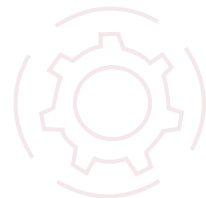
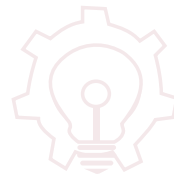


Africa Centres for Disease Control and Prevention
(Africa CDC)

Establishment of a Biobanking Network as a Sustainable Mechanism to Accelerate Development and Evaluation of Diagnostic Tests in Africa

August 2020



Acknowledgements

The Africa Centres for Disease Control and Prevention (Africa CDC) would like to acknowledge the following individuals for their contributions to the development of *Establishment of a Biobanking Network as a sustainable mechanism to accelerate development and evaluation of diagnostic tests in Africa*:

1. Rosanna Peeling (London School of Hygiene and Tropical Medicine, United Kingdom)
2. Noah Fongwen (London School of Hygiene and Tropical Medicine, United Kingdom)
3. Debrah Boeras (Global Health Impact Group, United States)
4. Amadou Sall (Institut Pasteur Dakar, Senegal)
5. John Nkengasong (Africa Centres for Disease Control and Prevention, Ethiopia)
6. Yenew Kebede (Africa Centres for Disease Control and Prevention, Ethiopia)
7. Abebaw Kebede (Africa Centres for Disease Control and Prevention, Ethiopia)
8. Annelies Wilder-Smith (London School of Hygiene and Tropical Medicine, United Kingdom)
9. Tomori Oyewale (Redeemer's University, Nigeria)
10. Alash'le Abimiku (Institute of Human Virology, Nigeria)
11. Hieronyma Nelisiwe Gumede-Moeletsi (World Health Organization, Regional Office for Africa, Republic of Congo)



Purpose of the the Biobanking Network

Outbreaks of infectious diseases are occurring with increasing frequency and unpredictability. The rapid development and deployment of diagnostics that can accurately and quickly identify pathogens as part of epidemic preparedness is essential, including now for the COVID-19 pandemic. Although the past two decades have seen rapid advances in diagnostic technologies, access to well-characterized specimens remains a significant barrier to test development and evaluation in Africa. Nevertheless, the past ten years have seen investment to build high-quality sustainable biorepositories within the continent. To accelerate access to quality-assured diagnostics in Africa nations, the Africa Centres for Disease Control and Prevention (Africa CDC) has launched the African Collaborative Initiative to Advance Diagnostics (AFCAD). Under the initiative, Africa CDC proposes to build on existing structures to establish a network of biobanks that facilitate and accelerate the development, evaluation and research on the diagnostics required for disease control and prevention programmes in the region.

The current document presents a sustainable model for a regional network of country-owned biobanks incorporating standardized methods for collection, characterization and archiving of specimens, and characterization of isolates to facilitate and accelerate diagnostics development and evaluation for COVID-19 and other diseases of epidemic potential. The Biobanking Network should be managed according to the guiding principles of transparency, equitable access, ethics, and respect for national laws that support country ownership and sustainability. By adapting the *Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity*¹; sharing of specimens from national biobanks can be rewarded through mechanisms such as equitable access to diagnostics.

¹See: <https://www.cbd.int/abs/>.

The overall objective of the Biobanking Network for Africa is to support diagnostic development, evaluation, and research, in particular:

1. Providing access to biological specimens and data for diagnostic test development, evaluation and research.
2. Facilitating the development and evaluation of diagnostic tests for diseases of epidemic potential and other global health priorities.
3. Facilitate genomic surveillance and epidemiological research.



1. Background information

1.1. Need for access to specimens to facilitate diagnostic test development and evaluation

Diagnostics play a critical role in outbreak investigations and control of epidemics^{1,2}. A triad of diagnostic tests is critically needed with varying modalities and applications for increased accessibility:

1. Highly sensitive and specific molecular assay to detect pathogens, confirm the diagnosis, and guide clinical management and public health measures such as isolation or quarantine.
2. Rapid simple-to-use antigen detection test that can be used to triage suspected cases at the point-of-care or in community settings.
3. Antibody assay that can be used to detect past exposure to the pathogen to understand the true extent of the outbreak, so that prevention and control strategies can be informed, at-risk populations identified, the attack rate estimated, and the effectiveness of control interventions assessed.

