Establishment of Public Health Laboratories in South East Asia
Establishment of Public Health laboratories in South East Asia Region
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Communicable diseases cause substantial morbidity and mortality in low- and middle-income countries, including those of the WHO South-East Asia Region. Region-wide, emerging and re-emerging communicable diseases have had significant impact on public health and the systems on which it depends. Even as the Region’s economies grow, such diseases will continue to pose a substantial threat due to several factors the Region contends with. Being prepared to respond with decisive effect is therefore critically important, with strong public health laboratories a key line of defence. To this end, laboratories must be able to support all three components of public health interventions – i.e. diagnosis, surveillance and control.

As the following pages outline, across the South-East Asia Region there is an urgent need to strengthen public health laboratories and to forge more robust national laboratory networks. Doing so will ensure public health professionals have sustained access to these services, including in rural and hard-to-reach areas.

WHO has been at the forefront of advocacy to achieve these outcomes. As this document outlines, there exists a range of policy options Member States can utilize to strengthen public health laboratories and the networks they are a part of, and to better prevent and contain emerging and re-emerging diseases.

Dr Poonam Khetrapal Singh
Regional Director

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<td>acute encephalitis syndrome</td>
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<td>AFB</td>
<td>acid-fast bacilli</td>
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<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
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<td>AMR</td>
<td>antimicrobial resistance</td>
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<td>APHL</td>
<td>Association of Public Health Laboratories</td>
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<td>APLAC</td>
<td>Asia Pacific Laboratory Accreditation Cooperation</td>
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<td>AST</td>
<td>antimicrobial susceptibility testing</td>
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<td>BSL</td>
<td>Biosafety Level</td>
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<td>CCs</td>
<td>collaborating centres</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CE-IVD</td>
<td>European Conformity – In vitro Diagnostics</td>
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<td>CHC</td>
<td>community health centres</td>
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<td>DG</td>
<td>dangerous goods</td>
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<td>EID</td>
<td>emerging infectious disease</td>
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<td>ELISA</td>
<td>enzyme-linked immunosorbent assay</td>
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<td>EQAS</td>
<td>External Quality Assessment Scheme</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GISRS</td>
<td>Global Influenza Surveillance Response System</td>
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<td>GLASS</td>
<td>Global Antimicrobial Resistance Surveillance System</td>
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<tr>
<td>HBsAg</td>
<td>hepatitis B surface antigen</td>
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<td>HBV</td>
<td>hepatitis B virus</td>
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<tr>
<td>HCV</td>
<td>hepatitis C virus</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>IATA</td>
<td>International Air Transport Association</td>
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<tr>
<td>IEQAS</td>
<td>International External Quality Assessment Scheme</td>
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<td>IHR</td>
<td>International Health Regulations</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>ILAC</td>
<td>International Laboratory Accreditation Cooperation</td>
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<td>IQC</td>
<td>internal quality control</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>LIS</td>
<td>laboratory information system</td>
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<td>LIMS</td>
<td>laboratory information management system</td>
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<td>LQSI</td>
<td>Laboratory Quality Stepwise Implementation</td>
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<tr>
<td>MERS-CoV</td>
<td>Middle East respiratory syndrome coronavirus</td>
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<tr>
<td>NABL</td>
<td>National Accreditation Board for Testing and Calibration Laboratories</td>
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<tr>
<td>NAT</td>
<td>nucleic acid testing</td>
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<td>NCD</td>
<td>noncommunicable disease</td>
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<td>NEQAS</td>
<td>national External Quality Assessment Scheme</td>
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<td>NIC</td>
<td>National Influenza Centre</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NIMHANS</td>
<td>National Institute of Mental Health and Neurosciences</td>
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<td>NTDs</td>
<td>neglected tropical diseases</td>
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<td>OIE</td>
<td>World Organisation for Animal Health</td>
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<td>PCR</td>
<td>polymerase chain reaction</td>
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<td>PEP</td>
<td>post-exposure prophylaxis</td>
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<td>PHL</td>
<td>public health laboratory</td>
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<td>PPE</td>
<td>personal protective equipment</td>
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<td>PPP</td>
<td>public–private partnership</td>
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<td>PT</td>
<td>proficiency testing</td>
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<td>QA</td>
<td>quality assurance</td>
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<td>QC</td>
<td>quality control</td>
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<td>QMS</td>
<td>quality management system</td>
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<td>R&amp;D</td>
<td>research and development</td>
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<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
</tr>
<tr>
<td>SARS</td>
<td>severe acute respiratory syndrome</td>
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<tr>
<td>SEA Region</td>
<td>South-East Asian Region</td>
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<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>STI</td>
<td>sexually transmitted infections</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Public health laboratory services are an essential part of any strong and effective health system, contributing significantly to the prevention and control of diseases as well as improvement of the nation’s health. Since the turn of the century, several outbreaks of severe acute respiratory syndrome (SARS), avian influenza, novel influenza viruses, Ebola, Middle-East respiratory syndrome corona virus (MERS-CoV), Chikungunya, and dengue have highlighted the limitations of public health laboratory capacity in different parts of the world in providing rapid and reliable diagnosis. Consequently, several outbreaks remain undiagnosed leading to considerable morbidity, mortality and economic loss. This also damages the credibility of public health agencies. The WHO South-East Asia (SEA) Region has made a considerable effort to improve health laboratory services capacity for the detection of novel, emerging and re-emerging pathogens.

Although laboratories are cost-intensive ventures, efficient public health laboratory services can provide accurate and timely data for analyses, information and consultation when making policy decisions that protect and enhance the health of the people as well as prevent, control and eliminate communicable diseases.

This document has therefore been conceived and developed to provide policy-makers, administrators and public health professionals in the SEA Region with an overview of the requirements for establishing good quality public health laboratory services.
Scope

This document covers key aspects of a public health laboratory in a developing country and addresses issues pertaining to policy and programme, infrastructure, human resource, technologies available, and high-quality diagnostic systems. It provides guidance on how to strengthen the public health laboratory network and also position it in the context of overall health. The document shall principally assist WHO Member States in expanding their public health laboratory capacity, profile and mandate, and should be used in conjunction with any other unique country requirements and national directives on containment and detection of diseases of public health importance.

Guideline development process

The WHO Regional Office for South-East Asia commissioned the Department of Neurovirology, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, India, to develop the first draft of this document with assistance from experts in the region. The draft guidelines were first reviewed by WHO and subsequently peer reviewed by experts from Bhutan, Myanmar, Nepal, and Thailand. Based on the recommendations made by the peer reviewers, the document was subsequently revised by NIMHANS.
Acknowledgements

The Health Laboratory Services (HLS), Department of Communicable Diseases, WHO Regional Office for South-East Asia (WHO SEARO), thanks Professor Dr V. Ravi and Professor Dr Anita Desai and the team of experts at the Department of Neurovirology, NIMHANS, for their contribution to the development of this document. This document was also reviewed by Dr Htay Htay Tin, Deputy Director General (Laboratories), National Health Laboratory, Yangon, Myanmar; Dr Geeta Shakya, former director, National Public Health Laboratory (NPHL), Kathmandu, Nepal; Mr Sonam Wangchuk, Chief Laboratory Officer, Royal Centre for Disease Control, Thimphu, Bhutan; and Dr Malinee Chittaganpitch, chief of Respiratory Virus Section, National Institute of Health, Department of Medical Sciences, Nonthaburi, Thailand. Dr GB Nair, Regional Advisor ag, RPC and Dr Apama Singh Shah, Regional Advisor, Health Laboratory Services and Blood Safety, WHO SEARO, helped in the development and review of this document.
Communicable diseases, including emerging, re-emerging and new infectious diseases, continue to exact a heavy toll on human life, in terms of both morbidity and mortality, particularly in underdeveloped or developing countries. These diseases have the potential to spread rapidly from one area to another regardless of man-made geographical boundaries. The International Health Regulations (2005) have been accepted by all countries to work collectively towards preventing the spread of communicable diseases and rapidly contain any event that could be a potential international public health concern. These internationally coordinated efforts are a critical step in assuring global health security. Given below are several prerequisites for facilitating global health security, timely and reliable public health laboratory capacity being one:

- adequate and trained public health staff
- strong information and communication systems
- timely and reliable public health laboratory capacity
- efficient and swift management of public health actions, including logistics
- adequate resources
- coordination with other sectors
- global commitment, transparency and legally bound obligations.

1.1 Laboratories and communicable diseases

Laboratories play a critical role in the early detection and containment of communicable diseases, both for the medical management of an individual patient in a clinical setting (clinical or hospital-based laboratories) as well as
for the communities in support of prevention and control of communicable
diseases through, for example, as public health events (public health
laboratories). Few salient differences exist between clinical and public
health laboratories (Table 1.1).

