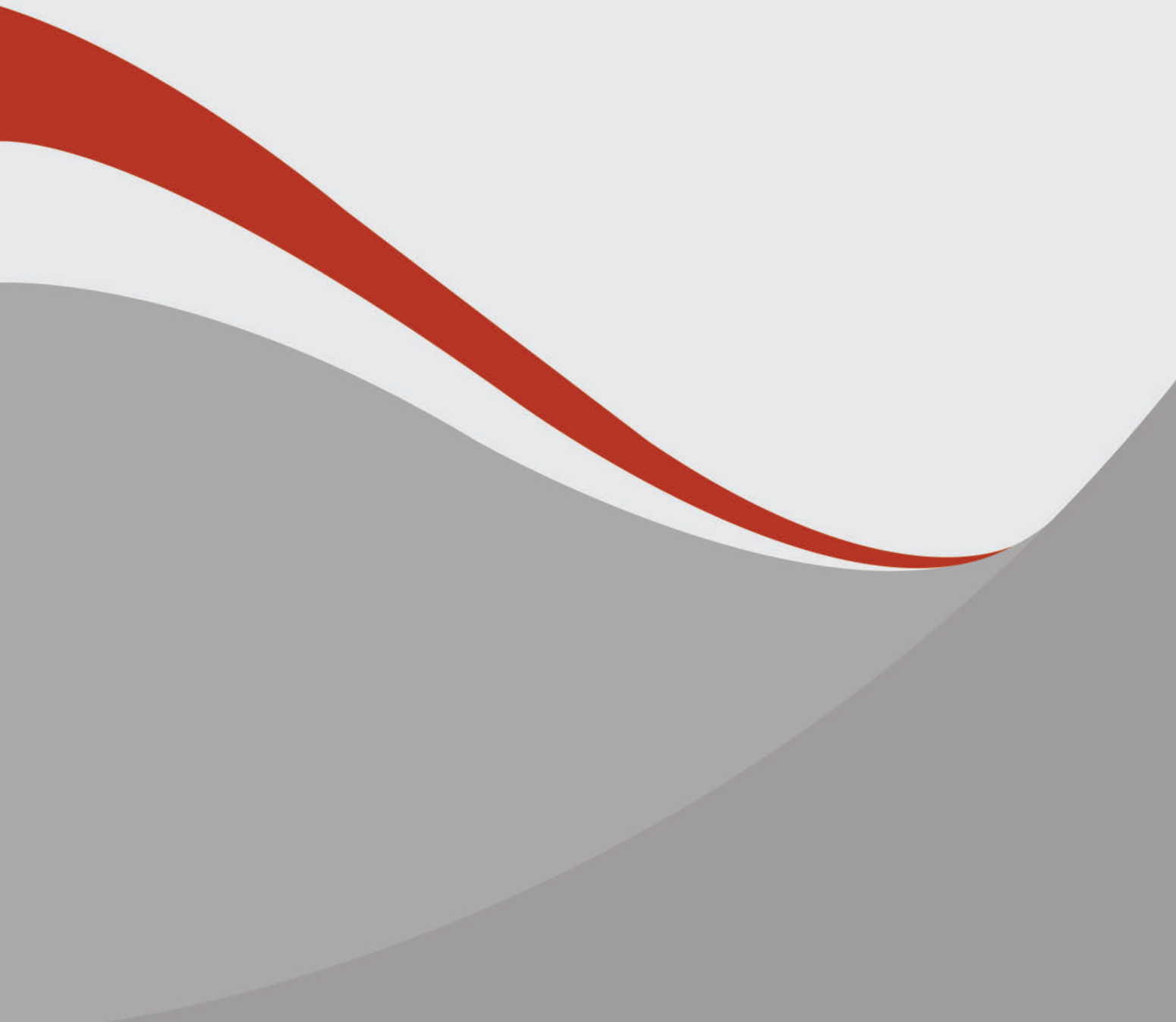




**Ethiopian Public Health Institute
Federal Ministry of Health**



Guidelines for Specimen Referral System in Ethiopia



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First Edition, January 2018

**Ethiopian Public Health Institute
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FOREWORD

Laboratory medicine encompasses testing services and associated practices for screening, diagnosis, treatment and prevention of numerous health related problems and deadly diseases. It helps detect, identify, and promptly report all diseases of public health significance. The laboratories are among the key components of any health care delivery system.

Some medical treatment is solely provided based on clinical findings and specialized laboratory services are limited to only a few health care facilities. Most of the public lacks accessibility to existing laboratory services in the country. In accurate clinical diagnosis, additional and unnecessary testing, and related increased costs can lead to inappropriate treatment, treatment complications and a delay in recovery from the disease.

Sustainable and consistent provision of laboratory services to all who require these is not feasible due to various reasons, for example lack of equipment and supplies, financial constraints, etc. The most prominent problem is the absence of or weak maintenance service at all levels of the laboratory system. In addition, some tests need special laboratories equipped with sophisticated equipment, qualified professionals, and a properly managed working environment. Availing these laboratories at all levels is financially and logistically unaffordable. Therefore, ensuring that accessibility of these services is available when required is to establish a laboratory network and specimen referral systems. Hence, testing services can be delivered on a referral basis to any of the four tiered laboratory levels of the country in line with the Maputo Declaration on Strengthening of Laboratory Systems.

Proper packaging and transportation, safety concerns and the quality of the specimen are some of the issues that need to be critically considered during referral. In this regard, the recent practice of transferring specimens and receiving the results back using the Ethiopian postal service is considered to be encouraging. Furthermore, this system will enable us to produce and report in a timely manner the test results both domestically and internationally (such as for an epidemiological profile) during public health emergencies, since Ethiopia is a WHO member country and has signed the International Health Regulations Agreement in 2007. Finally, I believe that this guideline helps standardize the laboratory network and specimen referral system, improve accessibility of laboratory services including specialized tests, establish safety conditions and improve the quality of referral specimen.



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ACRONYMS

Ab	Antibody
AFB	Acid Fast Bacilli
AFP	Acute Flaccid Paralysis
Ag	Antigen
AI	Avian Influenza
AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retroviral Therapy
BGS	Buffered Glycerol Saline
CBC	Complete Blood Count
CD4	Cluster Differentiation 4
CDC	Center for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
COV	Corona Virus
CSF	Cerebral Spinal Fluid
DBS	Dried Blood Spot
DNA PCR	Deoxyribonucleic Acid Polymerase Chain Reaction
EDTA	Ethylene Deamine Tetra Acetic Acid
EPHI	Ethiopian Public Health Institute
EID	Early Infant Diagnosis
FIND	Foundation for the Innovation of New Diagnostics
FMOH	Federal Ministry of Health
FNA	Fine Needle Aspiration
HBV	Hepatitis B Viral
HCV	Hepatitis C Viral
HEPA	High Efficiency Particulate Air
HIV	Human Immunodeficiency Virus
IATA	International Air Transport Association
IFA	Indirect Florescence Antibody Test
I-TECH	International Training and Education Center for Health
LDH	Low Density Lipoprotein

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LFT	Liver Function Tests
MSH	Management Sciences for Health
NA	Not Applicable
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PHEM	Public Health Emergency Management
PHSP	Private Health Sector Program
PPE	Personal Protective Equipment
PFSA	Pharmaceutical Fund and Supply Agency
QA	Quality Assurance
QC	Quality Control
RBC	Red Blood Cells
RDT	Rapid Diagnostic Tests
RFT	Renal Function Test
RHB	Regional Health Bureau
RNA	Ribonucleic Acid
RPHIs	Regional Public Health Institutes
RRL	Regional Reference Laboratory
RT-PCR	Reverse-Transcriptase Polymerase Chain Reaction
SARS	Severe Acute Respiratory Syndrome
SCMS	Supply Chain Management System
SOP	Standard Operating Procedure
SPS	Sodium Polyanethole Sulfonate
TAT	Turn Around Time
TB	Tuberculosis
VHF	Viral Hemorrhagic Fever
VTM	Viral Transport Media
UN	United Nations
USAID	United States Agency for International Development
WBC	White Blood Cells
WHO	World Health Organization

Terms of Definition

Biohazard: An agent of biological origin material or a condition that has the capacity to produce harmful effects on the health and safety of humans, animals, or the environment; i.e. microorganisms, toxins and allergens derived from those organisms, and allergens and toxins derived from humane.

Biosafety: Regulation of addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The practice of safe handling of pathogenic micro-organisms and their toxins in the biological Laboratory is accomplished through the application of containment principles and the risk assessment.

Biosecurity: The protection, control and accountability for biological agents and toxins within Laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.

Courier: An organizational entity personnel who has a responsibility for laboratory specimen transportation and result delivery in safely and confidentiality

Incidents - An event or occurrence involving infectious material, infected animals, or toxins, including a spill, exposure, release of infectious material or toxins, personnel injury or illness, missing infectious material or toxins, fire, explosion, flood, or other crisis situations.

Network: A Laboratory set of connections which indicate the flow (rout) of all referring Health Facilities with all their respective referral Laboratories for specimen testing and results delivery system.

Packaging: It includes the receptacle(s) and other components or materials necessary for the package to perform its containment function in support of the completed product prepared for transportation with the regulation's minimum packing requirements.

Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) and other agents such as prions which can cause disease in humans or animals.

Rejection Criteria: A set of requirements or preconditions standard (principle) to differentiate qualified specimens during the time of specimen accepting procedure to achieve quality result in Laboratory testing process.

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Referring Laboratory: A Health Facility that sends specimen for Laboratory testing or further investigation purpose to other Health Facility based on the available healthcare delivery tiered system.

Referral (Receiving) Laboratory: A Laboratory that received specimen for examination or further investigation analysis through the integrated Laboratory tiered structures healthcare delivery system.

Specimen: Are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, sputum, urine, blood, surgical drain fluid and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Triple Package: For transporting diagnostic specimens & biological agents based on National/ International accepted regulation system in tri part specimen container mechanism by once; that includes three distinct layers of protection Primary receptacles, Secondary packaging and Outer packaging.

Turn Around Time: The prolonged duration time from the time of receipt of the specimen at Laboratory to the time of report delivery to the patient (client) or referring Laboratory. Except on some extraordinary occasions, the result should be delivered as per the specified setting time.