Molecular assay protocols and diagnostic kits to detect pathogens can be developed rapidly once the genetic sequence of the pathogen is known. Genetic primers and probes can be designed to amplify a unique target sequence of the pathogen genome and the specificity of the assay can be checked against the sequences of potential cross-

reactive pathogens of interest. However, the development of antigen tests requires access to clinical samples for the identification of surface-exposed proteins that can serve as markers of acute infection. The development of antibody tests requires knowledge of the dynamics of the immune response to infection, such as when different types of antibodies are produced throughout the infection, so appropriate diagnostic targets can be selected. The development of antibody tests that can be used as markers of acute and past infection requires access to well-characterized patient specimens at different stages of infection, including convalescent blood samples in those who have recovered^{3,4}. Access to well-characterized specimens is also important for accelerating laboratory evaluation of test performance.

The establishment of the Biobanking Network in Africa will enable Africa CDC to have well-characterized specimens collected from different parts of Africa. Once established, such a network will help facilitate and accelerate the development and evaluation of diagnostic tests that are needed to address health security challenges such as epidemic preparedness, antimicrobial resistance, and infectious disease control and prevention in Africa. Isolates from clinical specimens or epidemiological surveillance can be sequenced and serve as reference materials for genomic surveillance and epidemiologic research.

1.2. Landscape and lessons learnt from other biobanking models and previous outbreaks

The idea of a biobank network to accelerate test development and evaluation for infectious diseases is not new. Table 1 shows examples of biobanks currently operating in Africa that can support product development for epidemic preparedness and research in the region.



Table 1. Examples of biobanks that directly or indirectly support product development for epidemic preparedness and research in Africa

| Biorepository or biobank | Biobank type | Objective | Locations | Activities |
|--|--|--|---|--|
| ECOWAS (Economic Community of West African States) | An institution, project-driven, centralized storage | To support the global health security agenda in the region | Côte d'Ivoire | <ul style="list-style-type: none"> • Still developing strategy |
| Human, Heredity, and Health in Africa (H3Africa) | Public (US NIH), project-driven, centralized storage | To study the genetic basis of diseases with African relevance | Nigeria South Africa Uganda | <ul style="list-style-type: none"> • Capacity development in genetic research • Storage of high-quality biological samples |
| Foundation for Innovative New Diagnostics (FIND) | Inventory of collections and disease-specific biobanks | To support the development/evaluation of new/existing diagnostic tools | Geneva | <ul style="list-style-type: none"> • Identify and update an inventory of biorepositories at the collections level • Manage biobanks for various diseases at the specimen level |
| International Diagnostics Centre (IDC)/LSHTM ZikaPLAN Biobank and Evaluation Network | Partnership, disease-centric, virtual network | To evaluate the performance of diagnostics | Brazil Cambodia Colombia Cuba Laos Senegal Thailand | <ul style="list-style-type: none"> • Inventory of well-characterized specimens available for evaluation panels • Multi-site evaluations of Zika diagnostics |
| Program for Appropriate Technologies in Health (PATH) | Institutional, disease-centric Centralized storage | To support the development of new diagnostics | United States | <ul style="list-style-type: none"> • Collection and storage of high-quality specimens • Share specimens with private industry to support the development of new products |

US NIS: United States National Institutes for Health; LSHTM: London School of Hygiene and Tropical Medicine)

The Economic Community of the West African States (ECOWAS) established a Regional Biobank (ECOWAS-RBB), located in Côte d'Ivoire, to provide a biological resource management platform for the fifteen ECOWAS Member States according to international standards and in order to support biomedical research for the implementation of better strategies of diagnosis, treatment, control and prevention of diseases⁵. This is part of a wider health strategy in ECOWAS, especially focused on fighting epidemics, in their preparatory measures for disease control and prevention. The biobank was set up as a response to Ebola outbreaks in the region, recognizing the need for a stronger framework and African approaches to the health crisis. This model sources geographically representative specimens and focuses on the needs of the region.

The Human, Heredity, and Health in Africa (H3Africa) is a network of centralized biorepositories in Nigeria, South Africa and Uganda, funded by the US National Institutes of Health, and aimed at making quality specimens available to researchers for genomic discovery and other biomedical research^{6,7}. The H3Africa biorepository program supports over 51 research projects for the Human Hereditary and Health in Africa initiative, led by African scientists and involving 30 African countries^{7,8,2}. The biorepository includes specimens (DNA, RNA, peripheral blood mononuclear cells etc.) as well as strains, and makes associated phenotypic data accessible through their database. This model is well funded, organized and managed.

The Foundation for Innovative New Diagnostics (FIND) is developing an inventory of biobanks that includes collections and disease-specific biobanks with well-characterized specimens that can support the development or evaluation of new/existing diagnostic tools⁹. These biobanks comprise catalogues of well-characterized specimens for facilitating test development and evaluation. The inventory of collections is useful for locating collections but does not contain information/resources at the specimen level.