**Table 1.1. Salient differences between clinical and public health
laboratories**

<table>
<thead>
<tr>
<th>Clinical laboratories</th>
<th>Public health laboratories</th>
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<tr>
<td>Focus is on the individual/patient.</td>
<td>Focus is on the population.</td>
</tr>
<tr>
<td>Isolation and identification of causative agent from patient and hospital environment.</td>
<td>Isolation and identification of causative agent from patient, contacts, environment, and its characterization, especially for surveillance and outbreak investigation.</td>
</tr>
<tr>
<td>Determination of antimicrobial susceptibility of pathogen to guide patient treatment.</td>
<td>Provide referral services to other public health and hospital-based laboratories.</td>
</tr>
<tr>
<td>Support the antimicrobial stewardship programme, including the development of hospital antibiotic use policy.</td>
<td>Determination of antimicrobial susceptibility of pathogen to support development of national and regional antibiotic policy.</td>
</tr>
<tr>
<td>Provide support in the diagnosis of noncommunicable diseases and develop specialized laboratory services according to the needs of the hospital.</td>
<td>Provide laboratory support for evidence-based surveillance and epidemiological tracing of infections.</td>
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<tr>
<td>Undertake research to improve patient management for communicable and noncommunicable diseases.</td>
<td>Undertake research to improve public health actions for communicable diseases.</td>
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<tr>
<td>Mostly hospital based or stand alone.</td>
<td>Development of human resource through training, development and dissemination of documents and troubleshooting.</td>
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<td>Promote and maintain the national External Quality Assessment Scheme (NEQAS) for laboratory services.</td>
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### 1.2 Need for efficient public health laboratories

In the recent past, outbreaks of avian influenza and novel influenza viruses, and those due to other viruses such as Ebola, Middle East respiratory syndrome coronavirus (MERS-CoV), Nipah with severe acute respiratory syndrome (SARS), Chikungunya, dengue, leptospirosis, and Japanese encephalitis in different parts of the world have highlighted the inherent
weakness of public health infrastructure to provide rapid and reliable diagnoses. As a result, several outbreaks remain undiagnosed and run their natural course leading to considerable morbidity, mortality, economic loss and social chaos. This also damages the credibility of public health agencies.

Laboratories are cost-intensive, but efficient public health laboratory services can provide accurate and timely data for analyses, information and consultation when making policy decisions to protect and enhance the health of the people as well as to prevent, control and eliminate communicable diseases.

1.3 Role of public health laboratories in combating communicable diseases

Laboratories are essential to all the three pillars of public health care, viz. diagnosis, surveillance and treatment for control (Fig. 1.1).

Broadly speaking, every public health laboratory system in a developing country should play the following crucial roles in the context of emerging, re-emerging and new communicable diseases (detailed functions of public health laboratories are described in Chapter 2):

- early diagnosis followed by its confirmation;
- molecular characterization of causative agents;
- confirmation of novel pathogens or variants;
- surveillance of emerging, re-emerging and new communicable diseases;
• identifying the source of infection, especially in outbreaks and epidemiological tracings;
• drug resistance (antimicrobial resistance) surveillance;
• screening of environment and blood products;
• research and development (R&D) for drugs and vaccines;
• operational and translational research;
• strengthen indicator systems to detect significant events in surveillance;
• integrate surveillance databases among public health laboratories and the private sector;
• apply molecular techniques for syndromic diseases surveillance and outbreak investigation for detection of multiple pathogens.

1.4 **Impact of public health laboratories on communicable diseases**

The best way to prevent the spread of diseases is to detect and respond to disease events early and effectively when the problem is still small and localized. The fundamental role of any public health laboratory is to support public health programmes and public health actions that can efficiently prevent, protect against and control the spread of diseases to obviate mortality, misery, economic loss and social upheaval through:

• early detection of warning signs
• reliable diagnosis of almost all outbreaks
• timely information on antimicrobial susceptibility
• assessment of the efficacy of public health actions
• responding to new threats.

Thus public health laboratories occupy a critical space essential for the smooth implementation of public health activities (Fig. 1.2).
Additionally, laboratory-based surveillance can yield vital information on trends in communicable diseases as well as the impending occurrence of a major event, thus giving adequate time to consolidate resources and take necessary action to combat any event. One such example is of the plague outbreak in India in 1994 when a significant circulation of plague antibody was detected by the public health laboratory in the erstwhile plague enzootic area and near to human habitation – a characteristic of plague.

Similarly, at times when two viruses circulate simultaneously, the usual public health inference indicates one etiology to the event. Laboratory support can clearly identify that though clinically similar the two cases are caused by two different viruses. This has been noted in several locations where both dengue and Chikungunya were responsible for a large number of cases each.

1.5 Access to quality public health laboratories: a challenge

One of the major challenges in ensuring an immediate response to outbreaks is inadequate access to quality public health laboratories across the country. Most communicable diseases originate in far-flung areas, and in the absence of diagnostic support spread due to lack of specific control interventions. A network of public health laboratories is thus the most cost-effective and practical solution. Both access and quality of services must be ensured to contain communicable diseases.

1.6 Issues to be addressed by public health laboratories

Apart from access and quality, there are several other important issues that national authorities need to address to make reliable public health laboratory services available to its entire population. Some of the key actions listed below must be addressed on priority basis:

- integrate public health laboratories in the national laboratory programme;
- ensure sustainability of finances and operations;
- provide adequate infrastructure and human resource for public health laboratories;
- map out, enhance and/or establish regional laboratory networks;
- strengthen national reference centres/institutes;
- strengthen virology and molecular biology services;
- encourage and support use of molecular technology/tools;
- promote and establish quality systems;
- consider accreditation;
• organize NEQAS;
• develop laboratory-based epidemiological support tools;
• generate antimicrobial resistance data and share with policy-makers at local and provincial levels;
• enhance laboratory-based surveillance of priority diseases;
• establish a laboratory biosafety, biosecurity and containment programme;
• develop linkages with laboratories in veterinary departments and other research and academic institutes.

1.7 Linkages with other laboratories in related sectors

Public health laboratories can benefit from the expertise and infrastructure available in various other sectors. The expertise available nationally (for example, veterinary science, environment sector, educational and research institutions, etc.; see Fig. 1.3) must be harnessed to benefit public health.

Fig 1.3 Key linkages of a public health laboratory with other sectors

1.8 Overview of a public health laboratory framework

An overview of the public health laboratory framework – national recognition of its importance, adequate access supplemented by network and collaborative activities, generating quality results in a safe environment, ensuring utilization of results by public health professionals and physicians.

The implementation of the national public health laboratory framework can be facilitated by a national laboratory policy, a programmatic approach to the public health laboratory, and a designated laboratory professional at the national level to oversee the working of this programme efficiently and effectively.
Samples received in a public health laboratory
(Source: NIMHANS, India)
The role of laboratory services is integral and important to both clinical and public health functions for the prevention and control of communicable diseases and is being increasingly recognized. Laboratories provide vital support and facilitate the initiation and monitoring of appropriate clinical and public health interventions, including surveillance, diagnosis, identification of new pathogens, prevention, treatment, research and health promotion. Most public health functions in the area of communicable diseases derive support from efficient public health laboratories.

In the past, the primary function of a public health laboratory was perceived as support to public health programmes and related activities. Accordingly, in the WHO South-East Asia (SEA) Region, considerable effort has gone into improving health laboratory services, with a focus on specific communicable disease control programmes such as for polio, measles and rubella, HIV/AIDS, tuberculosis and malaria, where funding has been available through global health initiatives. This assistance has built considerable capacity in Member States, which sometimes has had a positive spillover effect on other parts of health services. Frequently, however, the connection between the various laboratory initiatives has not been strong, especially between programme-owned disease-specific laboratories and general public health laboratories. There has been inadequate awareness and lack of foresight with regard to the utility and functions of public health laboratories in developing countries.

Public health laboratory services contribute immensely towards the prevention and control of communicable diseases and improving the community’s health. They also provide tools and evidence for disease assessments to epidemiologists and disease control personnel. Unfortunately,
strengthening nationally coordinated public health laboratory services has, until recently, received little or inadequate attention in many developing countries. This has resulted in public health laboratory services having very low national priority with regard to financing, planning and service delivery. In many countries, health systems per se are underfunded and, as a result, laboratory services are often accorded low priority and inadequate allocation of resources, thus hampering their optimal functioning and significant contribution to public health.

2.1 Core functions of public health laboratories

The essential functions of public health laboratories are diverse and are as follows:

- supporting policy formulation and programme development
- providing technical services
- undertaking environmental analyses
- developing human resource
- strengthening laboratory quality system
- biosafety and biosecurity
- supporting regulatory functions
- undertaking, promoting and coordinating research
- functioning as a repository of standard and characterized strains
- managing essential procurement and logistics
- managing laboratory data
- coordinating a network of laboratories
- providing interface with national and international partners and agencies
- communicating with the public and with partners.

2.1.1 Supporting policy formulation and programme development

Policy-makers need reliable data in order to formulate public health policies and programmes. Such data, in any defined area, can be provided by the public health laboratory to enable the development of evidence-based public health policies that are relevant in a local context. Additionally, the public health laboratory can also gather evidence with regard to the impact of these policies and public health programmes. Besides the data on disease pattern, the data pertaining to safety and quality of food and water can also bring about major changes in the provision of safe food and water, as well as assuring sanitation to protect and promote human health.