2. BACKGROUND

Laboratory services are often limited to certain routine testing types performed in most health facilities, especially in resource limited countries due to various reasons mainly because of material, financial and trained personnel constraints. The gaps between the need of the public for evidence based healthcare in one side and the scarcity of available resources on the contrary impede the type and quality of laboratory services. In order to alleviate such problems and increase access of the community with adequate and quality services, feasible and applicable linkage mechanisms among laboratories should be devised and implemented throughout the healthcare delivery system. One strategy is to design a network among the different laboratories in the healthcare system and implementing a specimen referral system.

The ultimate goal of creating the laboratory network and specimen referral system is to address the public demand at large for and provision of quality health service. The rationale includes the provision of and perpetuating adequate, reliable, and satisfactory laboratory diagnosis in the ever-expanding health care system. Communication, knowledge and experience sharing among the networked laboratories can also contribute to improve the quality of their services. In addition, this could facilitate a fair allocation and distribution of available resources.

Laboratories in Ethiopia are categorized into four structural levels ranging from the community to national. Health center laboratories including specimen collecting health posts fall under level one. Health posts may collect and refer specimens such as suspected TB, malaria, etc., to the nearest health facility, which is mainly a health center. Level two laboratories are comprised of all laboratories found in the different hospitals (District, Zonal, Regional and specialized referral Hospitals). Laboratories are an integral part of each health facility in level one and two categories. Regional and National Reference Laboratories are standalones and classified as level three and four respectively.

Referral- based services demand the systematic coordination of laboratories in the different health settings. The referral network facilitates communication between laboratories vertically with the type and mix of professionals and the scope of the laboratory services better as the hierarchy moves from bottom to top (level one to two). Alternatively, this can facilitate communication horizontally among similar laboratories in the same level. Sometimes specimens may also be referred to specialized health facilities without necessarily passing through each tier of the system (or through the different vertical levels).

In the implementation of a referral system, specimens are collected from any health facility and transported via a suitable courier system to referral laboratories where the testing service is available. The result is then returned back to the referring laboratory through an appropriate transportation route.

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The Federal Ministry of Health (FMoH), the Ethiopian Public Health Institute (EPHI), Regional Health Bureaus (RHBs) and health facilities are responsible for the implementation of the specimen referral system. The involvement of other stakeholders and partners also has paramount importance to ensure that the program is effective.

In the past few years, there have been several efforts to test specimens using the referral system though the service was limited to few testing types. An assessment was conducted to evaluate the outcome of this service including the advantages, disadvantages and challenges. Based on the assessment done in January 2010, nearly 71% (59/83) of the hospitals were providing referral services for tests monitoring antiretroviral treatment and each of them was linked to an average of five referring sites. The frequency of referrals or specimen transportation occurred an average of six times per month, and the average distance of referring sites was 53 kilometers (ranging from one to 200) away from the testing laboratories. The results of the assessment indicated that nearly 90% (53/59) of the assessed referring and referral laboratories faced challenges with regard to referral services. The main problems included poor coordination, logistics and safety issues. To address this situation, a guideline has been developed to assist in improving the quality of laboratory services and ensure the accessibility of quality testing services to the community through the establishment and strengthening of the national laboratory network and referral linkage system

3. PURPOSE OF THIS GUIDELINE

This guideline is aimed at:

- Standardizing the national specimen referral system for public health emergency management and clinical services to improve accessibility of laboratory testing services by the community
- Defining the laboratory network structure and its functions for specimen referral.
- Defining the roles and responsibilities of all parties involved in the implementation of the specimen referral system
- Facilitating communication among laboratories in the network

3. TARGET USERS

This guideline is useful for decision-makers, program implementers, partners, public and private health sector institutions, couriers and professionals in the public health and clinical laboratory practices in Ethiopia.

4. LABORATORY SPECIMEN REFERRAL NETWORK

A laboratory specimen referral network is composed of laboratories at each level of the healthcare system that are committed to facilitate the proper diagnosis of diseases, which have clinical and public health impacts. Until now, both administrative boundaries and geographical proximities were the basis for the laboratory network and referral system in the country. In this guideline, the laboratory specimen referral network is solely based on the geographic proximity, availability of road and testing services so that the referral will be to the geographically closest referral laboratory. The belief is that this arrangement minimizes the turnaround time for obtaining results, reduces transportation costs, and maximizes the benefits of the specimen referral testing services.

The health service delivery arrangement and laboratory network in Ethiopia at present are organized hierarchically with one National Reference Laboratory (EPHI) at the apex; the next levels below this are the Regional Laboratories/Regional Public Health Institutes (RPHI), hospital laboratories, and health center laboratories.

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Four Level Integrated Laboratory Networking in Ethiopia

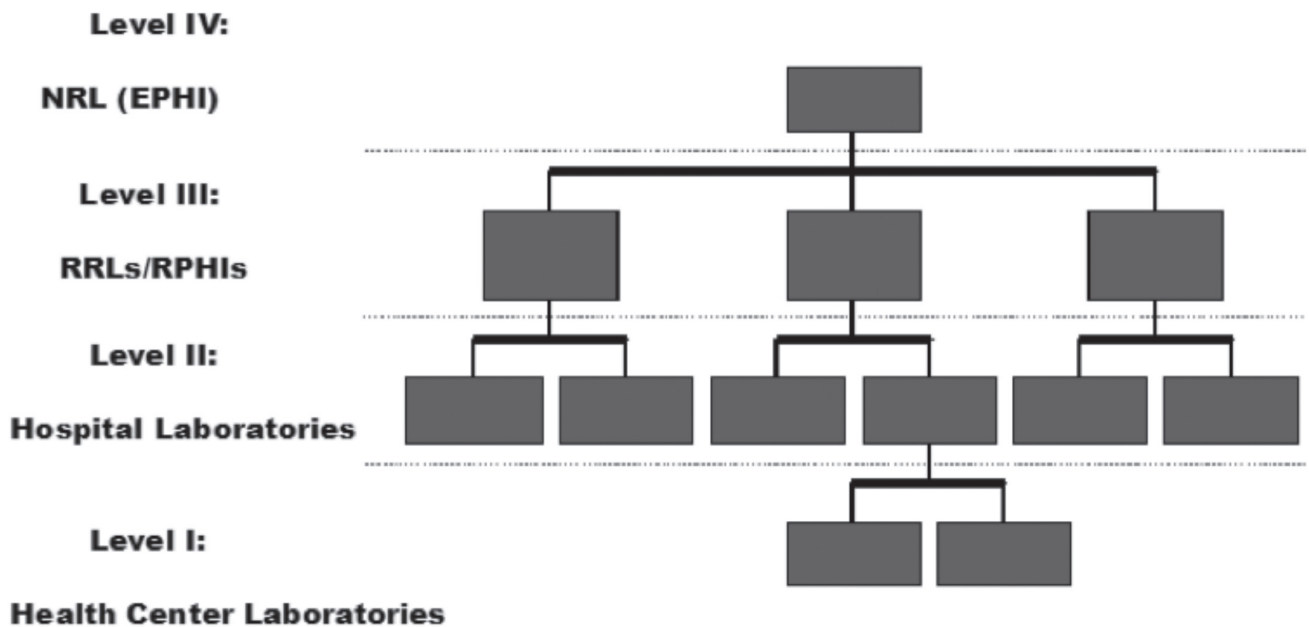


FIGURE I. STRUCTURE SHOWING THE ETHIOPIAN LABORATORIES SPECIMEN REFERRAL SYSTEM

4.1 FUNCTIONS OF THE NETWORK

The network generates information useful for disease diagnosis and prevention and can be used in decision making related to priority public health diseases in the country. This also promotes a strong linkage and collaboration among laboratories in the system. A functional laboratory network should have an established communication channel that is efficient, facilitates the exchange of information, and specifies ways in which each member communicates with other members and with the public health emergency management (PHEM) program at all levels. The network should have robust mechanisms for specimen transport and a results delivery system. The National Reference Laboratory may also communicate and interact as necessary with the World Health Organization's (WHO) regional and sub-regional networks and with international collaborating centers in the case of public health emergencies and for other clinical diagnostic needs.

5. COORDINATION

Under the guidance of the FMoH, EPHI is responsible for the coordination of the specimen referral at the national level. The RHBs and the Regional Reference Laboratories/RPHIs coordinate activities in their respective regions.

6. QUALITY ASSURANCE

Pertinent quality assurance measures will be implemented to ensure the proper collection, packaging, transportation, delivery, laboratory testing and the timely provision of results. For the receiving laboratory, record the date and time when the specimen was received and the quality.

6.1 SAMPLE REJECTION CRITERIA

Sample is not accepted if

- the sample is collected after commencing antibiotics
 - the sample is found in confirmed poor condition (the sample is with insufficient patient information(if the specimen not meeting the testing laboratory policy))
 - wrong sample is referred
 - insufficient sample volume is referred
 - the sample did not properly preserved with an appropriate preservative
 - the sample is transported for prolonged time (exceeding the specified time)
 - the samples are damaged or contaminated (leaked or broken) during transportation time
- Specimens not meeting the minimum requirements as stated above may be accepted by each laboratory division under the following circumstances;
- The test is time specific and delay for a new specimen would compromise patient care (i.e., drug levels).
 - The specimen has been acquired through an invasive procedure or is irretrievable (i.e. Sterile Body Fluids, tissue specimens, pathology sample).
 - Specimens submitted are from a patient in a life threatening situation.
 - Additional exceptions are based according to an individual laboratory's policies.
 - When compromised or irretrievable specimens are accepted for processing, a signature must be obtained from the person responsible for specimen collection.

