

*Insert Facility/Institute Logo Here*

**BIORISK MANAGEMENT SYSTEM**

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| Facility: | |
| SOP Title: SPECIMEN REFERRAL SYSTEM FOR PRIORITY DISEASE SURVEILLANCE PROGRAM PLAN | |
| Document Number: | Version Number: *00*  Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this Program (i.e., manuals, SOPs, forms, records):   * Biorisk Management Manual (*6-01-001)* * Biosecurity Program Plan (*6-01-001)* * External Transport and Shipping Security (*SOP-009-OP*) * Information Security SOP (*SOP-013-OP*) * Material Control and Accountability SOP (*SOP-010C-OP*) * BRM Document Control Plan (X-XX-XXX) * Assay specific SOP(s) (*SOP-XXX-OP*) * Specimen reception SOP (*SOP-XXX-OP*) * Additional SOPs and program plans, as required | |

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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

1. **Purpose**

This document describes the *[Insert Institution/Facility Name]* laboratory’s role as a reference laboratory, and its responsibilities within a Specimen Referral System (SRS) network for diagnostic specimens and suspected hazardous biological materials. This includes identification of roles and responsibilities of key entities involved in the SRS, establishment of systems for coordination and communication for specimen referral and return of results to referring sites. The *[National/Regional authority]* oversees this program.

1. **Program**

The following policies support this plan:

1. *[National/Regional authority]* will determine the priority pathogens for inclusion in the specimen referral system, the method of testing, handling, storage, and acceptable specimen types, based on national and international guidance and regulations.
2. *[Insert Institution/Facility Name]* will develop relationships with submitting entities and referral laboratories, such that training and resources can be provided to ensure specimens or pathogens of concern are recognized promptly and shipped safely and securely.
3. *[National/Regional authority]* will ensure that adequate laboratory testing capacity is available at the reference laboratory, including the necessary funding and staffing to accommodate testing volumes, data entry, and quality management, as well as funding for transport and collecting of specimens, and reporting of results.
4. **Scope**

This plan applies to all personnel who handle diagnostic specimens or samples within the specimen referral system (SRS), including submitting, receipt, testing, resulting, documentation, training, communication, and monitoring and evaluation. It also provides guidance for establishing a specimen referral system (annex A), interactions between reference laboratory and referring sites, and transport services.

1. **Staff Roles and Responsibilities**

* **Specimen referral technical working group (SRTWG)** *[or National/Regional authority]* will:
  + be responsible for developing, implementing, and monitoring the specimen referral system.
  + consider laboratory capabilities and identify referral and reference laboratories.
  + identify presumptive and confirmatory test methods.
  + provide technical support and oversight to laboratories performing clinical and public health functions.
  + communicate, coordinate, plan, and network with stakeholders.
  + designate points of contact to facilitate communication between the reference laboratory and referring sites.
* **Biorisk Management Advisor**:
  + Provide advice and guidance on biorisk management issues. The role and knowledge of the biorisk management advisor is key to develop, maintain, and continually improve a biosafety and biosecurity program based on a management system.
  + Support and document training for all personnel in biosafety and biosecurity.
* **Training Coordinator**
  + Plan, organize, and document training of referring and reference laboratories to include recognition of potential rule-out samples, risk management support for handling pathogens of concern, and safe and secure shipping methodologies (Table 2).
* **Quality Coordinator**
  + Ensure appropriate quality management in laboratories within the SRS.
  + Review and assess monitoring and evaluation measures to provide guidance to the TWG that informs optimization of SRS activity.
  + Oversee document control.
* **Epidemiologist**
  + Provide data analysis and interpretation.
  + Facilitate reporting from reference laboratories to higher levels of government, as needed.
  + Direct sampling efforts.
  + Identify contact cases for additional specimen collection.
  + Facilitate public messaging as needed.
* **Laboratory testing personnel**
  + Demonstrate and maintain competency in testing techniques for pathogens of concern.
  + Follow biorisk management policies and procedures for the handling hazardous biological materials.
  + Report results to referral laboratories and epidemiologists/higher levels of SRS as required.
* **Transport Personnel**
  + Complete documentation as required.
  + Responsible for the integrity and security of specimens during transport process (including appropriate storage conditions).
* **Sampling Collection Personnel**
  + [*Nurses, doctors, veterinarians, and farmers*] recognize signs and symptoms and the need to test for surveillance specimens and potential pathogens of concern.
  + Maintain the confidentially of patient information.
  + Are familiar with the advance notification process for referral laboratories.
  + Safely collect, label, and package specimens to prevent exposure during handling.
* **Security Personnel**
  + Understand the processes and procedures for sample collection and evidence collection in a biosecurity incident.
  + Safely collect and package sample evidence to prevent exposure during handling.
  + Are familiar with the advance notification process for reference laboratories.
  + Initiate chain of custody documentation, in the event of a biosecurity incident.