²See: www.h3africa.org.

The International Diagnostics Centre (IDC) Network, hosted by the London School of Hygiene and Tropical Medicine (LSHTM), was formed as part of ZikaPLAN, for the evaluation of Zika diagnostics^{10,11}. It comprises a global network of sites forms a distributed biobank of well-characterized specimens routinely collected, characterized and archived at each site. When a test is submitted to the network for evaluation, an evaluation panel is defined by the Steering Committee and each site contribute specimens towards the panel. This model can potentially be applied to any disease and can be quickly activated to support the development and evaluation of diagnostics for any disease of epidemic potential.

The PATH biobank stores specimens at their location in Seattle, USA. Shared specimens from around the world are shipped to this central location and made available to industry for the development of new diagnostic tests. These specimens can also be used to validate new diagnostic tests. This model focuses on providing vital specimens to the private sector to accelerate the development of quality products.

The Diagnostics Research Group of the United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)/World Bank/World Health Organization (WHO) Special Programme for Research and Training in Tropical Diseases (WHO/TDR) has developed different biobanks to facilitate the development and evaluation of infectious diseases of public health importance for the past two decades. The type of model developed for each disease depends on the location of laboratories with access to specimens, laboratory expertise in characterizing samples, country policy on the export of clinical specimens, facilities for archiving, geographic representation, available funding and the advice of expert working groups for each disease (Table 2).

The tuberculosis specimen bank was established as a centralized biobank at a single location to which well-characterized specimens collected around the world were shipped/added. However, many countries have strict laws prohibiting the export of specimens.

Shipment of specimens, even when they were permitted, presents many challenges, and are costly. The advantage of a centralized model is that specimens requested for test development are assembled from a single inventory and sent out from one location. The single inventory also simplifies specimen assembly for evaluation panels¹².

A regional model was developed for dengue with hubs in Asia and the Americas. Specimens collected from sites in each region were shipped to the respective regional hub. The dengue biobank samples were used primarily for test evaluations. Common protocols for specimen collection, shipping, archiving and evaluation were developed. Each regional hub selected samples from its biobank for its evaluation. Test kits for evaluation were sent by companies for evaluation at both regional hubs¹³. Results are analysed separately to determine if test performance is affected by endemic conditions in each region and in aggregate.

A decentralized network model was used to establish biobanks for diseases such as visceral leishmaniasis and syphilis. For related test development, requests from companies are referred to sites that have the requested samples in their inventory. For evaluation, a common protocol and evaluation panel was developed by each site. Diagnostic tests for evaluation are sent by companies to each of the network sites. Results are analysed per site and in aggregate¹⁴.

The network model can also be applied to sequencing networks established to determine the genomic sequence of pathogens and/or track their evolution over time in order to determine the rate of mutations and ensure that sequences targeted by molecular assays remain valid. The sites in a given network need to ensure that samples are stored properly once collected. Table 2 shows the advantages and disadvantages of each model. Many lessons were learnt from establishing and operating these biobank models, and the major lessons are:

1. Minimizing specimen transport across national borders should be a top priority as there are biosafety concerns and the process can be complicated with a risk of compromising sample quality or losing the shipment during transport.

2. The network model is the least costly and most sustainable approach. An added advantage of the network model is that by building capacity for test evaluations, sites can evaluate tests available locally and can conduct post-marketing surveillance of tests that have been approved for sale in their country.
3. The capacity in terms of infrastructure and trained personnel in each country should be utilized and built upon rather than duplicated.

Table 2. *Lessons learnt from various biobanking models*

| Model | Operations | Advantages | Disadvantages |
|-------------------------------------|--|--|---|
| Centralized model e.g. tuberculosis | <ul style="list-style-type: none"> ▪ A physical biobank of clinical and surveillance specimens and strains collected from different sites worldwide | <ul style="list-style-type: none"> ▪ Single inventory; easy to assemble evaluation panels and to distribute specimens to aid test development | <ul style="list-style-type: none"> ▪ Most expensive because of storage, shipping costs; risk of losing shipments and/or specimen quality during shipping ▪ Time-consuming ethical and regulatory agreements developed among countries; requires long-term sustained funding |
| Regional model e.g. dengue | <ul style="list-style-type: none"> ▪ Set up regional hubs: Specimens collected at different sites shipped to the hub in their region for characterization and storage | <ul style="list-style-type: none"> ▪ Tests evaluated at regional hubs against samples with different endemic background and/or co-morbidities | <ul style="list-style-type: none"> ▪ Requires shipping from 3–4 sites to a regional hub; more organizations required to assemble regional panels compared to centralized model. Also involves an agreement among countries |