Public health laboratories provide inputs on responses to outbreaks of communicable diseases, including the potential use of biological agents to harm human health. These help in appropriate strengthening of public health
actions, and in providing an early, alert and efficient response. Recognition of the critical role of public health laboratories allows additional resources to be made available to them by policy-makers, thus strengthening the laboratories too.

2.1.2 Providing technical services

Public health laboratories undertake isolation and identification of causative agents that may have caused an outbreak or which are prevalent in the defined geographical area using conventional diagnostic methods as well as modern molecular techniques. Detailed characterization of these organisms, including determination of antimicrobial susceptibility testing (AST) in the case of bacterial isolates, are functions of national and regional/provincial public health laboratories. These techniques also help in tracing the source of infection, thus facilitating mounting of appropriate interventions to contain any disease especially during the early phase of any outbreak. These services warrant a rapid response and interactions with epidemiologists and disease control personnel.

Public health laboratories also extend referral diagnostic services, including those for identification of rare and unusual microorganisms or their variants (serotypes or biotypes, etc.).

Public health laboratories must have adequate capacity to establish diagnosis of viral infections because of their growing public health importance. Modern techniques such as polymerase chain reaction (PCR) can be of great use.

These diagnostic and referral services aid in surveillance of locally prevalent infections and studying their trends. Population surveillance studies, such as immune status screening, and screening for risk factors, are also undertaken by public health laboratories.

Public health laboratories, through their good practices, ensure adequate biosafety for laboratory staff and biosecurity of the biological material that is received or generated in the laboratory to obviate their escape as a public health hazard.

2.1.3 Undertaking environmental analyses

The public health laboratory provides analytical and technical information in support of state and national environmental health programmes. Such programmes include surveillance for quality of water and air; pollution of large waterbodies; safety of swimming pools and beaches; testing of milk, water and food for contamination leading to food poisoning; and, testing of water, soil and fomites as sources of disease transmission and zoonotic diseases from domestic and wild animals to human beings.
2.1.4 Developing human resources

Within the public health laboratory system, skills of laboratory personnel at various levels need to match the functions undertaken by the laboratories in line with the national health laboratory policy. Skills need to be upgraded regularly. This can be done systematically by understanding the training needs of laboratory personnel, developing training materials, conducting training workshops, and providing post-training support to all laboratories in the network. Training of personnel can cover laboratory methodologies, biosafety, quality systems, data management, and laboratory-related management.

2.1.5 Strengthening quality systems

Quality has to be central to all activities of public health laboratories. Data generated by these laboratories trigger short-term actions (e.g., responding to outbreaks or improving quality of air and water) as well as long-term actions in policy formulation and programme development.

The national public health laboratory takes the lead in development of standard protocols for use across the network. It also organizes the National External Quality Assessment Scheme (NEQAS) for participation by all members of the network. Laboratories showing deficiencies in NEQAS obtain technical support and guidance from an intermediate or national laboratory. To demonstrate its own competence, the national laboratory participates in an International External Quality Assessment Scheme (IEQAS).

Public health laboratories must continuously improve their quality by maintaining a quality management system in all operational and reporting systems. This may require regular monitoring and evaluations spearheaded by the national laboratory to keep pace with global developments in this area.

2.1.6 Biosafety and biosecurity

Public health laboratories routinely handle infectious agents as part of their duties in providing diagnosis and recognizing and responding to outbreaks of infectious diseases (both natural and deliberate origin). These activities can raise concerns regarding the biosafety and biosecurity of the community. Biosecurity is important in order to secure infectious agents against those who would deliberately misuse them to harm people, animals, plants or the environment. The national public health laboratory plays an important role in providing laboratory biosafety and biosecurity guidelines, in addition to training public health laboratory personnel.
2.1.7 Supporting regulatory functions

Public health laboratories provide leadership by guiding and supporting the creation and enforcement of regulations and laws that contribute to laboratory improvement. Apart from assisting regulatory authorities in proper enforcement of regulations, these laboratories promote safe laboratory practices through education, training and consultation.

In some countries, laboratories in both public and private sectors require licensing from local government authorities. The national and regional laboratories provide assistance and guidance on compliance of laboratories with licensing conditions.

The utilization of imported or indigenously produced diagnostic kits requires approval of the regulatory authority in any country. The evaluation of such diagnostics or reagents is undertaken by public health laboratories. Public health laboratories may take the support of national, regional or global reference laboratories in performing this function.

2.1.8 Undertaking, promoting and coordinating research

The public health laboratory network plays an important role in undertaking both operational/translational and applied research on isolation and confirmation of new pathogens and their characterization, development of new technologies, evaluation of new/imported diagnostics and technologies, coordination of multicentric studies and supply of standard strains.

These laboratories also play a contributory role in various operational research projects that facilitate improvements in the efficacy of public health programmes and actions.

The functions of public health laboratories include collaborating with academic institutions to carry out or support clinical and translational research.

2.1.9 Functioning as a repository of standard and characterized strains

The public health laboratory, which receives specimens from a number of laboratories and has past experience with unusual organisms, can maintain pathogens that are new, unusual and fully characterized in a more cost-effective manner. These isolates can be provided to researchers in their pursuits.

In addition, some of the standard national or international strains can be legally stocked at the national public health laboratory and supplied to end users on fulfilling required conditions.
2.1.10 Managing essential procurement and logistics

Public health laboratories can be the resource centre for bulk procurement of essential reagents, assessing their quality and distributing these under proper transportation conditions to other laboratories. These may be cost effective and ensure that quality products become available to different laboratories within or outside the network.

2.1.11 Managing laboratory data

The public health laboratory is the hub where laboratory-related information on diverse aspects of communicable diseases from all types of laboratories is collected, analysed and disseminated as appropriate. Centralization of data supports rapid transmission of necessary information to epidemiologists, infectious disease specialists, and other decision-makers.

2.1.12 Coordinating the network of laboratories

Public health laboratories can coordinate the national laboratory network, especially in areas of communicable diseases, in addition to the network of public health laboratories at different locations in the country. This integrated approach can facilitate sharing of roles and responsibilities, communication and referrals, coaching and mentoring, and monitoring and evaluation required at and between each level of service.

2.1.13 Providing an interface with national and international partners and agencies

Several international development partners and agencies work on laboratory aspects of communicable diseases. Collaboration with them keeps the national public health laboratory system updated and in sync with international progress and developments. Technical support to the country from these international agencies can also be routed through the national public health laboratories.

At the national level, under the One Health approach, public health laboratories can take the lead in coordinating with corresponding laboratories in animal health and environment sectors in tune with the growing importance of collective interaction of humans, animals and environment in causation of communicable diseases.

In many countries, most laboratory services that have an impact on public health are provided by the private sector. The public health laboratory system collaborates with the private sector in deriving relevant information and providing them with confirmatory diagnostic support, especially for unusual diseases.
2.1.14 Communicating with the public and with partners

Communicating effectively with government and development partners is essential for the development of a public health laboratory system, as they can highlight the importance of laboratory contributions in support of public health. This in turn helps public health laboratories get public recognition and financial support from policy-makers.

The functions of public health laboratories, as stated earlier, provide an overview of the broad mandate to the national network of public health laboratories. Not all laboratory investigations can be made available at every facility or at every level of the health system. An organized network ensures that complex test methods are referred to the appropriate level. The transport of specimens or referral of patients is usually more cost-effective than developing sophisticated capacity in every facility.

2.2 Functions of public health laboratories at different levels

Public health laboratories at different levels are mandated to perform different yet complementary functions (the latter happens because of the networking among all laboratories within the country), as shown in Table 2.1. These functions may differ in countries based on the national health laboratory policy and specific needs of the country.

<table>
<thead>
<tr>
<th>Function</th>
<th>Subfunction</th>
<th>National/central</th>
<th>Provincial/intermediate</th>
<th>District/peripheral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy and programme formulation</td>
<td>Advise authorities on laboratory system development, funding requirements and maintenance</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Technical</td>
<td>Diagnostic &amp; AST services</td>
<td>++++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Diagnostic &amp; AST referral services</td>
<td>++++</td>
<td>++</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Surveillance of prevalent diseases including population screening</td>
<td>++++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Outbreak investigation</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Responding to the use of biologics to harm human health</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Biosafety and biosecurity</td>
<td>++++</td>
<td>++++</td>
<td>++++</td>
</tr>
<tr>
<td>Environmental analyses</td>
<td>Food analyses for safety</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Water analyses for safety</td>
<td>++++</td>
<td>++++</td>
<td>++++</td>
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<tr>
<td></td>
<td>Other environmental material analyses</td>
<td>++++</td>
<td>++++</td>
<td>++++</td>
</tr>
<tr>
<td>Quality assessment system</td>
<td>In-house quality management system</td>
<td>++++</td>
<td>++++</td>
<td>++++</td>
</tr>
<tr>
<td></td>
<td>Organization of NEQAS and support to participating labs</td>
<td>++++</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Participation in IEGAS</td>
<td>++++</td>
<td>++++</td>
<td>++++</td>
</tr>
<tr>
<td></td>
<td>Development of quality standards, SOP and other documents</td>
<td>++++</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Assistance in the implementation of a quality system</td>
<td>++++</td>
<td>++</td>
<td>–</td>
</tr>
<tr>
<td>Function</td>
<td>Subfunction</td>
<td>National/central</td>
<td>Provincial/intermediate</td>
<td>District/peripheral</td>
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<td>---------------------</td>
</tr>
<tr>
<td>HRD</td>
<td>Development of training material and curriculum</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Organization of trainings</td>
<td>++++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Providing post-training support</td>
<td>++++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td>Regulatory</td>
<td>Development of licensing and operative standards</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Support in lab assessments and accreditation</td>
<td>++++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td>Research</td>
<td>Development of new technologies</td>
<td>++++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Evaluation of new technologies/reagents</td>
<td>++++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Isolation/confirmation of new pathogens</td>
<td>++++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Coordinate multicentric studies</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Operational research</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Clinical and translational research</td>
<td>++++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Supply standard strains/isolates</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Repository</td>
<td>Standard strains/material</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Characterized pathogens/organisms</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Procurement</td>
<td>Quality control of reagents</td>
<td>++++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>management</td>
<td>Assist in proper shipment</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Data management</td>
<td>Collection, analyses and dissemination of data to labs and policy-makers</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Network coordination</td>
<td>National and regional network coordination</td>
<td>++++</td>
<td>++</td>
<td>-</td>
</tr>
<tr>
<td>International cooperation</td>
<td>Engage international development partners and agencies and collaborate with these technical areas</td>
<td>++++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Public and partner communication</td>
<td>On need basis, communicate with communities using various mass media mechanisms regarding role and contributions of laboratories</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