1. **Abbreviations and Definitions**

*BRM Biorisk Management*

*CoC Chain of Custody*

*LIS Laboratory Information System*

*LIMS Laboratory Information Management System*

*MC&A Material Control and Accountability*

*MOH Ministry of Health*

*MOU Memorandum of Understanding*

*MTA Material Transfer Agreement*

*SOP Standard Operating Procedure*

*SRS Specimen Referral System*

*TWG Technical Working Group*

*VBM Valuable Biological Materials*

*Additional abbreviations*

**Chain of Custody.** Document recording continuous accountability for a sample through collection, transport, and receipt.

**Confirmatory test.** A laboratory test or procedure that verifies the presence of a given pathogen in a specimen. Test method should differ from presumptive or screening test (e.g., molecular or immunology-based with high specificity for the pathogen)

**Material Transfer Agreement.** Legal document between two organizations – provider and receiver – authorizing the transfer, receipt, and specified use of materials.

**Memo of Understanding.** An agreement between organizations to work together under specific conditions or situations. The document provides a general description of each organization’s responsibilities in the relationship, including expectations and the communication of information.

**Presumptive test.** An initial analysis of a specimen that identifies the likely presence or absence of a pathogen. A test that has low specificity for a pathogen or identifies a group of similar pathogens.

**Priority disease.** Pathogen of heightened interest to national public health authorities.

**Reference laboratory.** A laboratory able to perform confirmatory testing for pathogens of concern and authorized to communicate results to the national laboratory (if a separate entity).

**Referring laboratory.** Laboratories, clinics, or offices that provide routine diagnostic services and may need to rule-out or refer samples to another lab for further testing.

**Rule-out specimen.** A specimen where a pathogen of concern is suspected but has not been confirmed by testing.

**Specimen Referral System (SRS).** A coordinated system that allows a health facility or laboratory lacking capability to perform test(s) safely to send a patient’s specimen to another or higher-level laboratory with capability to perform the requested test(s).

**Tracking Form.** Document that tracks pathogen of concern specimens through the reference laboratory, from receipt to destruction.

**Valuable Biological Materials.** Substances derived from living organisms that possess significant economic, scientific, or medical value, e.g., diagnostic samples, cell lines, biological data, nucleic acids/genomic material, tissues. Also known as high-consequence materials.

1. **Establishing the SRS Program**
   1. **Overview**

The following considerations are part of the SRS Program:

* + 1. Laboratory roles and responsibilities differ at each level of the program. Laboratory capabilities and responsibilities increase in complexity. Figure 1 shows the increasing levels of responsibilities for facilities in each part of the program.  *A flow chart can be used to show an overview of the process as in Figure 1.* 
       1. Controlled documents should be established that fully describe handling, transport, testing, reporting, and ‘next steps’ for all laboratories in the SRS Program.