7. ROLES AND RESPONSIBILITIES

7.1 FEDERAL MINISTRY OF HEALTH

- Provide policy guidance and related support
- Oversee the proper flow of information between all concerned bodies in the referral network
- Establish/enforce mechanisms for information and data flow among RHBs/Regional Reference Laboratories/Regional Public Health Institutes, EPHI and FMoH and that data/information does flow through these mechanisms and utilize the information generated for national directives.
- Mobilize resources

7.2 ETHIOPIAN PUBLIC HEALTH INSTITUTE

- Perform referral tests and provide timely feedback
- Oversee the quality , safety standards and bio-security of specimen during handling, packaging and transportation
- In collaboration with RHBs and Regional Laboratories/RPHI, conduct supportive supervision at specified sites to ensure that the program functions properly
- In collaboration with the Pharmaceutical Fund and Supply Agency (PFSA), ensure the proper procurement and distribution of supplies for specimen referral linkage services
- Coordinate all stakeholder activities to support the specimen referral linkage system
- Organize and provide trainings on collection, transportation and other safe handling practices
- Work with stakeholders to define uniform and the most sustainable logistics system for specimen transportation

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- Develop a referral linkage and networking database to manage, analyze, interpret and make decisions on the specimen referral testing data
- Communicate regularly with the RHBs and Regional Laboratories/RPHI to monitor and evaluate the activities
- Assemble and determine the specifications of the necessary items required for specimen packaging, transportation, and disposal
- Develop or revise policies and guidelines to improve the national specimen referral system in the same way to ensure the stability of the system
- Facilitate internationally (abroad) referral system for specialized test
- Communicate with WHO when public health concerns of the international community arise

7.3 REGIONAL HEALTH BUREAUS/ REGIONAL REFERENCE LABORATORIES/REGIONAL PUBLIC HEALTH INSTITUTES

- Work closely with EPHI and other stakeholders in the region to establish and properly implement the referral network system in their respective regions
- Coordinate specimen referral linkage activities at all levels (regional, zonal, woreda and facility levels) in their region
- Ensure that the specimen transportation network operates properly
- Ensure that the referral linkages are integrated for all diseases to maximize use of limited resources
- In collaboration with EPHI and other stakeholders, conduct regular supportive supervision in the region to evaluate the proper and consistent functioning of the network in their respective regions
- Provide training to all parties involved in the specimen referral system and ensure that all staff are adequately trained
- Oversee the proper utilization of resources and the implementation of the program
- Receive financial and activity reports from health facilities
- Regularly review the performance of the existing laboratory specimen referral linkages and networking
- Develop a regional specimen referral and networking database to manage, analyze, interpret and make decisions in their respective regions
- Monitor and evaluate the efficiency and effectiveness of the system in their respective regions
- Ensure the sustainability of the system.

7.4 REFERRING LABORATORIES

- Collect specimens properly, correctly label, pack and transport to referral laboratories together with the required documentation as per the standard operating procedures (SOPs) and follow flow chart for Specimen Referral Flow(Annex A)
- Ensure that safety procedures are in place and used to safeguard all individuals , environment and specimens involved in the entire referral process
- Maintain the early notification and proper communication with referral laboratories and sample couriers.
- Ensure the timely return of results and delivery to the customer
- Conduct a feasible and regular inventory

7.5 REFERRAL/RECEIVING LABORATORIES

- Check for integrity and safety of specimen.
- Ensure that all the formats are properly filled, that complete documentation is provided to the appropriate authorities and that all information is appropriate and adequate
- Inspect the packaging and transportation process as per the SOP
- Perform the requested test analysis using the referred specimens and provide timely results back to referring laboratories
- Establish and communicate TAT to referring laboratories
- Dispose of leftover specimen(s) appropriately
- Maintain proper reporting documentation
- Maintain early notification and proper communication with referring laboratories and couriers.

7.6 LABORATORY SPECIMEN COURIERS

- Transport the specimen(s) properly and safely from referring to referral laboratories and return results back to referring laboratories in a timely manner(per established TAT)
- Ensure the quality and/or safety of the specimen, environment and all parties involved in the process including keeping bio-security.
- Ensure that the required documentation is available and maintained
- Maintain Communicate with referring and referral laboratories
- Follow the memorandum of understanding and SOP.
- Must report any incident based on the incident report form (Annexed xxx)

8. SPECIMEN REFERRAL SYSTEM TO DETECT & IDENTIFY EPIDEMIC PRONE AND OTHER DISEASES

8.1 PRIORITY DISEASES REQUIRING LABORATORY CONFIRMATION

The priority diseases that are classified as the causes of epidemics and that are the leading causes of illness, death and disability in Ethiopia are listed in table 8.1. These diseases are divided into three major groups: epidemic-prone diseases; diseases targeted for eradication or elimination; and other diseases of health importance. Priority diseases are a combination of communicable and non-communicable diseases, and not all of them require laboratory testing for confirmation.

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TABLE 8.1: PRIORITY PUBLIC HEALTH DISEASES IN ETHIOPIA

Disease Category		Disease
Epidemic prone bacterial diseases		Cholera
		Dysentery
		Meningococcal meningitis
		Anthrax
		Relapsing fever
		Typhoid fever
		Typhus
Epidemic prone parasitic disease		Malaria
Epidemic prone viral diseases		Viral hemorrhagic fever
		Avian influenza
		Yellow fever
		Small pox
		Severe acute respiratory syndrome (SARS)
		Rabies
		Rota virus
Diseases targeted for eradication or elimination	Viral	Polio/ acute flaccid paralysis
	Parasitic	Measles
		Guinea worm
	bacterial	Oncocerciasis
		Leprosy
Non epidemic priority bacterial disease		Neonatal tetanus
Other commonly known epidemic prone conditions		Severe acute malnutrition
Endemic diseases of public health importance not classified as an “Epidemic prone disease”		Mycobacterium tuberculosis
		HIV
Other public health importance diseases		Brucellosis
		Listeriosis
		Food poisoning
		Hepatitis
		Diphtheriosis
		Pluegue
		Pertusis
		Leishmaniasis

In cases of a public health emergency, these diseases can be classified into immediately reportable and weekly reportable categories.

Immediately reportable diseases includes: acute flaccid paralysis (AFP), anthrax, avian human influenza, cholera, Dracunculiasis, measles, neonatal tetanus, pandemic influenza, rabies, smallpox, SARS, viral hemorrhagic fever (VHF) and Yellow fever. Immediate reporting allows for the timely action to be taken to prevent the reemergence or rapid transmission of epidemic prone diseases.

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Weekly reportable diseases includes: dysentery, malaria, meningitis, relapsing fever, Typhoid fever, severe acute malnutrition, and Typhus. Weekly reporting provides data for monitoring trends of diseases or conditions to detect epidemics.

8.2 TYPES OF SPECIMENS AND TESTS AT DIFFERENT LABORATORY LEVELS

The proposed list of specimens to be collected for each epidemic prone diseases caused by different microbial agents with the relevant laboratory tests to be conducted and the type of health facility where tests are available are shown in Table 8.2. The Reference Laboratories at each level of the health system should maintain an updated list of the laboratory tests. The referring laboratory also has the responsibility to confirm the type of tests and the sample type currently in use at the Reference Laboratory before referring the sample. Referring laboratories are expected to contact the testing laboratory before shipping and give the testing laboratory as much advance notice as possible so that testing can begin as soon as samples arrive. The transport mechanism and feedback (results) communication must be clear according to the specific specimen transportation and communication protocol.

TABLE 8.2: TYPES OF EPIDEMIC PRONE DISEASES AND TESTS USEFUL TO DIAGNOSE IN THE DIFFERENT LEVELS OF LABORATORY HIERARCHY

No	Disease	Causative Agent	Type of Specimens	Type of Laboratory Test	Refer to
1	AFP	Polio virus	A. Stool B. Rectal swab C. Serum	1. Cell culture (A, B)	EPHI(1)
2	Anthrax	B. anthracis	Blood Stool CSF Nasal swab Sputum Ascetic fluid Peritoneal fluid Swab from cutaneous vesicular lesion	1. Gram stain 2. Polychrome methylene blue 3. ELISA 4. Culture 5. PCR	EPHI(1, 4) Regional Laboratory(1) Hospital(1)
3	Avian human influenza	Avian influenza virus type A	Oropharyngeal swab/lavage Throat swab	1. Tissue/ cell culture 2. IFA 3. PCR 4. Serological tests (hemo-agglutination inhibition & micro-neutralization)	EPHI(1)
4	Cholera	Vibrio cholerae O1 & O39	A. Stool B. Rectal swab C. water	1. Stool culture (A,B) 2. Rapid test (A) 3. PCR (from isolates)	EPHI(1, 2, 3) Regional Labs(1, 2) Hospitals (2) Health Centers (2)

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No	Disease	Causative Agent	Type of Specimens	Type of Laboratory Test	Refer to
5	Guinea worm	Dracunulus mend- inosis	N/A	N/A	EPHI
6	Measles	Measles virus	Whole blood Serum Urine Throat/nasopharyn- geal swab Saliva	I.Serological (ELISA)	EPHI(1) Regional Labs(1)
7	Neonatal tetanus	C.tetani	Whole Blood	1. ELISA	EPHI (1)
8	Pandemic influenza (H1N1)	H1N1 Influenza virus	Throat swab	1. Real time PCR 2. Rapid influenza antigen 3. IFA 4. Cell culture	EPHI(1)
9	Rabies	Rabies virus	Saliva Neck biopsy Serum CSF Brain biopsy	1.Real time PCR 2. IFA 3.Viral neutralization	EPHI(2)
10	Smallpox	Variola virus			
11	SARS	Coronavirus (SARS-Cov)	Throat swab	1.Serological test(an- tibody test) 2.Cell culture 3.Real time PCR	EPHI(3)
12	Viral hem- orrhagic fever(VHF)	Arbovirus Arenavirus Marburgvirus Ebola virus Hantavirus Dengue fever	Blood Serum	1.Reverse passive hemagglutination (RPHA) 2.Tissue culture 3.Cell culture 4.ELISA for Ag/Ab 5.Immunochemistry 6.Histochemistry 7.Real Time PCR	EPHI(7)
13	Yellow fever	Yellow fever Virus (Flavivirus)	Serum Blood Liver tissue	1.Antibody neutral- ization 2.IgM capture 3.PCR	EPHI(1)