* Collection of specimens and their shipments

++++ : Mandatory function

+++ : Crucial function

++  : Essential function

+   : Desirable function

The optimal performance of these functions to assist national public health efforts requires smooth operation of the national network led by the national public health laboratory. It is hence essential that national authorities support development, and the implementation of such a network to protect and promote human health.
National Institute of Virology-Pune-Regional laboratory training
Member States of the WHO South-East Asia (SEA) Region are committed to achieving universal health coverage by strengthening the health-care system, and public health laboratory services play an important part here. Notable improvements have been made by Member States of the Region in the detection and characterization of communicable diseases including emerging/re-emerging and novel pathogens.

The situation

3.1 National laboratory policy and strategic plan

Establishing a national laboratory policy and national laboratory strategic plan provides a framework for the coordinated development and delivery of quality and accessible national laboratory services. WHO has developed a document titled “Development of national health laboratory policy and plan” (3) to assist Member States. The document provides a structure for developing a comprehensive policy and regulatory framework for establishing, operating and monitoring health laboratory services, and promoting better coordination of activities among health-care programmes and institutions. Since, it is acknowledged that “one size does not fit all”, each country’s national health policy and strategy should be planned according to that country’s unique health-care system.

Many Member States are in the process of developing a national health laboratory policy and strategy. Maldives, Myanmar and Timor-Leste have
developed a health laboratory policy and strategy. Bhutan is in the process of drafting a national health laboratory strategy. National health laboratory system assessments are ongoing in Member States. This information will support the formulation of evidence-based national health laboratory policies.

3.2 Organization, structure, function and human resource

Public health laboratory services are an integral part of the national health services and are established within its framework. The planning, organization and administration of national health laboratory services varies from country to country and depends on many factors. Each country’s laboratory system is planned according to their specific needs and availability of resources. The organization of laboratories is usually either three or four tier systems with various possible linkages between them.

One suggested network is shown in Fig. 3.1.

![Fig. 3.1. A suggested network of public health laboratories](image)

Public health laboratories mostly assist in early and reliable diagnosis and treatment of diseases, investigation of outbreaks of diseases, collection of reliable surveillance data for effective disease control, monitoring the quality of water and food, and monitoring the various vertical national health programmes. The functions and importance of public health laboratories have been described in Chapters 1 and 2. Public health laboratory services also coordinate with veterinary services and environmental service laboratories.
An important function of a national public health laboratory is to develop and sustain teaching and training programmes for laboratory staff employed in peripheral health-care services.

The aforementioned functions of public health laboratories differ from country to country based on their needs and the resources available.

### 3.3 Detection and characterization of pathogens and the referral mechanism

National public health laboratories, in addition to vertical programmes, have also made remarkable progress in the detection and characterization of emerging/re-emerging and novel pathogens. All eleven Member States in the SEA Region have the capacity to detect pathogens using polymerase chain reaction (PCR). The WHO Global Influenza Surveillance Response System (GISRS) has also supported the development of public health laboratories in Member States significantly. Eight of the 11 Member States in the SEA Region have National Influenza Centres (NICs). The remaining three Member States are working towards escalating their laboratory level to that of an NIC.

Timely and accurate laboratory diagnosis in a safe environment is the cornerstone of any surveillance and response system for communicable diseases in the SEA Region. There is a well-defined referral mechanism which facilitates the shipment of specimens to reference laboratories for further characterization and for validation of laboratory test results. Networking to enhance regional laboratory capacity has been established with premium reference laboratories, WHO collaborating centres (WHO CCs) and global experts.

WHO CCs and reference labs help Member States in detection and characterization of novel pathogens. Regular regional and national laboratory workshops on sample collection, storage, processing and reporting have been organized by WHO to further strengthen regional laboratory capacity. WHO CCs and reference laboratories also provide in-house non-commercial reagents at the time of outbreaks to laboratories in the SEA Region. WHO supported the supply of non-commercial laboratory reagents and personal protective equipment (PPE) to public health laboratories during outbreaks to facilitate early detection and containment of pathogens under proper biosafety practices. Regional and national training courses are organized to build national capacity for undertaking laboratory-based surveillance of antimicrobial resistance (AMR).
3.4 Quality management system and accreditation

The poor quality of laboratory results can lead to inappropriate intervention, and adversely affect the credibility of the laboratory. One of the best methods to strengthen laboratories is to implement a quality management system (QMS) that complies with the requirements of international quality standards, ISO 15189, or with a national standard with similar requirements. In the past few years, WHO has consistently advocated promoting the implementation of quality in public health laboratories in Member States. Realizing that Member States will require considerable technical support to strengthen QMS, WHO has developed the Laboratory Quality Stepwise Implementation (LQSI) tool. This tool ensures the correct implementation of all the processes of quality system essentials.

Member States of the SEA Region are in various stages of implementation of QMS. Public health laboratory staff are trained in the use of the LQSI tool through regional and international trainings, including training at the KIT Royal Tropical Institute, the Netherlands, a WHO CC.

National public health laboratories also participate in various international microbiology (bacteriology, mycology, virology) External Quality Assessment Schemes (EQAS) (microscopy, culture, serology, PCR). National public health laboratories provide national EQAS (NEQAS) to peripheral laboratories. However, this system is not uniform in Member States and is in different stages of implementation of the quality assurance programme.

Accreditation of health laboratories is the process by which an independent and authorized agency accredits the quality system and competence of a laboratory on the basis of certain predefined standards. “Guidelines for establishment of accreditation of health laboratories” (4) was developed by WHO to guide Member States on this aspect. This document is intended to provide guidelines on the facilities and personnel needed, and includes examples of how to initiate the establishment of an accreditation process in a system. Laboratory accreditation is recognized as an efficient tool for putting in place a quality system to achieve continuous improvement in laboratory service in a sustainable fashion. The laboratory accreditation system is important for the acceptance of test results nationally and internationally: accreditation is immensely beneficial in supporting an achievable and efficient health-care system. All medical services need reliable laboratory support for taking proper action, making decisions and formulating policies.

In many countries of the SEA Region, laboratory accreditation, especially in the areas of medicine and health, is gradually evolving. Accreditation of laboratories in the Region is largely voluntary. The accreditation body
in India is the National Accreditation Board for Testing and Calibration Laboratories (NABL), which has signed a Mutual Recognition Agreement with the regional cooperation, the Asia Pacific Laboratory Accreditation Cooperation (APLAC), and with the apex cooperation, the International Laboratory Accreditation Cooperation (ILAC).

The laboratory standard in Thailand is derived from multiple international standards, retaining the most important elements yet making the standard applicable to Thailand. The national accreditation programme was established as a local alternative for improvement in laboratory quality. The programme is affordable, feasible, scalable, sustainable and effective. Other Member States in the Region are in various stages in the process of establishing and strengthening their quality management system and gradually moving towards accreditation.

3.5 Laboratory biosafety

Biosafety includes every activity related to safeguarding a population from the biologically untoward effects of infectious agents. Biosafety aims to protect all those who are exposed, directly or indirectly, to infectious agents while handling laboratory specimens. WHO has long recognized that biosafety in the laboratory is an important international issue and has published a laboratory biosafety manual (5). This manual encourages countries to accept and implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic microorganisms in laboratories. Some Member States of the SEA Region have national guidelines for biosafety.