Figure 1. Specimen Referral System

* + 1. Identify pathogens for surveillance testing on a continual or seasonal schedule.
       1. Pathogens selected are those where the tracking of subtypes, species, or sequence variants is informative to public health treatment efforts, and routine testing is qualitative or of low specificity.
    2. Identify pathogens of concern that require rapid confirmatory testing by a laboratory with the appropriate safety and security control measures, instrumentation, and trained staff.
       1. Identify the panel of tests to perform on samples from potential biosecurity incidents.
       2. Generate a list of pathogens for which a confirmatory result requires notification of the *MOH or public health authorities*.
    3. Establish consistent and reliable modes of specimen transport.
       1. Specimen collection sites should be near testing laboratories, if possible.
       2. Transport from collection sites to testing laboratories should occur on a regular interval, to minimize time between collection and return of results.
       3. Packaging materials for surveillance testing are provided by the SRS.
       4. A process for on-demand transfer should be established (e.g., rapid confirmation, response to a biosecurity incident).
       5. Timing of specimen collection should be coordinated with transport schedule to minimize turn-around-time.
       6. Specimens should be stored at appropriate temperatures for testing prior to transfer to ensure specimen integrity.
       7. The type of transport may depend on local conditions.
       8. Ownership of transport vehicles can be by the facility, government, or a commercial company.
       9. Funding for transport should be built into overall SRS plan.
       10. Annex B of the ***GLI Guide*** [1] lists considerations for transport mechanisms.
    4. Assess and build laboratory capacity.
       1. Investment in reference and referral laboratories supports adequate staffing for increased testing volume, data entry, and quality management.
       2. Investment in infrastructure, equipment, consumables, reagents, waste management, and operating budget ensure the continued ability to provide critical services and manage public health emergencies.
       3. A needs assessment should be performed to determine appropriate methodologies for surveillance testing and confirmation of pathogens of concern.
       4. Standardization of equipment, instrumentation, and test methods across the SRS facilitates procurement and maintenance and creates efficient and rational use of resources.
    5. Standardize the referral processes.
       1. Establish a set of procedures and contact information for referring surveillance specimens and confirmatory test requests.
       2. Establish outreach training and materials to clinical laboratories, clinicians, veterinarians, enforcement agencies, and other submitters to educate personnel on the SRS program and referral processes.
       3. Generate and finalize MOUs between referral laboratories and the reference laboratory, and between the reference laboratory and enforcement agencies that would respond to security incidents where a biological agent is suspected.
    6. Generate materials and documentation required for submission of specimens for testing at reference laboratory (see Table 1, example).

Table 1. *Example:* Forms & Documents

|  |  |  |
| --- | --- | --- |
| Form/Document | Purpose | Location |
| Chain of Custody form | Documents sample movement throughout SRS as part of biosecurity incident evidence records. | Moves with sample throughout the transport, receipt, testing process |
| Specimen Tracking form | Internal form documenting all material received from submitter and tracks the location, use, and disposition of each item while in the reference laboratory. | Kept with shipping information and test report records. |
| Test Order/Requisition form | Indicates expected tests, allows clinicians to place orders for given test | Transported with specimen until receipt at testing laboratory |
| Result Reporting form | To transmit results back to submitting laboratories and/or submitting entities (clinicians, veterinarians, farmers, etc); may indicate reporting needed to higher levels of government. | Referring site, copies kept at reference site |
| Specimen Shipment Inventory log | Full inventory of all items in a given shipment | Reference site |
| Specimen Rejection log | Indicates reasons for specimen rejection, number of specimens rejected, confirms communication to referring sites. | Transporter, copies at referring and reference sites |
| Specimen Temperature log | Confirm temperature monitored prior to testing, during storage and transport. | Transporter, copies at referring and reference sites |
| SOPs   * Specimen referral handbook (*SOP-xx-OP*) * Specimen receiving SOP (*SOP-xx-OP*) * Testing for Biological Threats SOP (*SOP-xx-OP*) * Spill clean-up SOP(*SOP-xx-OP*) * Assay specific SOPs(*SOP-xx-OP*) * Reporting results SOP(*SOP-xx-OP*) * Biosecurity Program Plan (*6-01-001)* * Transport and Shipping Security (*SOP-009-OP*) * Personnel Reliability SOP (*SOP-011-OP*) * Information Security SOP (*SOP-013-OP*) * Material Control and Accountability SOP (*SOP-010C-OP*) * BRM Document Control Program (*SOP-xx-OP*) | *Understanding of laboratory policies, practices, and procedures.* | At reference facility, either in an electronic document control repository or physically printed, following document control processes. |
| *Additional forms* |  |  |