| Model | Operations | Advantages | Disadvantages |
|---|---|---|---|
| Decentralized or network model e.g. leishmaniasis, syphilis | <ul style="list-style-type: none"> All samples are stored and characterized at the site of collection. Companies with tests under evaluation ship test to sites that have specimens required for evaluation. All sites use a common evaluation protocol. | <ul style="list-style-type: none"> Least expensive as no shipping involved; tests evaluated at sites with specimens against a range of endemic conditions; empower more countries to conduct evaluations, post-marketing surveillance and research | <ul style="list-style-type: none"> Potentially more sample heterogeneity from site to site A significant effort needed is establishing a uniform quality management system Countries without capacity are left out |
| Sequencing network | <ul style="list-style-type: none"> All samples are already kept or stored by sequencing laboratories | <ul style="list-style-type: none"> No shipping of samples as they are already in sequencing facilities | <ul style="list-style-type: none"> Proper storage of samples is required for long term usage |



2. Setting up the Biobanking Network

2.1. Guiding principles

Since the use of biological specimens for the development of diagnostic tests from which companies may potentially derive a profit is a sensitive issue. In this light, WHO/TDR developed a set of guiding principles for its specimen banks:

- **Equitable access** ensures equal access to specimens and pathogen strains to both public and private test developers.
- **Transparency** of all processes.
- **Ethics and respect for national laws**, especially concerning the export of samples and the need for informed consent for specimen collection and storage, in accordance with the *International ethical guidelines for health-related research involving humans* prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO.

- **Country ownership** whereby each country retains the ownership of the specimens collected with informed consent, as described above. Each site donates specimens for test development or uses their specimens to participate in test evaluations voluntarily. Each site retains ownership of the evaluation data generated at its site but must agree to share them across the network.
- **Fairness** in compliance with the *Nagoya Protocol for equitable sharing of benefits arising from the sharing of biological resources*, such as subsidized pricing for diagnostics to countries that have contributed to their development and evaluation¹⁵.

2.2. Cost recovery and benefits of participation

A sustainable system for biobanking with stringent oversight and governance needs to be established as a global good. This would mean that biobanking sites could charge companies or research institutions requesting samples on a cost-recovery basis, including a reasonable cost of replenishing the samples used. Apart from being reimbursed for any expenses involved in sample collection, characterization, archiving and participation in test evaluations, sites that shared their samples should be eligible for subsidized pricing for diagnostic products they help to evaluate.

2.3. Governance

The Africa CDC Biobank Network will be governed by a Steering Committee coordinated by the head of Laboratory Division at the Africa CDC or a delegate, and can include interested members of the Africa CDC Laboratory Working Group. The Steering Committee will decide on the guiding principles for the Africa CDC biobank network, pathogen priorities for biobanking, a mechanism for site application and selection, and ensure that network specimens are used in accordance with the guiding principles listed above. Recognizing that well-characterized biological specimens in the biobanks are a precious resource and that the volume of some specimens collected may be small, an important task of the Steering Committee is the review of requests for specimens and accompanying data; and careful allocation and distribution of biobank materials.

Furthermore, a Scientific Advisory Board shall be established to provide independent advice on scientific matters related to the governance of the biobank, network priorities, and use of biobank materials for research.

2.4. Call for applications and criteria for site recruitment

The Biobank Network Coordinator will coordinate the call for applications for submission of expressions of interest to join the biobank network. Applications can be submitted by laboratories or clinics, or both. The call for applications will state clearly the guiding principles and governance of the Africa CDC Biobanking Network and the criteria for selection. Apart from access to appropriate specimens, the selection criteria include a set of quality indicators (Table 3).

Table 3. *Criteria for selection of biobank sites*

| S/No. | Criteria |
|-------|---|
| | ISO-accredited or good clinical laboratory practice (GCLP)-compliant laboratory |
| | Access to appropriate specimens including controls, including timed series if possible (multiple specimens from a single individual) |
| | Proficiency at performing reference standard testing to characterize specimens demonstrated through participation in external quality assessment programmes |
| | Robust data management system with data backup |
| | Electronic specimen archiving system and storage facilities, including conditions of storage such as freezers with monitored alarms |
| | A mechanism for ethics approval for specimen collection with informed consent |
| | Availability of 24/7 power and robust remote monitoring system for freezers |

2.5. A mechanism for site selection

After screening expressions of interest, the Steering Committee will use the site selection criteria to identify sites that will be invited to submit a full application. The distribution of biobanking sites across the five regional hubs of the African Union will also be considered. Site assessment visits may be necessary to ensure appropriate quality standards concerning facilities, archiving systems and data management systems.