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No	Disease	Causative Agent	Type of Specimens	Type of Laboratory Test	Refer to
14	Dysentery	A. E.histolytica B. Bacillary dysentriae	Stool	1. Microscopy(A) 2. Bacterial Culture(B)	EPHI (1, 2) Regional Labs(1, 2) Hospitals (1, partially 2) Health center (1)
15	Malaria	Plasmodium species	Blood Serum plasma	1. Microscopy 2. RDT	All health facilities except health post(1) Health post (2)
16	Meningitis	N.menigitidis S.pneumoniae H. influenza E. coli	A.CSF B .Blood	1.Gram stain (A) 2. Bacterial Culture(A, B) 3. Latex agglutination(A)	EPHI(1,2, 3) Regional Labs(1,2, 3) Hospitals(1, partially 2, 3) Health centers(1)
17	Relapsing fever	Borrelia recurrentis	Blood	1. Microscopy	All health facilities except health posts(1)
18	Typhoid fever	S.typhi	A.Blood B.Stool C.Rectal Swab	1. Blood Culture (A) 2. Stool Culture (B,C) 3. serological test(4 fold titer in 7-14 days) (A)	EPHI(1,2) Regional Labs (1,2) Hospital with culture(1,2) Hospital without culture (3) Health center (3)
19	Typhus fever	Rickettsia	A. Blood	1. Serological test	EPHI (1) Regional Labs (1) Hospitals (1) Health Centers (1)

9. SPECIMEN COLLECTION AND PREPARATION FOR TRANSPORTATION

9.1 BLOOD

Blood tests are used to determine physiological and biochemical states such as infections, pathological conditions, mineral content, drug effectiveness, and organ function. Most blood-based tests are ordered and performed for the purposes of hematological, clinical chemistry, microbiological, immunology and serology, blood banking, coagulation and genetic determinations. Although the term blood test is used, most routine tests (except for most hematology tests such as a complete blood count [CBC]) are conducted either on plasma or serum instead of whole blood. Blood components and products must be stored within the temperature range specified for that particular component or product as indicated in the table below and transported under the same temperature conditions, as they are stored.

TABLE 9.1: BLOOD SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Devices	Storage and Transportation Condition	Specimen Container	Remarks
Capillary blood	Blood smear for hemoparasite, blood morphology, Differential count	2 slides	Room temperature, free from dust and moisture by using slide box	Slide box	Smear can be prepared whenever requested
Whole blood	CBC, CD4 determinations and hemoparasite detection	2-5 ml for adults and children 1-2ml for infants and neonates	Room temperature for CD4 up to 48hrs CBC Room temperature up to 8hrs, if delayed more than 8hrs, 2- 8oC up to 24hrs	K2/ K3 EDTA tube	For CBC smear can be prepared whenever requested and if there is any abnormality
	Bacteriology and virology	For bacteriology culture 10-20 ml for adult & 2-5 ml for children Note-blood to broth ratio is 1:5	Room temperature with in 2 hrs bacteriological and at 2 – 8oC up to 24 hrs for measles culture	Blood culture Broth medium for bacteriology Viral transport medium (VTM) Screw capped Cryogenic tube	Before antibiotic administration 2-3 cultures per septic episodes

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Dried blood spot (DBS)	Early infant diagnosis (EID)	4-5 full circle of whatman 903 card	Room temperature for up to 3 months	Whatman 903 card	
Serum	Chemistry, serology, blood banking	2-5 ml	At 2-8oC for 10 days, Below -20 oC if delayed for more than 10 days. For chemistry, serological, acute phase viral detection and blood banking. transport at 2 – 8oC	Serum separator tube (SST) Screw capped Cryogenic tube	Second serum for polio should be collected after 2 weeks or after one month depending on phase of the disease
Plasma	HIV-Viral load, clinical chemistry, coagulation tests and serology	2 – 5ml	At Room temperature up to 24 hr and 2-8oC for 5 days	Screw capped Cryogenic tube Plasma preparation tube (PPT)	For viral load until transport store at 2-8 oC
Plasma/ Serum	HBV & HCV Viral load	1-2ml	At 15-30 oC for 24hrs and at 2-8 oC for 3days	Sterile 2ml propylene Screw capped Cryogenic tube	Use only EDTA test tube for plasma specimen

9.2 STOOL

For a stool analysis, a stool sample is collected in a clean container and then sent to the laboratory. Laboratory analysis includes microscopic examination, chemical tests, and microbiologic tests. The stool sample can be referred for epidemic prone disease and other clinical laboratory investigations.

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TABLE 9.2: STOOL SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Devices	Storage and Transportation Condition	Specimen Container	Remarks
Stool/ rectal swab	Bacteriology	5-10gm of fresh stool	Transport with appropriate transport media (cary-blair medium) if the transport is delayed refrigerates samples at 2-8°C.	Cary-Blair transport medium	Use sterile container for B.anthrax isolation Collect specimen before antibiotic administration
	Parasitology		Room temperature with appropriate preservative	Clean plastic container	
	Virology	A minimum of 10gm fresh stool	Transport at 2 - 8oc and Store at -20oC whenever needed	Sterile plastic container	For measles within 48-72 hours and 2- 6 weeks for polio after onset of illness; for SARS, if delayed it can be collected as late as one month
	MTB and other Mycobacterium	At least 5gm fresh stool with sterile container	Transport at 2 to 8oc as soon as possible	Sterile plastic container	

9.3 URINE

A complete urinalysis includes physical, chemical, and microscopic examinations. A urinalysis is a routine examination of the urine for cells, tiny structures, microbial infection, and chemicals that suggest various illnesses. Since urine is prone to contamination from urethral and vaginal commensals and urine by itself is a growth medium for microorganisms, the collection and transportation should strictly follow the SOPs.

TABLE 9.3 URINE SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Devices	Storage and Transportation Condition	Specimen Container	Remarks
Urine	TB culture	50 ml for 3 consecutive days	Transport at 2 to 8°C	Sterile Falcon tube of 50 ml	Early morning mid-stream clean catch specimen, before starting anti TB drug
	Bacteriological culture	>15ml	Transport at 2 to 8°C for a period of not more than 12 hours	Sterile wide mouth container	Early morning mid-stream clean catch specimen or strait catheter collection specimen in sterile container
	24hr urine chemical analysis	All 24hr urine starting on a specified time	Transport at 2 to 8°C as soon as possible	> 2 litter capacity brown bottle with preservative	
	Viral isolation	10 – 50 ml	Transport sediment in VTM within 48hrs	Viral transport medium	First passed morning sample in a sterile container

9.4 UROGENITAL TRACT SPECIMENS

Urogenital comprises anatomical sites of genital tract and part of urinary tracts. Most of the urogenital areas are colonized by normal flora hence accurate diagnosis of genital infections depends on the differentiation of pathogens from normal flora. Non-culture methods of detecting some genital infections or syndromes are available and, in some instances, really are the best choices for diagnosis. Recovery of specific pathogenic organisms depends on culture of the proper specimen, with special care taken to exclude normal flora. Urogenital specimen transportation needs special precautions because it may contain very fragile and fastidious pathogens such as *N. gonorrhoea*.

TABLE 9.4 UROGENITAL SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Devices	Storage and Transportation Conditions	Specimen Container	Remarks
Female genital tract cervical or endo cervical	Isolation of urogenital pathogens	Two swabs	Transport in appropriate transport media; do not refrigerate if <i>N. gonorrhoea</i> is suspected	Amies Transport medium with charcoal	Transport dried smear by slide box
Other female's genital tract specimens: swabs from high vaginal, fallopian tube, bartholin gland and others	To isolate urogenital pathogens like fungus, bacteria and viruses	2swabs/ 1-2ml aspirates	Transport in appropriate transport media in room temperature within 48hrs	Amies Transport medium with charcoal	If chlamydia and herpes are suspected, store at 2 - 80C for less than 48 hrs. and at -700C or less; if delay more than 48 hrs is anticipated
Male urogenital genital tract	Identifying urethritis	2 swabs	Transport at room temperature in appropriate transport medium	Amies Transport medium with charcoal	
Prostatic secretion	To diagnose acute prostatitis	Swabs Aspirate	Transport room temperature within 24hrs.	Sterile container	

9.5 RESPIRATORY TRACT SAMPLES

Respiratory infections are common in both hospital and community settings. Laboratory samples can be collected from both the upper and lower respiratory tracts. Upper respiratory tract regions are colonized by normal bacterial flora and most of the lower respiratory infections, due to the invasion of the commensals collection and transportation of respiratory tract pathogen, have to ensure the isolation of the pathogen microorganisms. Hence, transportation and handling of sputum sample vary according to the pathogen to be detected. Respiratory tract samples include sputum, saliva, swabs, aspirates and lavages.

TABLE 9.5 RESPIRATORY TRACT SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Devices	Storage and Transportation Condition	Specimen Container	Remarks
Sputum	Bacterial, fungal and parasitological culture	3 to 5 ml	Transport at 2 to 8oC	In sterile container any time after onset of illness and before starting anti-biotics	delay of > 2 hours compromise the ability to isolate fastidious organisms
	Mycobacterium (TB culture and molecular)	3 to 5 ml	Transport at 2 to 8oC within 3-5 days	Sterile container	early morning
	AFB microscopy	3 to 5 ml	Transport at 2 to 8oC within 7 days	Sterile container	For diagnostic purpose Spot –spot (2 different sample)
			2 smeared slides	Transport with slide box	Slide box
Saliva	Viral diagnosis	2-5ml	Transport in VTM at 2- 8oC;if immediate transport is not possible, store frozen at -20oC	Viral transport medium	Collect starting 2 -3 days before disease onset
Bronchial wash / secretion	Mycobacterium(TB)	2 - 5 ml	Transport at 2 – 8oC as early as possible	Sterile container	
	Viral detection(SARS)	0.5ml	Transport at 2-8 oC within 2days if delayed store at -70 oC	VTM	

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Specimen Type	Purpose	Volume/ Devices	Storage and Transportation Condition	Specimen Container	Remarks
Naso-pharynx -aspirate -lavage -swab	Bacteriology	2 swabs/not less than 1ml	2-8 oC		Use transport media based on the suspected pathogens
	Viral isolation	2 swabs/2-3 ml	Transport in VTM transport medium at 2 – 8oC within 24 – 48 hrs, if delayed keep at -70 oC for Hemagglutination Test (VTM	Collect during the onset of the disease; for HAI use balanced salt solution, bovine serum albumin and antibiotics
Throat swab	Bacterial isolation	2swabs	Transport in transport medium within 24hrs at room temperature; dry swab should be submitted within 1hr	Amies Transport medium or Stuart transport medium	Keep the swab in sterile test tubes
	Viral isolation	2swabs	Transport in VTM at 2 – 8 °C	VTM	
Gastric lavage	Mycobacterium (TB) isolation	At least 5ml	Transport at 2 to 8°C as soon as possible	Sterile falcon tube	In the morning with an empty stomach

9.6 DISCHARGE

Discharges/secretions can be collected directly into a vial or tube, or can be collected using swabs for any sort of bacteriological, fungal, parasitological investigations. Discharges can be collected from unruptured vesicles using a sterile needle and syringe, and immediately transferred to a securely sealed vial or tube. Samples for eye disease investigations can be obtained from conjunctiva, ocular scrapings, lacrimal fluids, corneal scrapings and other inner eye infections. Ear samples can be obtained from both outer and inner ear.