1. **Workflow For Referred Specimens / Samples**
   1. **Specimen/Sample Collection Sites**
      1. Collect specimen(s) from patient(s) or evidence from the site of a biosecurity incident.
         1. Ensure appropriate collection device is available and the specimen an acceptable specimen type for the test requested to prevent delays.
         2. Complete a Test Requisition/Order form and a Chain of Custody form (biosecurity incident only).
         3. Check that information on the collection container and the test order form match.
         4. Maintain specimen holding conditions as specified by the receiving laboratory.
      2. Package and obtain approval to ship specimen to the laboratory (Figure 2).
         1. Diagnostic specimens are prepared and shipped according to procedures stated in the **Transport and Shipping Security SOP** (*SOP-009-OP*).
         2. Referring facility staff or sampling personnel preparing shipments must have up-to-date IATA training and certification, if shipping by air or across borders (See Table 2).
2. Shipments of diagnostic specimens with confirmed or suspected VBMs must be packaged according to IATA Regulations by staff with current IATA shipping certification.
   * + 1. The following information is included with specimen submission:
3. Unique ID number
4. Patient identifiers such as name, date of birth
5. Ordering clinician or laboratory contact person
6. Laboratory order/submission/requisition form (detailing testing needed)
7. Quantity / volume per container
8. Responsible staff member in submitting organization
9. Contact information of the responsible staff member
10. Collection date/time
11. Collection location
12. Gender
13. Species
    * + 1. Ensure appropriate packaging and, if needed, shipping container is available.
        2. Store the specimen under conditions that maintain specimen integrity prior to transport.
      1. Transport personnel pick up specimen(s) from referring facility.
         + 1. Management of transport vehicles and personnel.
           2. Vetting and approval of transport employees.
         1. Transporter fills out Chain of Custody form. Laboratory makes and keeps a copy of the signed form.

Figure 2. *Example*: Submitting of Specimen(s) Workflow

1. **Reference Laboratory**
2. Specimen(s) are received by the reference laboratory and unpacked by testing personnel, who have been trained to safely handle pathogens of concern.
3. Specimens are received according to procedures stated in the **Sample Receiving SOP** (*Reference number*).
4. Notify shipper of receipt and complete any Chain of Custody forms.
5. Make a copy of the Chain of Custody form and return copy to the transport.
6. All specimens are stored and transported in the facility in a manner which maintains sample integrity.
7. Specimens are handled according to the biorisk management plan and applicable regulations (*list any regulations*).
8. For pathogens of concern, fill out a Specimen Tracking form and record all materials received from the reference laboratory or submitter.
9. Decontaminate coolers, racks, and packaging.