Five Member States have biosafety Level-3 (BSL-3) laboratories. Two more Member States are in the process of achieving BSL-3 status. Most public health laboratories undergo annual inspection of their biosafety cabinets. WHO has organized regional and onsite biosafety laboratory trainings to support Member States in strengthening their capacity to implement biosafety in laboratories. Regional and onsite trainings on doffing and donning of PPE have been conducted to assure no breach in biosafety. Trainings on shipping and packaging of infectious biological substances dangerous goods (DGs) and cold chain maintenance in accordance with International Air Transport Association (IATA) and United Nations (UN) norms were organized for national public health laboratory staff to assure safe shipment of infectious material to reference laboratories for detection/confirmation of test results.
3.6 Inter-sectoral collaborations

Major laboratory resources (expertise, diagnostic capacity, manpower, infrastructural support) are available both within and outside the traditional public health sector. These include medical colleges, the veterinary sector, basic research laboratories, the armed forces, food-testing laboratories, and water quality standard setting and monitoring agencies. In the absence of a clear plan, multi-sectoral collaborations are unstructured. It is apparent that some countries in the SEA Region need to channel special efforts through multi-sectoral actions to achieve prevention and control of diseases. Public health education and competency at various levels are needed to translate evidence into policy, and to implement and evaluate programmes. The emergence of new infectious diseases and multidrug resistance demands urgent scaling up of inter-sectoral collaborations and integrated approaches.

3.7 Challenges

Not all Member States of the SEA Region have a national health laboratory policy. Allocation of funds to health laboratory services is not regular. A rapid turnover of staff in laboratories leads to an absence of trained professionals to rapidly and reliably diagnose emerging infectious diseases. Countries have limited capacity to characterize new pathogens using modern technology and sophisticated infrastructure which require highly skilled professionals. The laboratory information management system (LIMS) in most public health laboratories as well as the coordination among epidemiologists is inadequate. Most agents of emerging infectious diseases carry high infectivity and pathogenicity and do not have specific prophylactic and therapeutic agents. These organisms can be handled only in laboratories with BSL-3 biosafety infrastructure and practices, which do not exist in several Member States of the Region. Movement of infectious material is at times restricted or shipment to reference laboratories located outside the country takes a long time thus resulting in delays in intervention, including containment. The absence of sustained funding to public health laboratories is also a big challenge.

These challenges have been summarized below and detailed in Chapter 4. They are:

- national laboratory policy and programme
- appropriate and sustained funding for laboratory infrastructure
- proper biosafety levels
- stable, skilled, adequate human resource with continuous skills upgradation
• laboratory information management system
• national network, efficient referral and shipment mechanisms
• strong quality management system.

3.8 The way forward

It is important to advocate the development and implementation of a national laboratory policy and strategy to Member States and allocate an annual budget to the national health system towards a public health laboratory component. An integrated approach for the detection and characterization of pathogens will save duplication of effort and resources. A single laboratory can be used for the detection of several pathogens using available infrastructure and trained laboratory staff. It is important to establish more state-of-the-art reference public health laboratories for emerging infectious diseases (EIDs) within the Region. Strengthening of national capacity in handling emerging pathogens under an exacting biosafety environment is needed. Forging a network of national public health laboratories in the SEA Region will contribute to enhanced regional capacity to respond effectively to prevent and contain emerging infectious diseases.
Establishment of Public Health Laboratories in South East Asia

Policy & programmatic

Technical

Financial

Human resource

Sustainability

Pillars of public health laboratory capacity
Source: NIMHANS, India
Efficient and reliable public health laboratories are an essential part of any strong and effective health system. In the South-East Asia (SEA) Region, considerable effort has gone into improving public health laboratory services in the recent past. Despite the progress and efforts being made to strengthen laboratory capacities in the Region, some challenges remain. The key challenges faced by countries in the Region in establishing efficient public health laboratories are in the following areas:

1. Policy and programmatic
2. Technical
3. Financial
4. Human resource
5. Sustainability of public health laboratory services

4.1 Policy and programmatic issues

In some countries, public health laboratories perform activities that overlap across various national health programmes. This reduces the effectiveness of the public health laboratory system. Therefore, the national laboratory policy may be formulated to outline the role and functions of public health laboratories at various levels. Such a policy will serve to guide the implementation of national public health laboratory programmes.

4.1.1 Resource allocation

There are a variety of laboratory facilities in the SEA Region, some functioning as purely diagnostic laboratories, while others are also research laboratories. Some countries have a network of state and district public health laboratories which perform the function of food and water testing.
in addition to some other infectious disease diagnosis. Some others have laboratories under vertical disease programmes. All these laboratories are usually funded from a single source, leading to competition for resources amongst them. Further, the varied structure may lead to confusion in defining their precise public health functions. Consequently, the essential public health mandates of laboratories have not been well defined at various levels of functioning in developing countries.

4.1.2 National laboratory policy and a strategic operational plan

A comprehensive national health laboratory policy, including public health laboratories outlining stakeholders, resources, processes and functions, is currently available in some countries in the SEA Region. Many other countries are in the process of developing these policies and plans, while others are yet to initiate the process. Nevertheless, in all countries, a strategic plan for laboratory strengthening as a policy is available for vertical disease control programmes, which may also be extended to public health laboratories.

4.1.3 Laboratory networking

While the need for “functional networking” of health laboratory resources and expertise has been recognized as essential, the functions and roles/responsibilities in these networks have not been well defined except for a few diseases. Many networks are an outcome of outbreaks in infectious diseases. Polio and influenza (Global Influenza Surveillance Response System or GISRS) are very good examples of established networks. These networks have been successfully operating for several years. They can be of immense importance and can support the detection and characterization of other emerging and novel pathogens of public health importance. Chapter 9 describes the possible mechanism and advantages of having a national public health laboratory network.

4.1.4 National focal point and national laboratory coordinating committee

A national laboratory focal point or department and national laboratory coordinating committee should be established. The terms of reference for the national focal point, and the composition and terms of reference for the national laboratory coordinating committee, should include responsibility and accountability for steering and monitoring the health laboratory services. At present, such mechanisms are available only in some countries in the SEA Region.
4.2 Technical challenges

4.2.1 Laboratory facilities

Physical infrastructure and equipment are essential components of a public health laboratory system and should be planned according to the needs of the country and mandate of the laboratory in line with the national health laboratory policy. When deciding on a building and its location, consideration must be given to the following: country context; number and distribution of human resources; utilities such as electricity and water supply; maintenance and replacement of equipment; other recurrent costs. Appropriate building space, design, utilities and equipment are essential to deliver safe and effective services. Implementation of appropriate technologies at various levels of the laboratory network should be cost-effective and improve efficiency. Any equipment that is not appropriate for a purpose, is outdated, or not well maintained or used affects the quality of the results generated.

4.2.2 Procurement and supply chain management

In several countries, the administrative structure of the health ministry is such that laboratories are only considered alongside pharmacies, radiology and clinical services. Quite often, more emphasis is placed on the procurement of medicines rather than laboratory services, adversely affecting public health laboratory services. In order to ensure continuous laboratory supplies and to avoid stockouts, it is imperative to establish an evidence-based system. The selection and standardization of laboratory supplies and reagents must be based on the type of tests performed at each level of the health laboratory. Establishing an effective national laboratory procurement and supplies management system, with appropriate storage facilities and timely distribution system (as per the calculated demand to avoid expiry), evaluation and validation of reagents, identification of a national centre for independent quality assurance of reagents, development of clear guidelines for accepting and receiving donated supplies to ensure that they are appropriate for the laboratory and, above all, establishment of a standardized system for inventory and stock control, are important aspects laboratories should consider to overcome challenges.

4.2.3 Regulation of diagnostics

A number of diagnostic products are required for surveillance and diagnosis. Some of these are manufactured locally within the SEA Region, while others are imported. A quality assurance system for evaluating all these diagnostics is not in place in all countries in the Region. Even when available, it is restricted to certain vertical disease control programme needs and does not encompass the entire gamut of public health services. Further, there
is no designated agency or institution that has been entrusted with the responsibility to assess the performance characteristics of these products. This poses a great challenge for quality and reliability of data generated, resulting in an inability to compare data generated across the country/region. It can also result in situations where incorrect results are provided for clinical diagnosis and medical management, thereby resulting in adverse outcomes.

4.2.4 Research

Research in laboratories is largely disease-based. Operational and translational research and research into issues relating to strengthening public health laboratory capacity have been neglected. Therefore, most public health laboratory strengthening efforts have not been based on sound evidence. Research priorities that need to be addressed by public health laboratories are described in Chapter 11.

4.2.5 Quality assurance and accreditation

Quality is of paramount importance in a testing laboratory. While quality assurance (QA) mechanisms are established in several national public health laboratories in the SEA Region, they need to be strengthened at all other levels. Further, accreditation of public health laboratories at all levels should be the ultimate goal.

4.2.6 Biosafety and biosecurity

The salient concepts of biosafety and biosecurity are well recognized in public health and diagnostic laboratories in the SEA Region. More than 50% of the Region’s Member States have BSL-3 labs at their national public health laboratories. Many Member States have also developed national biosafety guidelines and maintain adequate safety measures in all laboratory practices. Implementation of biosafety measures varies from country to country and also within the country. Concrete regulatory mechanisms for monitoring biosafety and biosecurity practices need to be strengthened in the Region.