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TABLE 9.6 DISCHARGES/SECRETIONS SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Device	Storage and Transportation Conditions	Specimen Container	Remarks
Eye discharge	Bacterial and fungal isolation (conjunctivitis, corneal scraping)	2 swabs/ 1-2 ml aspirates in transport medium	Transport at room temperature within 24hr	Amies transport medium without charcoal	For fluid aspirate include fungal culture
Ear discharge	Bacterial isolation (external ear)	2 swabs	Transport as soon as possible at room temperature within 2 hours	Amies transport medium without charcoal or stuart transport medium	For otitis external, vigorous swabbing is required since surface swabbing may miss streptococcal cellulitis
	Bacterial isolation (inner ear)	2 swabs or not less than 1ml aspirates	Transport as soon as possible at room temperature within 2 hours	Amies transport medium without charcoal or stuart transport medium	

9.7 WOUNDS/ ABSCESSSES

Abscesses are accumulations of pus in the tissues and any organism isolated from them may be of significance. They occur in many parts of the body as superficial infections or as deep-seated infections associated with any internal organ. Pus/ wound abscess is collected on swab and transported for laboratory identification of pathogens. Specimens should be transported and processed within 24 hours.

TABLE 9.6 DISCHARGES/SECRETIONS SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume / Device	Storage and Transportation Conditions	Specimen Container	Remarks
Wound/abscesses	Bacterial isolation	2 swabs or abscess in sterile test tube	Transport at room temperature and to be delivered immediately on collection when anaerobes are suspected, use anaerobic transport conditions	Amies transport medium without charcoal or stuart transport medium	Wound could be deep closed and superficial; indicate collection site; keep the swab in sterile normal saline

9.8 BODY FLUIDS

9.8.1 CEREBROSPINAL FLUID (CSF)

Lumbar punctures (LPs) are performed to collect cerebrospinal fluid (CSF) for laboratory evaluation to establish a diagnosis of infection (bacterial, fungal, mycobacterial, or amebic meningitis), malignancy, subarachnoid hemorrhage, multiple sclerosis, or demyelinating disorders. CSF has to be collected into three tubes, which do not contain any anticoagulant. The tubes are distributed to the appropriate laboratory according to their sequence of collection. The following description indicates the specimen conditions and suitability of the sample for each test type.

- First tube is for clinical chemistry chemical analysis.
- Second tube is suitable for microbiological testing.
- Third tube is useful for cell counts.
- If only one tube of CSF is collected, it should be submitted to microbiology.

TABLE 9.8 BODY FLUID SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/Device	Storage and Transportation Temperature	Specimen container
CSF	Funga, viral and parasitic isolation	A minimum of 2 ml	Transportation at room temperature as soon as possible; for viral at 4 oC	Sterile plain test tube
	Mycobacterium (TB) detection	At least 3 ml at any time after onset of illness	2 to 8oC and transport as early as possible	Sterile plain test tube
	Bacterial isolation	1 – 2ml	Transport at room temperature in TI transport media as soon as possible; CSF sample without transport medium should be transported in less than 1hr	Sterile plain test tube
	Hematology	At least 1 ml	Transport at room temperature within 2 hrs	Sterile plain test tube
	Clinical chemistry and serological tests	At least 1 ml	Transport at 2 - 8oC immediately	Sterile plain test tube

9.9 OTHER BODY FLUIDS

These fluids can be collected from the pericardial, thoracic, or peritoneal cavity, or from joint spaces, by aspirating with a needle and syringe. Body fluid samples are collected for different laboratory tests including, microbiological, hematological and clinical chemistry. When collecting pus from abscesses or other sites, special care should be taken to avoid contaminating the specimen with commensal organisms from the skin. A volume of 1–5 ml is adequate for isolating most bacteria, but 10–15 ml is optimal for recovery of mycobacteria and fungi, which are generally present in low numbers. Moreover, to diagnose peritonitis associated with chronic ambulatory peritoneal dialysis, collection of at least 50 ml of fluid may improve recovery of the responsible pathogen.

TABLE 9.9 OTHER BODY FLUID SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Device	Storage and Transportation Conditions	Specimen Container
Peritoneal, pericardial and pleural fluids	Mycobacterium (TB)	>10ml	Transport 2 to 8 oC as soon as possible	Sterile falcon tube
	Bacterial and fungal isolation	10-15ml	For bacterial culture transport at room temperature; for fungal detection, ≤ 24 hr at 4°C	Sterile container
	Cell count and differential	3-5 ml in EDTA tube	Transport at room temperature	EDTA tube
	Chemical analysis (t. protein, LDH, glucose and amylase)	0.5 – 1 ml	Transport at 2-8oC not later than 7 days	Sterile plain test tube
Amniotic fluid	Bacteriological	1-10 ml in anaerobic condition	Transport at 2-8 oC temperature within 72hrs	Anaerobic transport medium
Synovial fluid	Cell count and differential	3ml in EDTA tube	Transport at 2-8 oC not later than 48hrs	EDTA tube
	Crystals	3ml in sodium or heparin tube	Transport at 2-8 oC not later than 48hrs	Sodium or heparin tube
	Bacterial and fungal isolation	Minimum of one ml	Room temperature for bacterial as soon as possible and 2-8 oC for fungal within 24hrs	Sterile container
	MTB	More than 10ml	Room temperature as soon as possible	Sterile falcon tube

NOTE: For bacteriological analysis specimen can placed directly in to blood culture bottle.

9.10 TISSUE AND BIOPSY

TABLE 9.10 OTHER BODY FLUID SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume / Devices	Storage and Transportation Conditions	Specimen Container	Remarks
Fine-needle aspiration (FNA)	For histological evaluation	N/A	Transport at room temperature (both the slide and/or the fluids in a test tube as soon as possible)	Slide box and/or Clean container	Never transport in a syringe and needle
	Mycobacterium (TB)	In 0.9% saline solution	Transport at 2- 8°C as early as possible	Sterile falcon tube	Any time after onset of illness and before start of anti-TB treatment
Bone marrow biopsy (bone marrow aspiration) Synovial fluid	Mycobacterium(TB)	0.5-2ml; In 0.9% saline solution	Transport 2 - 8oC and transport as early as possible.	Sterile falcon tube	
	For blood disorders	0.5-2ml and prepare smear in duplicate	Transport at room temperature in slide box	Slide box	
Liver Biopsy(post mortem)	Viral isolation (YF)	N/A	Transport 2 - 8oC and transport as early as possible.	Clean container	
Skin vesicle for Anthrax	To detect and identify B.anthraxis	N/A	Ambient for immediate or 2 – 8 for >1 hr		

NOTE: if the specimen cannot be recollected, discuss the issue with the physician. It may be possible to examine the specimen with disclaimer indicating on the report the problem, it is important to indicate the name of the physician taking the responsibility of accepting the specimen.

9.11 DERMATOLOGICAL SAMPLES

TABLE 9.11 DERMATOLOGICAL SPECIMEN COLLECTION & PREPARATION FOR TRANSPORTATION

Specimen Type	Purpose	Volume/ Device	Storage and Transportation Conditions	Specimen Container
Nail	Fungal identification	N/A	Room temperature	
Scalp scraping	Fungal identification	At list 10-15 infected hairs	Room temperature	
Skin	Fungal identification	N/A	Room temperature	

9.12 BACTERIAL ISOLATES

TABLE 9.12 BACTERIAL SPECIISOLATES MEN COLLECTION & PREPARATION FOR TRANSPORTATION

Isolate Type	Purpose	Volume/ Devices	Storage & Transport Conditions	Specimen Container
Bacterial isolates (E.coli, K. pneumonia, Acinetobacter baumannii, S. aureus, P. aeruginosa, etc)	For further anti-microbial resistance confirmation	Harvest >5 pure colonies and transfer to TSB with glycerol	Transport at -20 oC temperature or using dry ice	Nunc tube

10. BIO-SAFETY AND BIO-SECURITY

Biosafety is the containment and combination of principles, procedures, technologies, practices and measures that are implemented when handling biohazardous materials to provide prevention of risk to human health and safety, and environmental exposure from disease or harmful biological agents.

The process of Laboratory Specimen referral involves the transportation of specimen, which causes a risk to the specimen handlers and the environment. It is, therefore, essential that laboratory personnel and other persons in the laboratory environment including individuals who have contacts with specimens are aware of potential hazards. They must be trained and be proficient in the practices and techniques of safely handling of specimens and related materials.

Biosafety measures in referral network shall comply with the universal safety precaution, waste segregation and disposal protocols. Laboratory personnel safety practices and techniques must be supplemented by recommended immunizations (Hepatitis B virus, Yellow fever, etc.).

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The term “Bio-Security” refers to the protection of microbial agents from loss, theft, diversion or intentional misuse. This is accomplished by limiting access to specific facilities, types of research materials and information. Laboratory bio-security activities should be established with clear and consistent policies and guideline.

10.1 GENERAL SAFETY PRECAUTIONS

10.1.1 LABORATORY SAFETY RELATED TO SPECIMEN COLLECTION, PREPARATION AND STORAGE

All staff involved in handling of laboratory specimens should receive specimen management training and be covered by appropriate vaccinations.