Figure 3. *Example*: Reference Laboratory Workflow

1. Diagnostic testing.
2. Procedures for handling of specimen(s) with appropriate safety equipment and internal tracking to maintain biosecurity have been established.
3. Standardized testing procedures are established and performed.
4. Appropriate validation or verification of testing methods is completed, approved, and documented.
5. External quality assurance (proficiency testing) has been performed routinely (at least annually) on test methodologies.
6. Standard operating procedures (SOPs) developed and testing personnel competency documented.
7. Reagents and supplies are available for rapid testing of specimens.
8. Additional forms relevant to the type of testing are completed and reviewed.
9. Quality control results are interpreted and confirmed.
10. Secondary review process in place for results, as required.
11. Results Reporting
12. The reference laboratory reports result to the referring laboratory, Epidemiologist, *[MOH, or other authorities]*.
13. Initial report of results is conducted by phone and documented in the [*LIS,* *phone log*].
14. Printed, faxed, SMS, or electronic reports are conducted through the internal result management system file [*LIS, LIMS*].
15. For biosecurity incident investigations, additional procedures to secure evidence, information, and reports must be taken by the laboratory as described in [*SOP #, Testing for Biological Threats*].
16. Referring laboratory reports result to the submitter (physician, clinic, veterinarian, etc.).
17. Results received from the reference laboratory by phone are recorded in the [*LIS,* *phone log*].
18. Results are reported to the submitter by phone and the report documented in the [*LIS,* *phone log*].
19. Printed, faxed, SMS, or electronic reports are received from the reference laboratory and added to the internal result management system file [*LIS, LIMS*].
20. Epidemiologist coordinates with the [*health ministry*] and/or enforcement agencies for any actions to protect the public from exposure to pathogens of concern due to outbreak or biosecurity incidents. Epidemiologist received surveillance testing results for analysis, tracking, and follow-up.
21. Specimen Disposition
22. Surveillance specimens are destroyed according to national regulations [cite regulation].
23. The reference laboratory may ship specimens or cultures to *[national repository, WHO, WOAH, CDC, others*] if requested.
24. If not authorized by the [*MOH, national authority*] to retain pathogens of concern, the reference laboratory destroys material in a manner which prevents the recovery of viable organism (bacterial, viral) or a complete genome.
25. Include original specimen, primary containers, cultures, aliquots, extracted nucleic acids, frozen specimens.
26. In the case of biosecurity investigations, the reference laboratory must retain and secure all material (samples and documents related to testing) and coordinate disposition with the submitting enforcement agency as stated in the MOU.
27. Referral laboratory destroys any residual specimen confirmed with a pathogen of concern in a manner which prevents the recovery of viable organism (bacterial, viral) or a complete genome.
28. The laboratory should assess the risk of exposure to workers in contact with the specimen as part of its biorisk management program.
29. **Program Support Considerations**
30. **Record Management**
31. The following forms and documents are used to manage and record referral and transport processes and assist with tracking the monitoring and evaluation metrics (list documents and forms used to track specimens, example list in Table 1).
32. Define time periods and storage locations for all documentation, including completed forms, records associated with all testing, training, SOPs.
33. **Training**
34. *Facility* staff are trained on this program plan and associated standard operating procedures. Required training is listed below:
    * + - 1. *This can be a list or a table as shown in Table 2.*
35. Training records include:
36. Sign in sheets and quizzes, location, responsible staff.
37. Records of initial and annual competency assessments, location, responsible staff.
38. Proficiency testing results, location, responsible staff.
39. SOP acknowledgement (sheets, forms, etc.), location, responsible staff.
40. Certificates from external trainers, location, responsible staff.