4.3 Financial resources

Financing laboratory services in a sustainable manner is pivotal to the success of the public health system of any country. Financing of public health laboratory services, in general, is frequently given low priority, and this is true in countries in the SEA Region as well. The national laboratory plans of Member States should include a robust and dynamic financial plan designed to minimize interruption of services. This should be based on sound epidemiological and laboratory evidence generated by the country. Consequently, financial resources required for laboratory services should be
part of the country’s overall health budget. Member States should explore and encourage public–private partnerships (PPPs) wherever feasible.

4.4 Human resource

The availability of trained technical manpower is a challenge facing many countries today. A comprehensive human resource plan for laboratory personnel that includes issues of basic and in-service training, continuing professional development, motivation and incentives, retention, remuneration and career development is a critical component of the public health laboratory system of every country. In addition, the human resource plan should also address the issue of adequate supply of appropriate human resource, and guide teaching institutions and universities in educating the future workforce. While several Member States have such human resource plans in place, they must clearly articulate the strength of the workforce required based on job functions/roles and the volume of work at every level. Additionally, the plan must include a clearly defined roles and responsibilities and training requirements (induction and in-service training) at each level.

Issues relating to retention of trained manpower as well as proper supervision of laboratory staff must also be addressed by Member States.

4.5 Sustainability of public health laboratory services

Public health laboratory services are given low priority and recognition by national authorities in general. This results in inadequate financing, low priority to recruitment of human resources, poor training and infrastructure.

A weak, legislative and regulatory framework for public health laboratory services and lack of robust mechanisms for evidence-based policy and planning processes at the national level have also contributed greatly to a lack of sustainability of public health laboratories.

Among the urgent actions required by Member States is to formulate and implement a strategic framework for action that is aligned with national priorities, regulations and specific contexts. Health ministries should ensure availability of adequate resources (for implementation of national laboratory policies and strategic plans) through a robust resource planning and programme budgeting process.

The major challenges faced by the public health laboratories in the SEA Region are summarized in Table 4.1.
### Table 4.1. Major challenges faced by public health laboratories

<table>
<thead>
<tr>
<th>Type of challenge</th>
<th>Components of the Challenge</th>
</tr>
</thead>
</table>
| Policy and programmatic issues        | • low priority accorded to laboratory services in national health strategy;   
                                            • absence of national laboratory policy and strategic plan;   
                                            • inadequate implementation of laboratory regulations;   
                                            • lack of national focal point   
                                            • weak or absent laboratory networking. |
| Technical                             | • inadequate laboratory facilities at all levels;   
                                            • unregulated procurement and management of equipment and material absence of national policies;   
                                            • lack of effective equipment maintenance systems;   
                                            • lack of a robust procurement and supply management chain;   
                                            • lack of standardization and harmonization of laboratory services;   
                                            • poor coordination with clinical services;   
                                            • inappropriate utilization of resources;   
                                            • lack of quality assured testing and accreditation mechanism;   
                                            • limited scope of laboratory-based research;   
                                            • inadequate monitoring of biosafety and biosecurity procedures;   
                                            • lack of LIMS for recording and reporting;   
                                            • incomplete documentation. |
| Financial                             | • inadequate resource allocation;   
                                            • lack of cost-effectiveness analysis. |
| Human resource                        | • inadequate number of laboratory professionals and technicians;   
                                            • lack of mechanisms to address manpower needs and availability;   
                                            • inadequate training and supervision programmes;   
                                            • lack of strategic plans to retain trained staff;   
                                            • lack of career structure and opportunities;   
                                            • inadequate use of information technology. |
| Sustainability issues                 | • ever-increasing demand for health laboratory services;   
                                            • weak, legislative and regulatory frameworks for health laboratory services;   
                                            • lack of robust mechanisms for evidence-based policies and their implementation;   
                                            • no formulation and/or implementation of a strategic framework for action. |
Health ministries should be advocated to combine available tools and technical expertise (both domestic and international) to translate national priorities into evidence-based and detailed resource plans and, further, into budgetary implications. This will greatly facilitate strategic financial negotiations and increase the chances of mobilizing needed funds from either domestic or external sources.
A view of a national public health laboratory (Source: Public health laboratory, Bhutan)
The development of a national public health laboratory system can be considered in three main phases: inputs, processes and outputs to reach the final outcome.

- **Inputs** include the appointment of a public health laboratory leadership team or working group; conducting a situational analysis; drawing up the national laboratory policy and strategic plan; establishing the monitoring and evaluation framework; and allocating financial resources for public health laboratories.

- **Processes** include undertaking consultations; establishing technical working groups; carrying out monitoring and evaluation; conducting regular reviews and revisions; and financial accounting.

- **Outputs** include, among others, the regulatory framework, management and administrative structures and national standards that address all key elements of the national public health laboratory system, including laboratory workforce, laboratory infrastructure, equipment and supply management system, information management, safety, and overall quality management system.

The outcome of the overall process is the development of an integrated, functional, high-quality public health laboratory network that provides quality laboratory services at all levels of the health system as outlined in Table 5.1.

### 5.1 Leadership/governance and organization

Both technical and administrative leadership is required to provide direction to the development of the national health laboratory policy and strategic plan and to monitor the implementation of the public health laboratories.
5.1.1 National laboratory focal point

The national laboratory focal point is created to develop, guide, coordinate and monitor laboratory services in accordance with the national laboratory policy and strategic plan; to work out the cost and identify, allocate and distribute financial resources for the implementation of the plan; to institute national standards for quality systems in the public health laboratory (including infrastructure, tests, techniques, staff competence and equipment) at each level of the public health network.

5.1.2 National laboratory coordinating committee

The national laboratory coordinating committee comprises technical experts with the knowledge, vision and mandate to:

- advise on national health policies and pertinent medical and technical developments relating to laboratory services (for communicable and noncommunicable disease control, including emerging infections);
- contribute to the development of legislations and regulations governing health laboratory practices;
- coordinate initiatives/proposals wherein public health laboratory services contribute to the overall health strategy;
- evaluate new laboratory initiatives and technologies.

Table 5.1. Key cross-cutting elements of a national public health laboratory system

<table>
<thead>
<tr>
<th>Key Elements</th>
<th>Process</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial considerations</td>
<td>Country situational analysis</td>
<td>National health laboratory policy</td>
</tr>
<tr>
<td>Regulatory framework</td>
<td></td>
<td>Monitoring and evaluation</td>
</tr>
<tr>
<td>Organization of the laboratory system</td>
<td></td>
<td>Quality Health Laboratory Network</td>
</tr>
<tr>
<td>Organizational and management structure</td>
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<td></td>
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<tr>
<td>Reference laboratories</td>
<td></td>
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<tr>
<td>Laboratory-based disease surveillance</td>
<td></td>
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<tr>
<td>Laboratory networking</td>
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<tr>
<td>Laboratory standards</td>
<td></td>
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<tr>
<td>Laboratory workforce</td>
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<tr>
<td>Quality management system</td>
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<tr>
<td>Laboratory infrastructure</td>
<td></td>
<td></td>
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<tr>
<td>Equipment – maintenance and calibration</td>
<td></td>
<td></td>
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<tr>
<td>Supply chain management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory safety and waste management</td>
<td></td>
<td></td>
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<tr>
<td>Laboratory information management system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public–private partnerships</td>
<td></td>
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</tbody>
</table>
An organizational structure/chart for national public health laboratory services should clearly define all management and technical roles and responsibilities for each level in the network and their relationships with other health programmes.

5.1.3 National laboratory policy and strategic plan

The national laboratory policy and national laboratory strategic plan are developed in line with the national health policy and the national health sector strategic plan. It is the responsibility of the designated laboratory department/division or unit in the Ministry of Health, which provides the leadership function, to develop these documents describing the roles, responsibilities and operations of public health laboratories within the overall ambit of national health laboratories.

5.2 Country situational analysis

The situational analysis is a baseline assessment of the current status of public health laboratory services at all levels of the tiered health system, in the form of a SWOT analysis—strengths, weaknesses, opportunities and threats. A selected technical working group should develop a thorough description of the current structure, practices and functions of the laboratory system. The assessment should address public health laboratory infrastructure, equipment, staffing profiles, type of tests performed at each level, quality assurance systems, reporting, supervision and sources of funding. Standard assessment tools from WHO and other international agencies are available to assist countries to conduct baseline assessments in a selected number of laboratories at all levels of the health system. Based on the findings of the assessments, the laboratory policy and strategic plan are drafted through a consultative and consensus-building process.

5.3 National laboratory policy

The National laboratory policy is an indicator of the national commitment towards health laboratories. It provides the overall framework and direction for establishing, strengthening and maintaining the national health laboratory system. It states the vision, mission and objectives of the national health laboratory system. The public health laboratory component should be highlighted and appropriately described in this document.

5.4 National laboratory strategic plan

The national laboratory strategic plan identifies the strategies and activities required to achieve the objectives defined in the national laboratory policy over a designated time frame, such as 3 to 5 years. Principles chosen for the development of the plan should consider unique aspects of the country.
A designated working group should carefully design and finalize a realistic and practical strategic plan.

The national laboratory policy and national laboratory strategic plan should be governed by a process of continuous improvement. The plan and policy may need to be reviewed and updated as circumstances change. Once the national laboratory strategic plan is developed and approved, annual operational plans including those for public health laboratories are drawn, detailing activities, time frames, implementing partners, budgetary allocations and annual funding sources.