Successful sites will be notified within a maximum of five weeks after the deadline of the call for applications. After notification, sites will be expected to sign an agreement with the Africa CDC Biobanking Network.

2.6. Compliance with site agreement

All participating laboratories in the Biobank Network must sign an agreement with Africa CDC in which they agree to abide by the Africa CDC Biobank Network guiding principles, governance and operational procedures that ensure standardization, transparency, efficiency and effectiveness. They must be compliant with GCP/GCLP and agree to use standardized protocols for specimen collection, characterization and will share information on well-characterized specimens available for facilitating test development and evaluation. For quality assurance purposes, sites must take part in an international or national external quality assessment (EQA) programme and agree to site monitoring visits, as necessary.

Biobanking sites can also act as evaluation sites if they agree to use the unified evaluation protocol and to share their data with the Steering Committee. They will sign an agreement with the test manufacturers that submit tests for evaluation.

2.7. Ongoing assurance of quality

Sites will adhere to ISO standards for laboratory management and follow standardized protocols for specimen collection, characterization and storage. Africa CDC, in collaboration with partners, will be responsible for ongoing assurance of the quality of reference tests and testing by sending out proficiency testing (PT) panels to each site at least twice a year. All laboratories will agree to receive PT panels, perform panel testing and report results in a timely way to the EQA providers.

3. Biobanking operations

Diagnostics and research are an essential component of disease control and prevention strategies. The development and evaluation of novel diagnostics for epidemic preparedness and response depends on a biobanking system that can act with speed without compromising any quality or ethical principles. For the long term, a sustainable mechanism for maintaining a biobanking network is critical to the ability of the Africa CDC to facilitate and accelerate diagnostic test development and evaluation for diseases of epidemic potential and other priorities, such as antimicrobial resistance and disease control and elimination. Table 4 shows the critical attributes of the Africa CDC Biobanking Network.

Table 4. Critical attributes of the Africa CDC Biobanking Network

| Attribute | Justification |
|---|--|
| Speed | An inventory of expert laboratories and specimens/pathogen strains should be rapidly assembled and made readily available, especially in the event of an outbreak. |
| Ethics and governance | All biobanking sites in the network should be compliant with the guiding principles and governance; specimens should be collected with informed consent; a Steering Committee provides oversight on requests for specimens for test development or evaluation. |
| Standardized protocols and harmonized data collection forms | All sites must agree to use the same collection, characterization and evaluation protocols, so that evaluation results can be aggregated across all the sites. |
| Quality materials | The biobanks within the network must be compliant with GCP and GCLP standards and have facilities to maintain specimen integrity and quality. |
| Coordination and sharing of documents and samples | Efficient organization and management of all activities to provide results on time. |
| Sustainability | A mechanism for maintaining the quality and infrastructure of the biobanking network must be in place to ensure sustainability. |

3.1. Consensus on specimens to be collected

For each pathogen of interest, the Steering Committee should develop a consensus on the type of specimens to be collected and present to the Scientific Advisory Committee for input.

3.2. Collection, characterization and archiving of specimens

For new and re-emerging pathogens, new protocols for specimen collection, characterization and storage should be developed by a sub-group of the Steering Committee, for rapid review by the Scientific Advisory Board, and disseminated to all biobanking sites in the network. Data on specimens collected at each site should be shared with Africa CDC so that the use of these specimens for facilitating test development and evaluation – and other forms of research required for surveillance – can be coordinated by Africa CDC. Periodic site monitoring visits should be scheduled by the Africa CDC Steering Committee to ensure that all biobanking sites are compliant with standardized protocols for specimen collection, characterization and biosafety.

Sites should be able to satisfy biosafety criteria for laboratories working with pathogens such as SARS-CoV-2.

3.3. Standardized case report form for epidemiological and clinical data

Each specimen should be collected with a standard set of epidemiological and clinical data through the use of case report forms that will be developed by a sub-group of the Steering Committee.

3.4. Replenishing specimens in the biobank

Each site contributing specimens for test development or test evaluation should be able to pass on to companies their costs related to performing evaluations and replenishing specimens used. The cost of replenishing specimens may differ from site to site depending on salary, supplies, and infrastructure costs, but Africa CDC should play a role of negotiating what is fair for both companies and the participating countries and/or communities.



4. Biobank contributions to test development

4.1. Setting priorities

The priorities of test development can be set by international organizations such as the WHO, UNICEF; continental or regional organizations such as Africa CDC; and/or national control programmes.