Table 2. *Example:* Specimen Referral Training Matrix

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Training | Purpose | Type | Schedule | Records Location |
| Basic BRM | Familiarization with biosafety and biosecurity principles | Seminar | Annually | *BRM Advisor files* |
| Specimen collection | Safe and appropriate specimen collection. | Hands-on | As needed | *BRM Advisor files* |
| Spill clean-up training | Any personnel handling specimens. | Hands-on | Annually | *BRM Advisor files* |
| Material Control and Accountability | MC&A Plan requirements and SOP | Seminar | Annually | *BRM Advisor files* |
| IATA Shipping Training | Shipping of Category A and B materials  *\*only for staff packaging & shipping specimens* | Hands-on Training | Every 3 years | *BRM Advisor files* |
| Bloodborne pathogens training | Training for all personnel that are exposed to human blood samples, including sampling, testing, and transporting personnel. | Seminar | Annually | *BRM advisor files* |
| Handling Protected Health Information | Information security for PHI, de-identification of samples if needed. | Seminar | Annually | *Quality Coordinator* |
| Waste Handling Procedures | Transport, documentation, and security requirements when handling VBM waste | Hands-on Training | Annually | *BRM Advisor files* |
| Identification of suspected pathogens of concern | Microbiological determinants that may require rule-out testing of specimens. | Hands-on Training | Annually | *Training coordinator* |
| Communication of testing requests and results | Communication between submitting laboratorians and the reference or referring laboratory | Hands-on training | Annually | *Training coordinator* |
| SOPs   * Specimen referral handbook (*SOP-xx-OP*) * Spill clean-up SOP (*SOP-xx-OP*) * Assay specific SOPs (*SOP-xx-OP*) * Reporting results SOP (*SOP-xx-OP*) * Biosecurity Program Plan (*6-01-001)* * Personnel Reliability SOP (*SOP-011-OP*) * Transport and Shipping Security (*SOP-009-OP*) * Information Security SOP (*SOP-013-OP*) * Material Control and Accountability SOP (*SOP-010C-OP*) * BRM Document Control Program (*SOP-xx-OP*) | *Understanding of laboratory policies, practices, and procedures.* | Read and understood | initially and at each revision | *Quality/Training Coordinator* |

1. **Communication**
2. Reliable and consistent communication methods are established between referring and reference laboratories to:
3. follow-up on missing or rejected specimens,
4. resolve any identified problems before or during testing,
5. prevent delays in result reporting, and
6. allow for timely notification of testing interruptions.
7. Authorized personnel at submitter/collection sites, referral laboratories, and the reference laboratory are identified. Contact information is clearly identified for all personnel.
   1. Contact information is checked for accuracy *[bi-annually, monthly]*, and revised as needed. Changes are communicated to all members of the SRS and submitters if applicable.