5.5 Financial support

The public health laboratory system requires a dedicated, integrated budget. Cost estimates must be prepared for all activities in the national laboratory strategic plan and its implementation in the public health laboratory network for the next 3 to 5 years. Costs should include laboratory renovation, equipment, human resources, reagents and supplies, quality assurance, external quality assessment and accreditation, specimen referral, training, and other costs.

5.6 Regulatory framework

National laboratory standards, including those for public health, should be laid down and must apply to all laboratories and testing facilities operating in the country. These standards would cover a variety of areas, including human resource, infrastructure, equipment, in vitro diagnostic test kits/reagents, procurement and supply, test methods/technologies data management, sample collection and transportation, biosafety and biosecurity measures, code of ethics and laboratory networks.

5.7 Public health laboratory network system

Laboratory tiers/levels are determined by their test menus and functions, and a referral network is established in order to perform tests at the most appropriate level of the tiered system (Fig. 5.1). The number of tiers in the laboratory system and the test menu performed at each level may vary depending on infrastructure available, testing needs of the community, service-level needs, priority diseases, geographic coverage, referral capabilities, and the resources available. WHO has recently developed a list of essential diagnostics (in vitro diagnostics) and suggested its use at different levels of health-care facilities.

The key objectives of the national public health laboratory system include the following: monitoring and evaluating laboratory capacities; increasing coordination and communication among laboratories; building partnerships between public health and clinical, veterinary, agriculture and...
environmental laboratories; developing the laboratory workforce through training and education; and promoting laboratory standards.

Fig. 5.1. An illustrative example of a laboratory network

5.8 Laboratory human resource development

The number and cadre of staff required to meet projected requirements, for each tier of the public health laboratory network, needs to be defined for:

- laboratory workers including supervisors, scientists, technologists, laboratory auditors, phlebotomists and technicians;
- non-laboratory cadres necessary for the operation of laboratory services – equipment maintenance engineers, information technologists and data managers.

5.9 Information management and communication system

Public health laboratory information/data must be captured and transmitted on a regular basis, either through written reports or electronically in a laboratory information system. A standardized national laboratory information management system (LIMS) that addresses both management and operational issues is essential. The ability to meet specialized patient care needs, integrated disease surveillance needs and laboratory testing/reporting with one health information management system will be the most efficient and cost-effective for the country. An alternative is LIMS, which interfaces with a variety of other systems/databases in the country.
5.10 Quality management system

A laboratory quality management system (QMS) is a coordinated approach to directing and controlling laboratory functions with the aim of ensuring accurate, reliable and timely results for clinical and public health purposes. Standards relating to specific aspects of laboratory work may be internationally recognized, such as the standards set by the International Organization for Standardization (ISO), including ISO 15189:2012 Medical laboratories: Requirements for quality and competence which specifies the requirements for quality and competence in medical laboratories, and relevant national standards.

Key considerations should include:

- establishment of a position for a laboratory quality manager at both national and state levels;
- institution of quality assurance implementation and coordination structures at all levels;
- development of national standards followed by their dissemination and training;
- development and implementation of a laboratory QMS and monitoring of a national internal quality control (IQC) system;
- development, implementation and monitoring of a national External Quality Assessment Scheme (NEQAS) including proficiency testing (PT) providers;
- establishment of a national laboratory audit/assessment and certification/accreditation system along with relevant training programmes for all cadres of staff;
- establishment of a national monitoring and evaluation system for quality management implementation (Chapter 12).

5.11 Laboratory infrastructure

There is a need to ensure that every public health laboratory maintains a facility that provides adequate space, workflow and environmental conditions to support quality of work and safety for all health-care personnel, patients, visitors, community and the environment.

5.12 Harmonization in laboratory networking

Public health laboratory networks require central management and direction that is achieved through national laboratory policies, regulatory oversight and coordination of operational functions such as procurement, after sales services, quality assurance, and logistics to ensure efficient
operation and collective benefits across health systems. Policies and
guidelines that promote the standardization of test menus, the use of
common testing technology, instruments and test devices (platforms),
consumables and service delivery across laboratories in the network
result in more efficient and cost-effective organization, operation and
management of the network. Standardization also allows for easy referral of
specimens to other network laboratories, and makes the job of developing
standard operating procedures (SOPs), training, competency assessment,
and reference intervals easier. General criteria for selection of diagnostic
devices for the network include the following:

- certified or recommended test method
- demonstrated accuracy (sensitivity and specificity)
- test capacity matching volume demand
- cold-storage requirements matching available cold chain
- good domestic and international track record of quality and
technical support
- successful under local or international evaluations (e.g. Food and
  Drug Administration, European Conformity – In vitro Diagnostics, World
  Health Organization, or Centers for Disease Control and Prevention)
- compatible with quality assurance programmes
- reliable distributor available
- reliable service and maintenance provider available.

5.13 Validating testing algorithms

National testing algorithms, where applicable (e.g. HIV), should be
developed and validated by the national reference laboratory as
designated by the national authorities. The study should validate a specific
combination of diagnostics, according to a standardized testing strategy.
WHO has provided such algorithms for HIV, viral hepatitis and some other
diseases, and the same can be adapted to suit national needs.

5.14 Equipment management

Equipment management in a public health laboratory network should
address the following:

- equipment selection based on specifications appropriate for each
  level of the tiered laboratory system; facility, environmental and
  engineering requirements including uninterrupted power supply,
  availability of user and service manuals in the appropriate language;
• development of national protocols, policies, procedures and checklists for procurement, acquisition, distribution, installation, operation, calibration, maintenance and disposition (retirement) of laboratory equipment, in line with the national medical equipment management system, with provision of adequate logistical and financial resources.

5.15 Supply chain management

Supply chain management is an important component of the national laboratory policy and should address:

• the selection and standardization of reagents, test kits, controls, calibrators, chemicals and consumables based on specifications appropriate for each tier of the public health laboratory level, taking into consideration equipment, test methods, costs, availability, shelf life and storage conditions;

• the utilization of pre-qualification guidance provided by international organizations in selection of specific reagents and test kits.

5.16 Specimen collection, referral and transportation

Public health laboratories at peripheral sites in the network will generally have a more limited test menu. Laboratories must have trained staff to collect and package specimens and transport them to the next level of a tiered network for testing, without compromising the quality of the specimens or integrity of the packaging and safety of transport staff and environment.

The network of public health laboratories at all levels should be provided training for packaging and transport of specimens. In addition, a mechanism for monitoring and evaluation of sample referral across the public health laboratory network should be in place.

5.17 Laboratory safety and waste management

Public health laboratories need to ensure that adequate and appropriate safety measures are applied in all practices. Laboratory safety procedures should be developed in alignment with national health and safety guidelines, and infection control policies. A national policy and regulations on laboratory safety and waste management should align with national and international occupational safety and health (OSH) and environmental standards. It should address the following:

• hazard recognition, evaluation and control
• workplace design and engineering
• training and orientation
• safety performance management
• emergency management
• hazardous waste management
• occupational health
• biosecurity.

5.18 Research and development

Research is needed to continually improve national policy, the functions and quality of the public health laboratory system, and to address emerging health challenges. Research in public health laboratories may include evaluation and implementation of new technologies and analytical methodologies to ensure the provision of state-of-the-art, cost-effective and timely analytical and diagnostic services in support of the nation’s health-care communities.
Test being performed in a public health laboratory
(Source: Public health laboratory, Bhutan)
Every Member State requires an effective laboratory network to address and combat emerging and re-emerging threats in order to safeguard the health of its population. Towards this end, an accurate, reliable and timely laboratory analyses is vital to identify, study and limit adverse events. Defining the role of public health laboratories at every level of health care service delivery is therefore crucial. This in turn will provide the basis for assessing and improving quality in laboratory functioning and will enable fixing performance standards in line with international best practices. Public health requirements are evolving with changes in the disease landscape and dynamics; consequently, laboratories must ensure continuous quality improvements in testing and surveillance activities.

6.1 Key functions

Periodic reviews of the functions, responsibilities and capacities of public health laboratories will facilitate better management of health challenges. The key functions of the public health laboratory are described in detail in Chapter 2.

6.2 Tests carried out at various levels of public health laboratories

It is important for Member States to define the number of levels in the public health laboratory network and the type of tests and services to be offered by the laboratories at every level. Typically, the levels in the public health laboratory network may vary from three to five depending on the country’s needs and population. While doing so, national priorities should be taken into account with due consideration to the requirement and the resources (finances, infrastructure and manpower) available. Further, the disease landscape and epidemiology prevalent within each country and the
Establishment of Public Health Laboratories in South East Asia

A broad outline for tests that may be performed at various levels is provided in Table 6.1.