4.2. Responding to requests

The Africa CDC Biobank Network will require specific information from the requesting party to justify the use of its specimens or strains to facilitate test development and research. All information will be handled in strict confidence and will not be discussed, published or otherwise distributed outside the members of the Steering Committee. The safe and reasonable handling of materials, as well as the legal and ethical rights and responsibilities of end-users, will be indicated on a 'Materials request form' – the only means by which organizations or individuals can obtain banked samples. A biospecimen request form will be available with the appropriate fields for requesters to complete when requesting biospecimens. Upon receipt of a request for a biospecimen, the Biobank Network Coordinator will notify the Steering Committee electronically. The BioBank Steering Committee will review the scientific merit of the request and suggest approval, rejection or deferral. Upon approval of a request, the distribution of specimens will be handled by the site within the Biobank Network that has been contracted and assigned to maintain the reference materials in question, along with the database of associated clinical information.

As the samples are precious resources, the request will be filled in two stages. Upon initial approval, a small preliminary panel will be sent. Larger panels based on scientific justification as determined by the Steering Committee would be sent subsequently if results were promising:

Level I: The request will be open to any investigator, commercial or academic, who has an assay or concept ready to be tested. Level I requirements include:

- Institutional affiliation is required.
- The requesting party will disclose the use/indication, diagnostic target, format and the appropriateness for developing countries.
- The request for access to biobank materials will be reviewed by the Steering Committee.
- If approved, a small preliminary panel will be released, the size of which is based on the discretion of the Steering Committee.

Level II: Open only to entities that have met Level I requirements. Level II requirements include:

- For diagnostics: Disclose laboratory or field evaluations, characteristics (e.g. specificity, sensitivity, ease of use, speed, or cost etc.) that make ongoing sponsorship of development reasonable. This disclosure may take the form of public reports or raw data with comments. In most cases, a non-quantitative description of the test will not be adequate. For other research activities: preliminary data on the subject of research such as the pattern of drug resistance etc.
- For diagnostics: Requesting party will need to disclose the nature of the test (e.g. IgM antibody detection, RNA nucleic acid test, etc) the matrix needed (e.g. sera, saliva, etc.) and the test format (e.g. ELISA using a monoclonal antibody, point-of-care using RNA NAAT, etc.), both useful to determining the scientific validity of the concept under evaluation.
- If results with the Level 1 development panel are satisfactory, a larger validation panel based on the scientific justification – as determined by the Steering Committee – will be released.

4.3. Release criteria and agreement

The threshold criteria for release of material and decisions regarding release will be driven by scientific and/or technical merit (e.g. for research, internal or external quality management) and compliance with acceptable biosafety practices, to limit the potential for harm. For all requests for pathogen strains to support test development, the requesting party must describe the activities including disclosure of the nature of the test and at least general comments on the format of the assay under development. All applicants will be required to provide a brief CV, institutional profile, and a description of laboratory facilities and biosafety practices, as well as proof of required import permits.

For example, based on the WHO guidance for SARS-CoV-2: non-propagative diagnostic laboratory work (e.g. sequencing, NAAT) should be conducted at facilities and procedures equivalent to biosafety level 2 (BSL-2). Propagative work (e.g. virus culture, isolation or neutralization assays etc.) should be carried out at a containment laboratory with inward directional airflow (i.e. BSL-3). The Africa CDC Biobank Network requires that recipient laboratories are adequate for safe handling, manipulation and storage of specimens and strains. Since the Steering Committee cannot inspect all requesting laboratories, the strategy for managing biosafety and potential liability is:

- i. Accreditation or certification scheme
- ii. Biosafety level of the laboratory
- iii. Quality control programme
- iv. Acceptance of responsibility form
- v. Material transfer agreement covering safety, liability and indemnification issues.

Requesting laboratories will be requested to provide copies of recent laboratory assessments and indicate how they have responded to any recognized deficiencies. The experts in the Steering Committee will gather additional information about the applicant's technical and biosafety practices.



5. Biobank contributions to test evaluation

5.1. Setting priorities

The priorities of test evaluation are set by international organizations such as the WHO, UNICEF, or continental or regional organizations such as Africa CDC, in collaboration with governments and funding bodies.

5.2. Responding to requests

The requesting parties can be individual researchers, commercial or academic institutions, or funding bodies that might need the independent evaluation of given diagnostic tests to authorize their procurement and distribution in Africa. The Africa CDC Biobank Network is a source of well-characterized specimens that can be used for such diagnostic evaluations. To minimize the transport of specimens to a central evaluation site, a virtual evaluation panel will be assembled from sites that can contribute specimens towards the evaluation panel.