- Use personnel protective equipment when processing biological specimens.
- Take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments.
- Do not recap, bend or break needles by hand or remove needles from disposable syringes.
- Discard all sharp instruments in puncture-resistant sharp containers located close to the work area.
- Secure lids immediately to avoid spillage and contamination during transport.
- Place all liquid specimens in containers that will prevent leakage during transport.
- Preferably use vacutainer tube with needle rather than ordinary (syringe with needle) Do not overfill specimen containers, as they can ‘explode’ upon opening.
- If hands or other skin surfaces become contaminated with blood or other body fluids, wash them immediately and thoroughly with soap and water.
- Remove gloves and wash hands with soap and water upon completion of processing after contact with each patient.
- Use a biological safety cabinet for procedures that have a high potential for generating droplets.
- Use mechanical pipette devices to manipulate all liquids in the laboratory.
- Decontaminate laboratory work surface area daily and after any spill of potentially dangerous materials with a freshly prepared household bleach (0.5% NaHCl).
- Disinfect refrigerators and centrifuge component primary by 1:10 dilution of household bleach then clean with water finally wipe with 70% ethanol. Autoclave or soak racks in 1:10 dilution of household bleach for Ten minutes and then rinse thoroughly with water.
- Dispose biological waste & disinfect all non disposable components with 1:10 dilution bleach and wipe with 70% ethanol.
- Allow disinfectant to remain in contact with surfaces for at least ten minutes at an ambient temperature for optimal effectiveness against dried blood or serum.
- If equipment needs maintenance, clean and decontaminate them in the laboratory before transporting to repair/maintenance.
- Incinerate or autoclave all waste before disposal in a sanitary landfill. Solutions containing bleach may corrode the autoclave; therefore, these solutions may be poured down a drain connected to a sanitary sewer.
- After decontaminating, carefully pour down a drain connected to a sanitary sewer bulk blood, suctioned fluids, excretions, and secretions.

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- Decontaminate spills of blood and body fluids by wearing disposable gloves.
- Cover visible blood or body fluids with paper towels and soak this with a 1:10 dilution of household bleach. Allow to stand for at least ten minutes. Discard contaminated towels in infective waste containers. Wipe down the area with clean towels soaked in a 1:10 dilution of household bleach.

10.1.2 HANDLERS' INSTRUCTIONS

Improper collection, transport, storage and handling of specimens between the laboratories carry a risk of infection to the personnel involved and the environment. As a result, it is important to strictly follow the rules of general laboratory safety:

- Ensure that containers are leak-proof with a screw cap so that no material remains on the outside of the container. To avoid cracking or bending this container, never use mechanical devices to tighten the cap.
- Avoid spills and splashes during the opening and closing of tubes by using appropriate materials such as paper towel (absorbent pad), gauze, etc.
- When applicable, ensure that the outer part of triple package is large enough to hold the containers.
- Label containers to facilitate identification; do not wrap request or specification forms around the containers.
- To avoid accidental leakage or spillage, use secondary metal or plastic containers fitted with racks so that the containers remain upright. The secondary containers should be autoclavable or resistant to the action of chemical disinfectants and should be regularly decontaminated.
- For laboratories that receive large numbers of specimens, designate a particular room or area for this purpose.
 - Shipping cartons or carriers must be immediately unpacked in a designated area equipped with a discard container (infectious, non infectious and sharps), alcohol swabs and paper towels.
 - Use a Class II biosafety cabinet to limit exposure of laboratory staff to potential pathogens.
 - If a biosafety cabinet is not available, use a clean workbench that can be easily disinfected using common laboratory disinfectants; this should be located away from areas used for other laboratory activities.
- Open the package safely and record and maintain all related documents:
If there is linkage, broken container and contaminated paper manage it according to universal safety precaution.
- For blood specimen, ensure that appropriate safety measures are adopted to prevent laboratory infections; the handling of patient's blood and arthropods is particularly hazardous because the specimens are suspected to contain infectious agents.

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10.1.3 HANDLING EXTERNALLY CONTAMINATED CONTAINERS AND LABELS

- Ensure that the container is free from contaminant.
- Using gloved hands, close the cap tightly.
- Detach the contaminated label, if there is one.
- Wipe the container with a disposable paper towel or a piece of gauze soaked in appropriate disinfectant and let dry.
- Decontaminate the area where the leak has occurred.
- Copy all information on a new label and attach to the container.
- Discard the contaminated label into the biohazard container for disposal.
- Ensure specimen placed in upright position by using rack.
- When multiples are contaminated, ensure that they are correctly labeled and are readable.
- For all non conformities recorded in occurrence log sheet and communicate according to laboratory quality manual. Ensure that corrective actions taken accordingly.

10.1.4 GENERAL SAFETY FOR TRANSPORTATION OF SAMPLES

The WHO Guidance on Regulations for the Transport of Infectious Substances (2017–2018)

provide detailed procedures to be followed depending on the material to be transported.

- When applicable, place dry ice between containers and the outer shipping container (outer part of triple package) to keep the temperature at 4-80c.
- Ensure each container is individually protected by triple packaging to reduce shock or prevent breakage.
- Transport as soon as possible to the testing laboratory.

11 TRIPLE PACKAGING SYSTEM

Triple Package System: is a method of transporting diagnostic specimens & biological agents for various testing, investigations and research purpose from one site to other site or from in country to out of country based on the National & International regulation accepted system in tri part specimen container mechanism at once.

Primary Receptacles

- Contains a single specimen
- Must be watertight and leak proof
- Must be appropriately labeled as to content
- Wrapped in enough absorbent material to absorb all fluid in case of breakage or leakage

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Secondary Packaging

- Encloses and protects the primary receptacles
- Must be watertight and leak proof
- Several wrapped primary receptacles may be placed in a single secondary packaging.
- Specimen requisitions may be placed in plastic baggie and/or envelope and placed between secondary and outer container. Package to maintain patient confidentiality

Outer Packaging

- Protects secondary packaging from physical damage while in transit
- Contains specimen data forms, letters, and other types of information that identify or describe the specimen and identify the shipper and receiver, and any other documentation required. Place the documents in a sealed plastic bag to protect from moisture
- Must be a sturdy container with a latch or able to be taped shut
- Ship To and Ship From laboratory contact information is clearly marked on the outer shipping packaging
- Infectious substances should be labeled as “infectious substance.” Care must be taken not to contaminate the outside of the container.
- The packed specimen must be labeled with name, address, phone number and signature of the shipper/responsible person and the name, address, phone number of the consignee.
- Package orientation arrows must be shown on two sides.
- Every specimen container and request form must describe the nature of the specimen, source, and patient information.
- All specimens should be placed in a designated secure collection area until ready for transportation.
- Specimens should reach the laboratory as soon as possible.
- Prior to sending referral specimens, the referral site should be informed.
- Frozen specimens should be transported on dry ice/ice pack. The following precautions should be observed:
 - Place tubes in containers or wrap them in paper to protect them from dry ice. Direct contact with dry ice can crack glass tubes.
 - If the specimens are not in leak proof containers, protect them from exposure to carbon dioxide by sealing the screw caps with tape or plastic film or by sealing the tubes in a plastic bag. Carbon dioxide will lower the pH of the transport medium and adversely affect the survival of organisms in the specimen.
 - Ensure that the cool box is at least one-third full of dry ice.

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According to their hazard classification and their composition dangerous goods are assigned UN numbers and proper shipping names. . In this regard, infectious substances are classified in Division 6.2, and based on their disease cause potential & type categorized in to Category A and Category B. This proper shipping name is used to clearly identify the dangerous article or substance from one to the other. Such infectious substances include excreta, blood and its components, skin scrap, sputum as well as other tissues and body fluids. Diagnostic specimens do not include live infected part.

Category A Infectious Substances

An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. These categories assignment must be based on known medical history, symptoms of the source patient/ animal, endemic local conditions, or professional judgment.

NOTE: An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

Proper Shipping Names and UN Numbers

- Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN number, UN 2814.
- Infectious substance which can cause disease only in animals shall be assigned to UN 2900. Infectious substances in category A transported in packaging system that meets the IATA guideline requirement known as P620, or Packing Instruction 620.