1. Regular communication between members of the SRS Program allows for the:
   1. sharing of best practices, opportunities, and challenges,
   2. integration of test results into reported epidemiological data, and
   3. rapid communication between laboratories in times of public health emergency.
2. **Monitoring and Evaluation**
3. Performance Metrics
4. An assessment of Program performance is conducted annually by the [*Quality Coordinator or other responsible position*] and communicated to the SRS Program (SRTWG).
5. Program assessment performance metrics include: *may be organized by sentinel or referring site, test, specimen type, etc. (Examples below)*
6. Number of referred specimens tested at reference laboratory.
7. Proportion of shipments that arrive at reference laboratory within the specified transport time.
8. Proportion of test results that were picked up by the transport service or transmitted electronically within the specified turnaround time after generation of the test result.
9. Proportion of specimens that were rejected due to factors such as inadequate/improper transport, packaging, or documentation.
10. Completeness of documentation.
11. For percentage data, a result of 100% is considered Excellent, 99 – 90% Good, and below 90% Needs Improvement. *Suggested percentages can be set separately for different performance metrics.*
12. For numerical data, a target number has been established and is determined to be met or not met.
13. Additional metrics may be used as determined by the [*Quality Coordinator*, *SRSWG* or *Epidemiologist]*.
14. Corrective/Preventative Actions
    1. Program performance falling below acceptable levels set by the SRS Program (SRTWG) are subject to the Corrective/Preventative Action process. *(Reference Corrective and Preventative Actions SOP)*
15. Review of Documents
    1. The [SRTWG or Quality Coordinator] reviews the content of the SRS Program – including training records, documentation, monitoring and evaluation metrics - annually for relevance and appropriateness of content. For example, documents may be added or removed, or documents may be revised to reflect current or modified procedures.
16. **Program Changes**
17. Changes to the SRS program plan will be reviewed and approved by the SRTWG or Quality Coordinator.
18. Changes to this document are completed through Document Control Program procedures [SOP #].
19. **References**
20. **GLI Guide to TB Specimen Referral Systems and Integrated Networks**. Good Laboratory Initiative. 2018. <https://www.stoptb.org/gli-guide-to-tb-specimen-referral-systems-and-integrated-networks>
21. **Guidance for developing a specimen transport and referral system for viral load and infant virologic HIV diagnosis testing networks**. Beard and Kasipo, 2016. CDC/USAID.
22. **WHO benchmarks for strengthening health emergency capacities**. 2023. World Health Organization.
23. **Laboratory Biosafety Manual**, version 4. 2020. World Health Organization.
24. **Laboratory Quality Management System Handbook**. 2011. World Health Organization. ISBM 978 92.4 154827 4.
25. **Developing laboratory networks: A practical guide and application**. Kirk and Shult. 2010. Public Health Reports 125, supplement 2.
26. **Combatting global infectious diseases: a network effect of specimen referral systems**. Fonjungo PN, Alemnji GA, Kebede Y, Opio A, Mwangi C, Spira TJ, Beard RS, Nkengasong JN. Clinical Infectious Diseases. 2017 Mar 15;64(6):796-803.
27. **Appendices**
    1. **Creating a Specimen Referral System**
       1. Needs assessment and mapping of current specimen referral systems.
          1. Conduct a situational assessment of current referral systems (such as those in place for TB or HIV) prior to initiation of changes or pilot project.
          2. Identify stakeholders and primary sources of funding.
          3. Coordinate with any national regulations or guidelines.
          4. Annex A of the ***GLI Guide*** [1] supports assessment process, providing questions to assess current state, identify gaps, and support integration.
       2. Design a specimen referral system pilot
          1. Initiate a pilot project to assess integrated specimen referral strategy at a smaller geographical level (e.g., local, county).
          2. Operational plan for pilot project should include monitoring and evaluation of quality indicators to allow evaluation.
          3. Must provide adequate funding and staff, as well as communication and training of staff to support the project.
          4. Collect pre-implementation data to use in pilot assessment.
       3. Set up and implement pilot
          1. Engage with stakeholders and others to communicate the plan.
          2. Establish clear lines of communication between all sites.
          3. Train participants on the new system, processes, procedures, and forms.
       4. Review the pilot
          1. Analyze data collected during pilot project implementation.
          2. Redesign or modify SRS as needed prior to expanding capacity.
       5. Scale-up SRS
          1. Extend network to greater geographical area, throughout nation or regionally among multiple countries in a phased approach, as available given resources and needs.
       6. Establish ongoing monitoring and evaluation for continuous improvement.
          1. Establish proficiency testing.
          2. Identify trainers for outreach to ensure uniform messaging for all submitter and laboratory locations.
28. **Costs and sustainability**
29. Cost considerations in establishing an SRS include:
30. Procurement of services for specimen transport, including shipping containers (coolers, cold packs, secondary containers, overpack, labels, etc.).
31. Initial infrastructure improvements to increase the security and capacity of current laboratories (e.g., back-up power supply, laboratory space, cypher locks), and equipment (e.g., dedicated refrigerators, freezers, centrifuges) for specimen preparation and storage prior to shipment at submitter sites and referral laboratories.
32. Procurement of standardized equipment and instrumentation for diagnostic testing (e.g., plate washers, centrifuges).
33. Procurement of computers, tablets, scanners, real-time temperature monitoring devices (e.g., data logger). Includes Wi-Fi or secure networks for transmitting patient information and results within the SRS.
34. Investment in education programs to provide adequately trained staff to safely work in the reference and referral laboratories.
35. Ongoing costs include:
36. Fuel, vehicle maintenance, insurance for transport network.
37. Reagents and supplies for testing platforms.
38. Specimen collection devices (e.g., blood tubes, swabs).
39. Packing and shipping materials.
40. Personal protective equipment.
41. Maintenance for facility operations, laboratory instrumentation and equipment.
42. Waste management.
43. **Attachments** 
    * 1. *Attachment 1: Chain of custody form*
      2. *Attach any additional forms or documentation relevant to sample referral system program plan.*