The following steps describe the procedure when responding to requests for evaluation. The timelines will be determined by the Steering Committee in collaboration with the funding body.

- i. Companies or other requesting parties such as individual researchers or institutions will submit test format and performance claims or research concepts.
- ii. Africa CDC will review claims/concepts and assess its Biobank Network capacity to support the evaluation or research by defining the composition of evaluation or research.
- iii. Sites will review suggested panel composition and inform the Africa CDC Steering Committee if they can participate in evaluation or research.
- iv. Africa CDC will finalize the list of participating sites that can contribute to the research or virtual evaluation panel, and inform the requesting parties.
- v. Requesting parties, such as companies, will make necessary arrangements with sites – e.g. contracts and agreements that include cost recovery.

- vi. Requesting parties send an appropriate number of tests to sites and may conduct training as necessary.
- vii. Sites will conduct evaluations or research using archived samples from the biobank and report results to Africa CDC.

5.3. Site agreement with requester

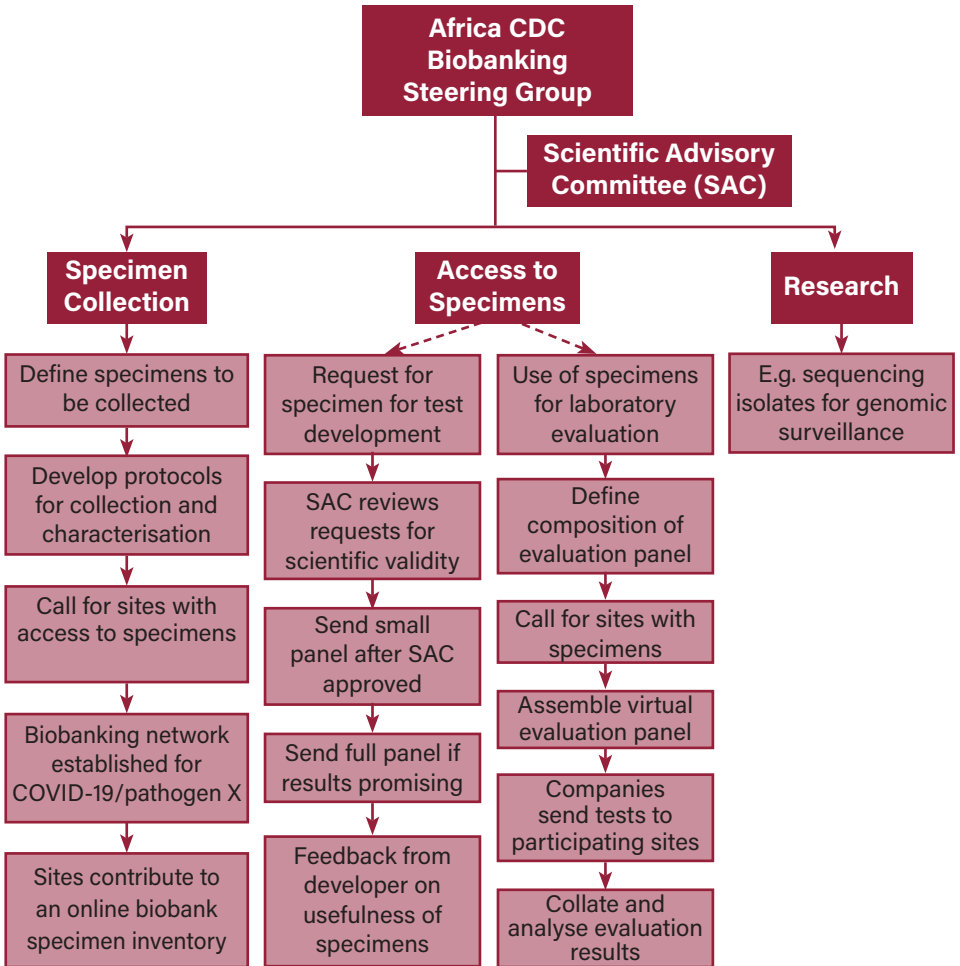
Each site that participates in the evaluation or research should be able to charge the requester on a cost-recovery basis for expenses associated with the activity and the cost of replenishing specimens used. The cost of replenishing specimens may differ from site to site depending on salary, supplies and infrastructure costs. The template agreement sets out the terms of an agreement between the requester and the biobanking site in terms of the independence of the evaluation, free from requester interference. A requester will have 30 days to review the data and pose questions, but not to change the results or conclusions reached by the Africa CDC Steering Committee and Scientific Advisory Board. If the test is already commercially available or research findings are reported, the results will be disseminated through publications. If not, the results will not be published to allow the requester to improve or optimize the assay or research if needed.