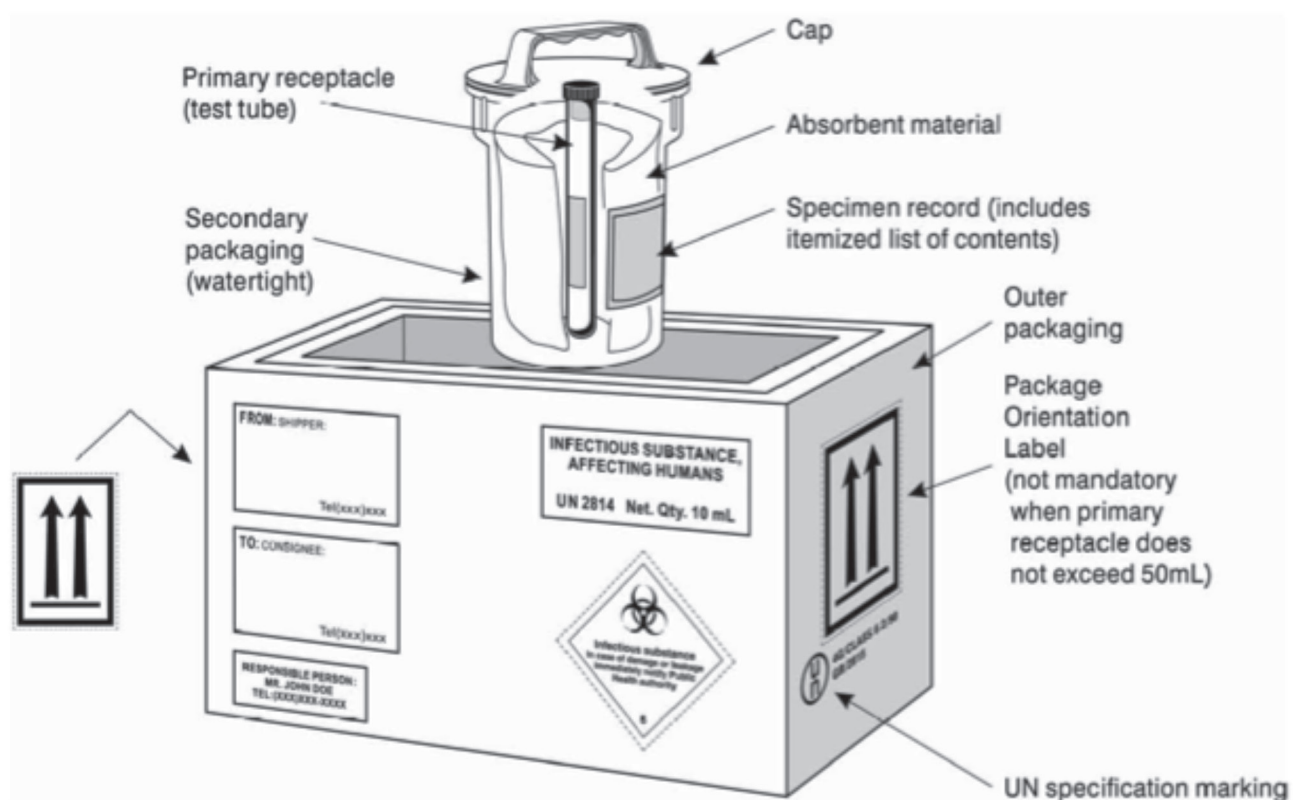


FIGURE 2: TRIPLE PACKAGING SYSTEM FOR THE PACKAGING AND LABELING OF CATEGORY A INFECTIONOUSUBSTANCES

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Category B Infectious Substances

A category B substance is an infectious substance which does not meet the criteria for inclusion in Category A. This can be human, animal, bacterial, viral, or fungal material transported for research, diagnosis, disease, or treatment.

Cultures

In addition to Category B infectious substances, cultures must be shipped following the IATA Dangerous Goods regulations. Cultures are defined as the result of a process by which pathogens are intentionally propagated.

NOTE: This definition does not include patient specimens (for example, throat swabs) intended for diagnostic purposes.

Proper Shipping Names and UN Numbers

- Biological Substance, Category B: UN Number: UN 3373
- Dry Ice
 - UN 1845 Dry Ice

If a diagnostic substance has been classified as belonging to category B UN3373, when it needs to be transported to another place or country then it must be packed for transport according to a set of IATA guidelines requirement known as P650, or Packing Instruction 650. This is a list of requirements covering the quality and construction of the packaging used for transport.

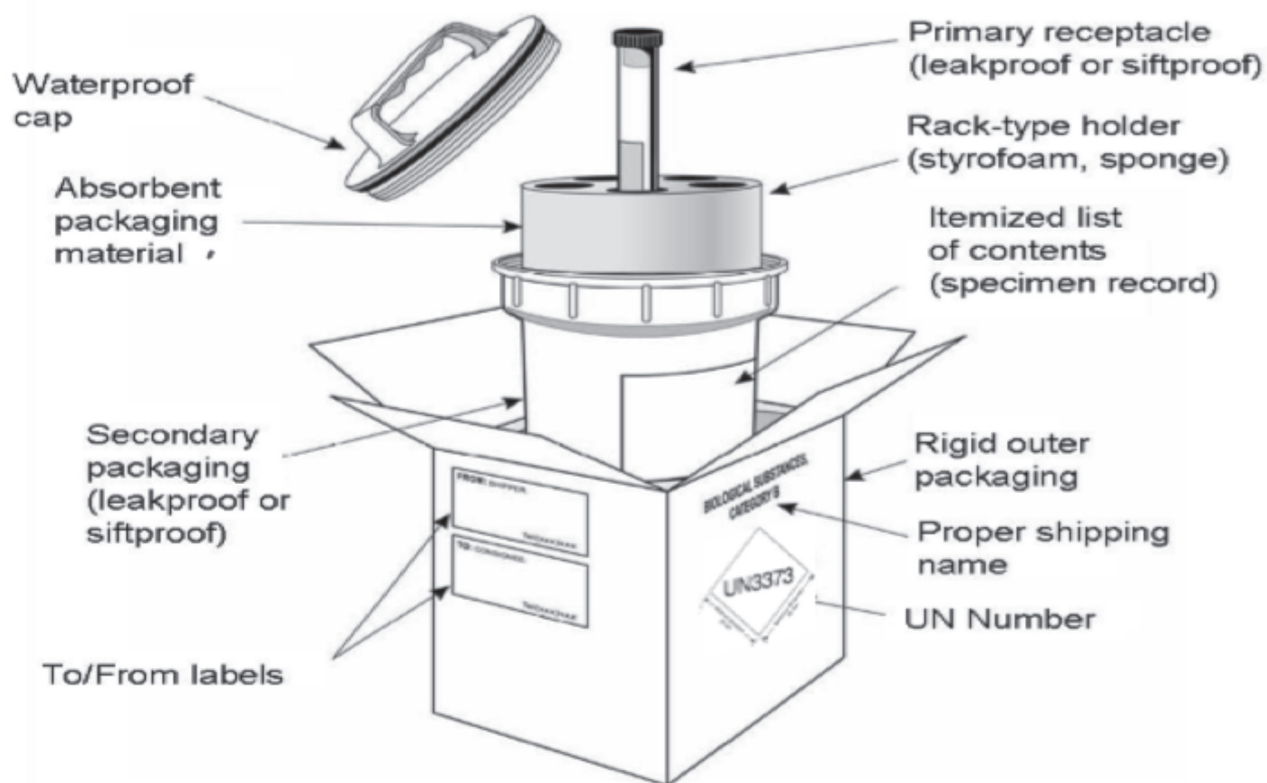


FIGURE 3: TRIPLE PACKAGING SYSTEM FOR THE PACKING AND LABELING OF CATEGORY B INFECTIOUS SUBSTANCES

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Exemptions Substances (Exempt Patient Specimen):

These substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk, or that do not contain infectious substances to cause disease in humans or animals; hence, are not subject to in dangerous goods regulations, except they meet the criteria for inclusion in another class.

Such as environmental samples (including food and water samples) which are not considered to pose a significant risk of infection Dried Blood Spots which collected by applying a drop of blood onto absorbent material, faecal occult blood screening samples and blood or blood components pregnancy tests, biopsies to detect cancer, antibody detection in humans/animals. which have been collected for the purposes of transfusion or for the reparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation as well as samples drawn in connection with such purposes are not subject to dangerous goods regulations.

If exempt patient specimens shipping, do not mark UN3373 on the air waybill or on outer package. Only mark outside of package and air waybill with: “Exempt Human Specimen” or “Exempt Animal Specimen.”

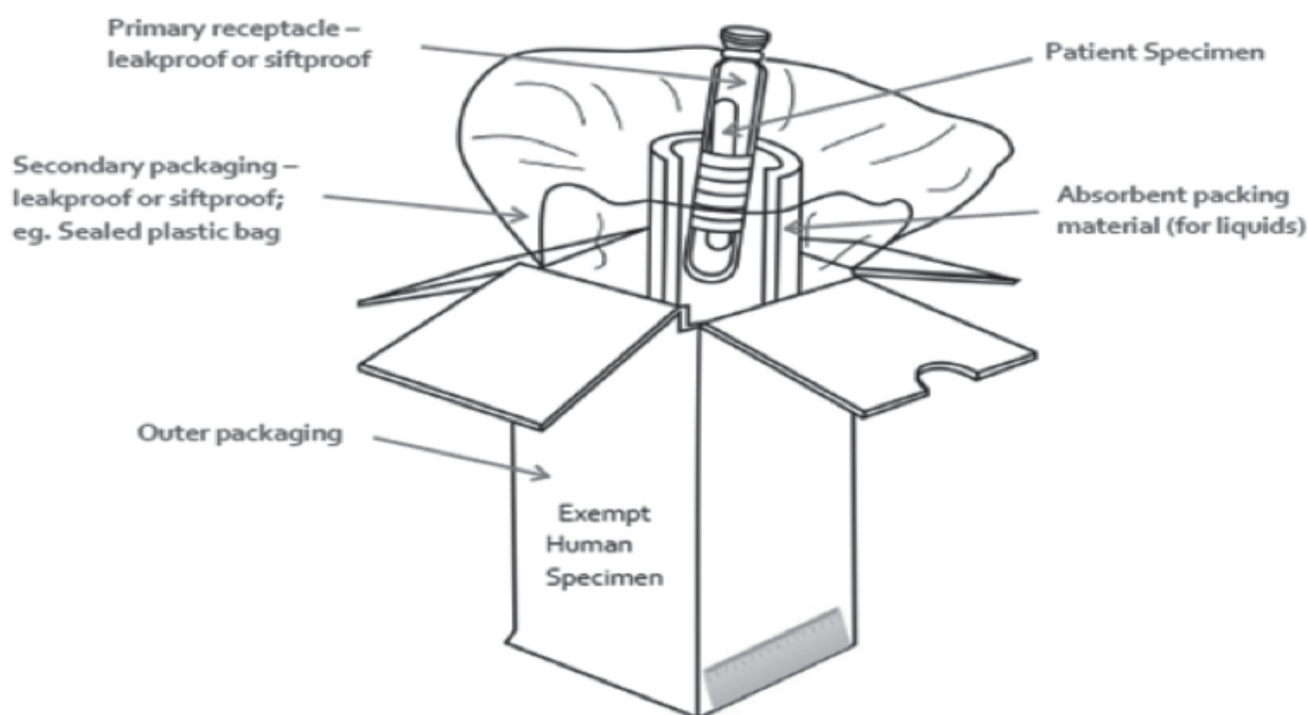


FIGURE 4: TRIPLE PACKAGING SYSTEM FOR THE PACKING AND LABELING FOR EXEMPT SPECIMENS

12. MONITORING AND EVALUATION

The operation of the referral network system should be monitored to track if the planned activities are being properly implemented. Regular tracking of implementation based on technological and manual methods should be supplemented with a periodic assessment of the overall effectiveness and outcome/impact of the referral network system using the appropriate laboratory monitoring indicators. The Health Management Information System indicators for the laboratory services and other relevant indicators will be used to monitor and assess the sample referral system where applicable.

