GHSA National Laboratory System Action Package  
(*GHSA Action Package Detect-1*)

**Five-Year Target:** Real-time biosurveillance with a national laboratory system and effective modern point-of-care and laboratory-based diagnostics.

**As Measured by:** A nationwide laboratory system able to reliably conduct\(^3\) at least five of the 10 core tests\(^4\) on appropriately identified and collected outbreak specimens transported safely and securely to accredited laboratories\(^5\) from at least 80 percent of districts in the country.

**Desired Impact:** Effective use of a nationwide laboratory system capable of safely and accurately detecting and characterizing pathogens causing epidemic disease, including both known and novel threats, from all parts of the country. Expanded deployment, utilization, and sustainment of modern, safe, secure, affordable and appropriate diagnostic tests or devices.

**Country Commitments to Action Package:**
- **Leading countries:** South Africa, Thailand, United States
- **Contributing countries:** Canada, China, Ethiopia, Finland, Georgia, Israel, Japan, Malaysia, Mexico, Peru, Switzerland, United Kingdom, Yemen
- **Contributing international organizations:** FAO, OIE, WHO

**Five-Year Action Items:**

Actions will be coordinated, as appropriate, with relevant international organizations including FAO, OIE and WHO.

1. Evaluate capacity needed at national reference, provincial, and district laboratories and implement a five-year approach based on experience with Integrated Disease Surveillance and Response (IDSR) and other ongoing platforms to build capacity at each level.
2. Integrate or increase collaboration among human and animal laboratory systems for a One Health approach.
3. Field-test novel point-of-collection diagnostics appropriate for screening outbreak specimens.
4. Train biomedical engineers in-country to certify biosafety cabinets and repair/maintain general laboratory equipment (centrifuges, fridges, freezers, incubators).
5. Systematically submit microbial samples or isolates to the public health reference laboratory/ies at the regional or national level.

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\(^3\)The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting. Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results.

\(^4\)The list of 10 core tests in each country includes six testing methods selected according to the IHR immediately notifiable list and the WHO Top Ten Causes of Death in low-income countries: polymerase chain reaction (PCR) testing for Influenza virus; virus culture for poliovirus; serology for HIV; microscopy for mycobacterium tuberculosis; rapid diagnostic testing for plasmodium spp.; and bacterial culture for Salmonella enteritidis serotype Typhi. These six methods are critical to the detection of epidemic-prone and emerging diseases, and competency in these methods is indicated by the successful testing for the specific pathogens listed. The remaining four tests should be selected by the country on the basis of major national public health concerns (see Ijaz et al., “What gets measured gets done. *Emerging Infectious Diseases* July 2012;18:1054-7).

\(^5\)For example, accredited laboratories could be those that have completed appropriate activities according to the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist; the Strengthening Laboratory Management Towards Accreditation (SLMTA) accreditation process; International Organization for Standardization (ISO) standards (e.g., 9001, 15189, and 17025); and/or WHO disease-specific programs (e.g., measles and polio).
6. Establish a laboratory information management system that links with the national disease reporting system.
7. Provide infrastructure improvements, security enhancements, freezers, and a pathogen access control software system to archive and protect collections of dangerous pathogens.
8. Implement step-wise improvement toward accreditation at the district and central levels.
9. Implement basic microbiology training for district-level laboratory technicians, including modules on specimen collection, packaging, transport, and disposal.
10. Identify mechanisms to integrate and sustain national and regional diagnostic capability, including acquisition of reagents and media and access to reference laboratories to support ongoing validation of point-of-care diagnostic tests.

**Baseline Assessment and Planning Activities**

1. Use WHO’s IHR Monitoring Framework and OIE’s PVS Pathway (including IHR/PVS laboratory assessment tools) and other appropriate instruments to identify countries’ priorities for strengthening core competencies.
2. Identify the five priority test-pathogen combinations to form the basis for nationwide laboratory system strengthening efforts.
3. Determine the level of diagnostic capability practical and needed at each level of the public health hierarchy from national to district.
4. Obtain results from prior laboratory assessments and ensure that future assessments are not conducted unless action will follow.
5. Develop national plans for developing and transitioning diagnostic approaches and training.
6. Map all laboratories in the country with geographic information system (GIS) technology, based on population density and disease burden, and calculate the number of additional testing facilities or specimen referral routes (based on the country’s tiered health care system) needed to ensure population access, especially by rural and vulnerable populations, to diagnostic testing and care facilities. Mapping should include laboratory capacities, networks, and partner domains and competencies. Calculate the number of additional strategic sites necessary for storage of rapid tests for priority diseases.
7. Identify existing system vulnerabilities (e.g., laboratory commodity supply chain weaknesses).
8. Develop national protocols to address specimen handling (safe and secure collection, packaging, transport, and disposal), controlled archiving, and import/export procedures. Identify public-private partnerships that could support a more robust specimen transport system and/or use of mobile health technology for laboratory result reporting.
9. Develop a complete toolkit of best practices, guidance, lessons learned and capacity building actions to offer to countries and to contribute to measurable progress.
10. Identify and/or define performance measures, target laboratories for phased improvements, tier-specific testing capacities, and result reporting pathways and identify existing performance measures for laboratory-based disease surveillance.
11. Identify and/or develop appropriate accreditation programs at the district and central levels.
12. Develop a catalog of diagnostics, both currently available and in development, which may be of use to partners interested in incorporating new diagnostic capabilities.

**Monitoring and Evaluation Activities**
1. Train long-term laboratory assessors and conduct biannual proficiency panel testing on testing capacities defined by tier at each testing site.
2. Conduct proficiency testing for animal diseases with guidance from FAO or OIE reference laboratories.
3. Monitor turn-around time and laboratory result reporting and ensure that they are within defined limits.
4. Review system performance during outbreaks or execute drills to assess performance of system improvements at least biannually.