5.4. Site evaluation/research

- i. The site investigators will conduct the evaluation/research using consensus protocols.
- ii. Since well-characterized specimens are a precious resource, Africa CDC will conduct evaluations or research in two phases where the initial phase will screen with fewer samples to determine if the test or research concept is viable or not before engaging in the full evaluation/research with larger samples.
- iii. The sites will report the results from the preliminary and final evaluations/research as soon as possible to Africa CDC for their record and collation before publication.
- iv. Africa CDC will analyse the results and present them to the Steering Committee for review, recommendation and dissemination.

The procedures proposed above are summarized in Figure. 1. The Africa CDC Biobanking Network Steering Committee can maintain a degree of flexibility about what type of biobanking model to use for each disease of epidemic potential, depending on the epidemiology of the disease on the continent, resources available and location of laboratory expertise, among other factors. A sustainable biobanking system to facilitate test development, evaluation and research was needed yesterday, it is needed today, and we will need it tomorrow.

Figure 1. Schematic outline of operations of the Africa CDC Biobanking Network



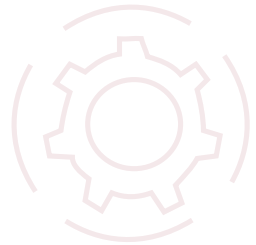
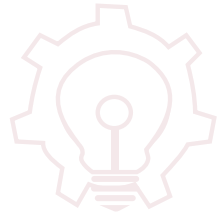
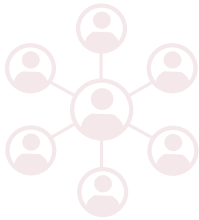


References

1. Peeling RW, M Murtagh and PL Olliaro. Epidemic preparedness: why is there a need to accelerate the development of diagnostics? *Lancet Infectious Diseases*. 2019; 19(5): e172–e178.
2. Kelly-Cirino CD et al. Importance of diagnostics in epidemic and pandemic preparedness. *BMJ Global Health*. 2019; 4(Suppl 2):e001179.
3. Petherick A. Developing antibody tests for SARS-CoV-2. *The Lancet*. 2020; 395(10230): 1101–1102.
4. Peeling RW et al. Need for sustainable biobanking networks for COVID-19 and other diseases of epidemic potential. *Lancet Infectious Diseases*. July 2020.
5. Kintossou AK et al. Study of laboratory staff' knowledge of biobanking in Cote d'Ivoire. 2020 (in press).
6. Beiswanger CM et al. Accessing biospecimens from the H3Africa consortium. *Biopreservation and Biobanking*. 2017; 15(2):95–98.
7. Consortium HA. Enabling the genomic revolution in Africa. *Science*. 2014; 344(6190): 1346–1348.
8. Abimiku AI et al. H3Africa biorepository program: supporting genomics research on african populations by sharing high-quality biospecimens. *Biopreservation and Biobanking*. 2017; 15(2):99–102.
9. Tessema B et al. FIND tuberculosis strain bank: a resource for researchers and developers working on tests to detect *Mycobacterium tuberculosis* and related drug resistance. *Journal of clinical microbiology*. 2017; 55(4):1066–1073.
10. Wilder-Smith A et al. ZikaPLAN: zika preparedness Latin American network. *Global Health Action*. 2017; 10(1):1398485.

11. Wilder-Smith A et al. ZikaPLAN: addressing the knowledge gaps and working towards a research preparedness network in the Americas. *Global Health Action*. 2019; 12(1): 1666566.
12. Nathanson C et al. The TDR Tuberculosis Specimen Bank: a resource for diagnostic test developers. *International Journal of Tuberculosis and Lung Disease*. 2010; 14(11): 1461–1467.
13. Hunsperger EA et al. Evaluation of commercially available diagnostic tests for the detection of dengue virus NS1 antigen and anti-dengue virus IgM antibody. *PLoS Negl Trop Dis*. 2014; 8(10): e3171.
14. WHO and UNICEF. *Visceral leishmaniasis rapid diagnostic test performance*. Geneva: World Health Organization and United Nations Children’s Fund ;2011.
15. Buck M and C Hamilton. The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity. *Review of European Community & International Environmental Law*. 2011; 20(1):47–61.





Africa Centres for Disease Control and Prevention (Africa CDC), African Union Commission
Roosevelt Street W21 K19, Addis Ababa, Ethiopia

+251 11 551 7700 africacdc@africa-union.org www.africacdc.org [africacdc](https://www.facebook.com/africacdc) [@AfricaCDC](https://twitter.com/AfricaCDC)