12.1 DATA MANAGEMENT IN THE NETWORK

A system for the seamless flow of information among laboratories in the network is critical for the success of the referral system. Since up-to-date information and modern communication technologies have the potential to significantly improve data-sharing even in the most remote areas of the country, such technologies should ideally be available to all laboratories in the referral network. Information may be shared at any time with any or all of the network members depending on the type of information.

Efficient data flow ensures regular exchanges of information among laboratories within and outside of the country and creates a means of rapid communication with national and regional authorities responsible for public health emergencies. Given the trans-regional arrangement of the national referral system, it is important to follow proper channels of data flow in order to avoid duplication of reporting at various levels. In accordance with this guideline, a regular laboratory data report has to be compiled and sent by the testing sites to the concerned bodies, and the test results have to be returned to the referring site for care and treatment of the patient. The referring site will capture these data as information on the laboratory services provided through the referral system, but should not be reported as tests done by the referring site. Laboratory test results for the PHEM activities will be reported in accordance with the PHEM guideline. The testing laboratory has to maintain the laboratory data.

Laboratories in the network, both referring and referral, must have the capacity, resources and tools to capture, communicate, store, and analyze appropriate data of all referral specimens. It is the responsibility of the referring sites to capture details of the specimens that have been referred, including tracking mechanisms, until the results are delivered back to the referring sites. All referral specimens from a referring health facility should be managed by its laboratory, i.e., the collection, packaging, sending, receiving and delivery of results to the appropriate service points, and the keeping of records of all activities. Pertinent data related to sample tracking or transportation should be shared to couriers using technology support.

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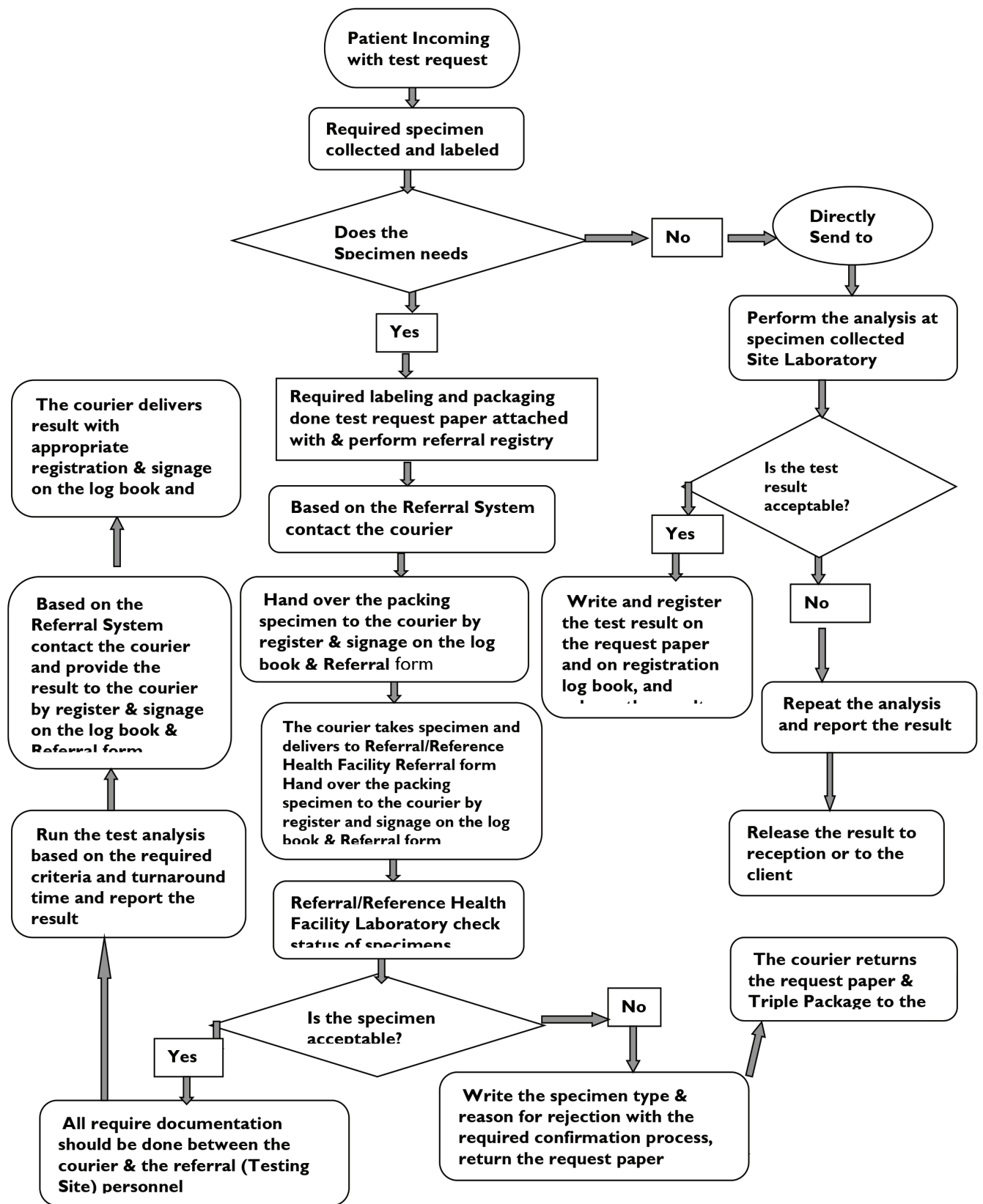
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ANNEXES

ANNEX A. Specimen Referral Flow Process



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ANNEX B INCIDENT REPORTING FORM

Date of incident: _____ Time of incident: _____ AM/PM

Location of incident: Region: _____ City _____

Specific place name: _____

Type of incident:

Car accident Physical Fall/Slid Health illness Specimen lost
Dispute with other persons Specimen dripped & leaked Other

Detail information of incident

.....
.....
.....
.....
.....
.....
.....
.....

Name of the affected person: _____ Mobile No: _____

Region: _____ Sub City: _____ Organization _____

Office Tel. No: _____

Was the immediate supervisor notified of the incident? Yes No

If yes, **Name of Supervise:** _____ Mobile No: _____

Notify the incident to the referring Health Facility.....Yes No

Incident reported by: _____ Mobile No: _____

Date of Report: _____ Time of Report: _____ AM/PM Signature: _____

Immediate action taken:

.....
.....
.....
.....
.....
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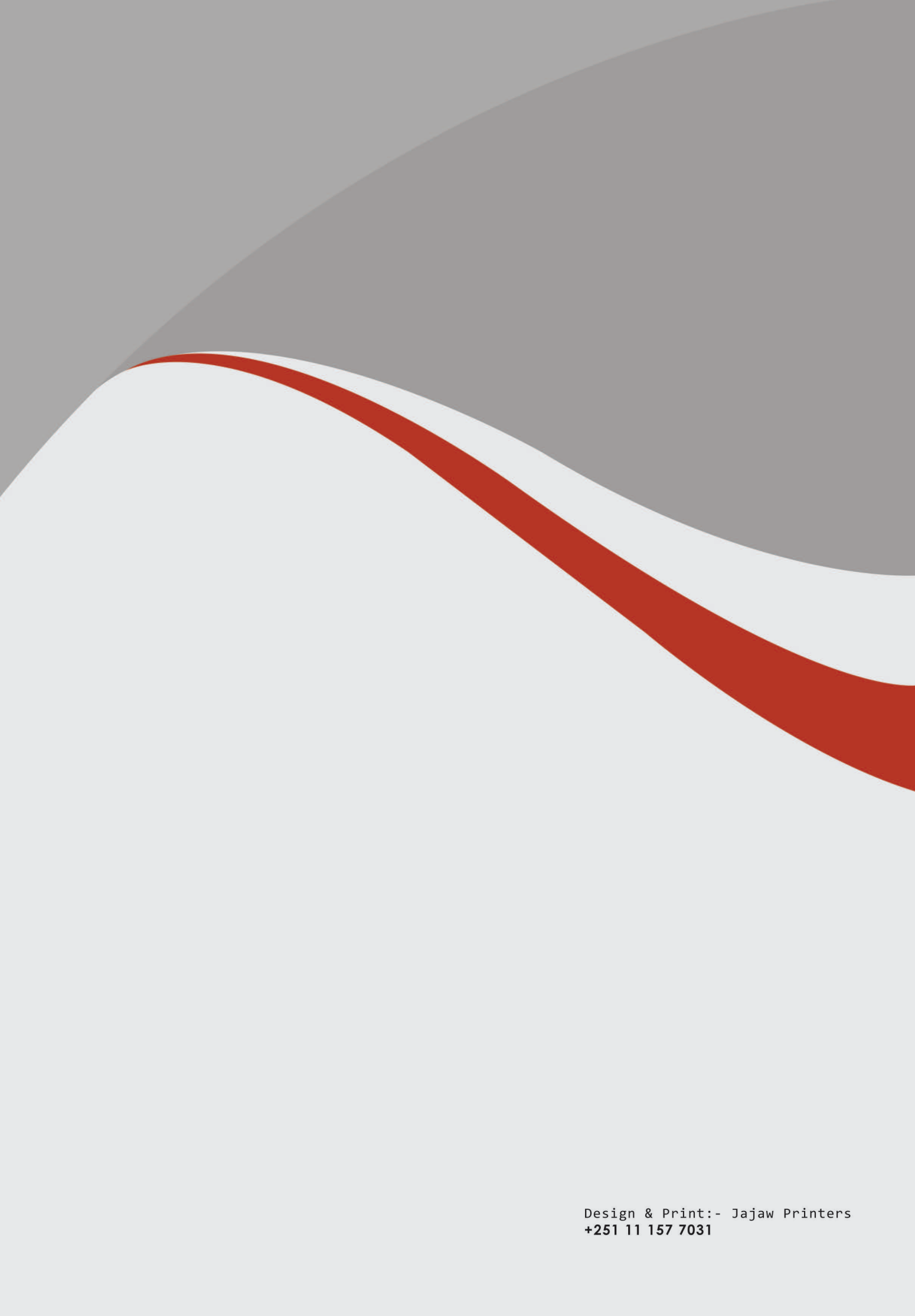
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