### Table 6.1. Tests suggested for public health laboratories at various levels*

<table>
<thead>
<tr>
<th>Level of public health laboratory</th>
<th>Tests suggested</th>
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</table>
| Level I  
Peripheral public health laboratory | • Haemoglobin  
• HIV Rapid Test (HIV1/2)  
• Malaria/Blood Parasite Smear  
• Malaria rapid diagnostic Tests  
• Syphilis rapid diagnostic Tests  
• Sputum smear for tuberculosis (TB) Urine dipstick for sugar and protein Specimen collection for referral to higher tier laboratories |
| Level II  
District public health laboratory | In addition to all the tests carried out at Level I, the following tests will be done at the district public health laboratory:  
• cholera and other enteric pathogens (culture and sensitivity, serotyping)  
• typhoid: blood culture and antimicrobial sensitivity (including isolate confirmation with specific antisera)  
• bacterial meningitis (rapid latex agglutination test)  
• cerebrospinal fluid (CSF) examination (wet mount, gram stain and culture and antimicrobial sensitivity)  
• Hepatitis A virus & Hepatitis E virus-IgM ELISA  
• measles-IgM ELISA  
• dengue-IgM and NS1 ELISA  
• leptospirosis-ELISA/Rapid test  
• diphtheria smear examination, culture and toxigenecity testing)  
• ELISA for Chikungunya virus, Japanese encephalitis virus  
• any other tests for locally prevalent epidemic prone disease (to be identified by the state)  
• complete blood count (CBC) with automated differential  
• Basic Chemistry Panel with ALT and creatinine  
• CSF/body fluid and urine microscopy  
• Cryptococcus Antigen and/or India Ink  
• Water quality and test for faecal contamination of water |
<table>
<thead>
<tr>
<th>Level of public health laboratory</th>
<th>Tests suggested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level III State public health laboratory</td>
<td>In addition to all tests carried out at Level II, the state public health laboratory may carry out the following tests (smear, stains, special stains, culture and sensitivity, serotyping, strain typing, PCR):</td>
</tr>
</tbody>
</table>

**Bacterial infections**
- Bacillus anthracis (s, C, PCR)
- Brucella (S, C, sero, PCR)
- Cholera (wet mount, Cul, AST, serotyping)
- Diphtheria (smear, culture, toxin detection, strain typing)
- Leptospira interrogans (sp stain, RDT, Culture, MAT, IFA),
- Tests for antimicrobial resistance (AMR)
- IgM ELISA, PCR
- Neisseria/Haemophilus
- Pneumoccus/Streptococcus
- Pertussis
- Shigella/Salmonella/E.coli
- Syphilis
- TB
- Rickettsia
- Yersinia spp.

**Viral infections**
- Avian influenza
- Chikungunya
- Dengue
- Hepatitis (A, B, C, E)
- HIV
- Human seasonal influenza
- JE
- Measles/rubella
- Rotavirus
- West Nile fever

**Parasitological/fungal infections**
- Leishmania
- Cryptococcus
- Malaria
- Screening for immune status
- Participate in risk factor surveillance for NCDs
- Outbreak investigation

**Other functions**
- Screening for immune status
- Participate in risk factor surveillance for NCDs
- Outbreak investigation
<table>
<thead>
<tr>
<th><strong>Level of public health laboratory</strong></th>
<th><strong>Tests suggested</strong></th>
</tr>
</thead>
</table>
| **Level IV**                         | In addition to the tests performed at Level III, the following tests may also be carried out:  
Regional/provincial public health laboratory |  
- testing for environmental contaminants  
- food safety testing (assays to detect organisms such as E. coli 0157, Campylobacter, Staphylococcus, Salmonella, Shigella, Vibrio, Listeria, Clostridium botulinum and Clostridium perfringens)  
- preparation of standard material for testing and manuals  
- referral laboratory in the national surveillance programme – quality check  
- distribution of reagents to the linked laboratories  
- coordinate, supervise and provide technical guidance to the linked laboratories in the region  
- train laboratory personnel |

| **Level V**                          | In addition to all tests being performed at Level IV, the following may also be carried out:  
Disease-based national reference laboratory/national public health laboratory |  
- isolation of viruses from clinical samples  
- characterization of the strains/isolates (serotyping/identification)  
- maintain repository of standard strains and reagents  
- production of diagnostic antisera / reagents  
- standardization of procedures  
- quality assurance for linked laboratories  
- operational research  
- participate in international EQAS  
- ISO 15189 accreditation |

* The levels in the public health laboratory network as well as the choice of tests to be performed at different levels shall be determined by individual Member States according to their priorities, needs and population.

Public health laboratories represent a range of testing capabilities (Table 6.1). A peripheral laboratory could perform point-of-care testing for diagnosis, while a large laboratory could provide comprehensive testing services (e.g. clinical, environmental, water, and food testing). Public health laboratory (refer to Chapter 2 for details) functions focus on issues of public interest, specifically:
• infectious diseases
• public supplies of water, milk and food
• sewage disposal
• the production of vaccine, antitoxic sera and anti-rabies treatment
• education of the public regarding health and disease.

The ultimate purpose of testing is the protection of those who are healthy. The purpose of a public health laboratory is not to suggest extraordinary treatment measures, but, rather, to provide information on appropriate precautions that need to be taken to prevent the spread of diseases.
A typical workstation in a microbiology laboratory
(Source: NIMHANS, India)
A public health laboratory provides diagnostic and public health-care services. It is an essential and integral component of a comprehensive health-care system for all Member States.

**Fig. 7.1. Role of a public health laboratory**

The role of a public health laboratory is wide-ranging and includes laboratory services for disease surveillance, diagnosis, prevention, treatment and health promotion (Fig. 7.1). Other roles include guiding the standards of training of personnel to be deployed in laboratories; standardization of equipment, reagents and consumables; and, quality control of testing procedures and...
results. In order to perform these roles, the laboratory is expected to achieve and maintain certain minimum standards. Following are key considerations: laboratory premises; laboratory staff; the policies that guide operations; the equipment used and the level of competency in the use of the equipment; mechanisms for the communication of test results; the availability of financial resources. It must be stated that all Member States should have written policies to guide and regulate laboratory operations depending on local priorities as well as the resources available. Member States must evolve a comprehensive policy on laboratories that addresses all relevant requirements to enable the performance of minimum functions. The policies should describe the laboratory administration organogram, and recommend the physical infrastructure, human resource and equipment requirements for all levels of the laboratory pyramid, from health centres to national reference laboratories. Further, the policies should also address quality assurance, information management, health and safety practices, and infection control. Finally, policy implementation should be guided by clearly defined strategic implementation or business plans.

The essential requirements for the proper functioning of a public health laboratory can be broadly classified under the following heads:

- laboratory management
- physical infrastructure
- human resource
- equipment
- sample collection and storage
- quality control and quality assurance
- supply chain management
- information management
- biosafety
- shipment of samples
- coordination with the national programme and field staff.

### 7.1 Laboratory management

All public health laboratories should have a well-defined quality policy, along with clearly defined management structure, roles and responsibilities of all the staff, lines of authority, quality system procedures, training plans, competency assessments, staff vaccination records, biosafety manual and waste management plans. These should be reviewed periodically.

### 7.2 Physical infrastructure

The premises housing a public health laboratory should meet certain minimum standards. The laboratory premises will vary in size and the
structural requirements will be determined by the functions of the laboratory. Guidelines for the design and specifications of the physical structure of laboratories have been published by many authorities, including the National Institutes of Health (NIH) in the United States of America (USA) and WHO. These guidelines vary according to the levels of biological safety and physical containment that are required. It is desirable that all Member States invest in BSL-3 facilities at appropriate levels in order to meet the increasing demand in testing for emerging and re-emerging microbial threats. In order to meet the minimum standards for national reference laboratories, Member States must ensure that:

- laboratory buildings are constructed from stable materials and meet fire safety standards;
- working surfaces of laboratory benches are made of appropriate materials that are impervious to water and resistant to acid, alkali, organic solvents and moderate heat;
- laboratory buildings have adequate equipment (including fridges, freezers and cold rooms, and cryostorage facilities);
- the floor plan is designed to allow unhindered workflow;
- there is adequate natural lighting and ventilation;
- there is adequate room for patient reception, phlebotomy and testing;
- separate staff dining areas are provided, with controlled access depending on the services provided;
- back-up electricity generators are available;
- there is adequate provision for public health functions (including surveillance, quality management and training);
- adequate storage space for reagents and consumables is provided;
- an adequate communication system is provided in line with the needs and size of the laboratory (telephones, intercom, pagers, computers, internet, fax).

7.3 Human resource

The human resource component of public health laboratories is determined by the size and operations of the facility. Administrative, technical and specialized human resources should be included in the organogram. Diagnostic services should be provided by the well qualified technical staff in the respective disciplines. Member States should have laboratory human resource policies in place. As outlined in Chapter 8, Member States must ensure the following:
human resource policies and the staffing norms must accommodate technical (technicians, technologists, scientists, pathologists, microbiologists) as well as non-technical, laboratory personnel;

human resource policies must accurately describe the qualifications expected of laboratory personnel, and recommend capacity building mechanisms to ensure that candidates achieve the required qualifications;

staff retention policies are developed and implemented, and that these address remuneration discrepancies (thus helping reduce the brain drain);

facilities for basic and post-basic training of technicians or technologists are established or strengthened and that the number of consultants is increased;

defined and structured career development pathways are charted in order to upgrade the qualifications and competencies of current personnel;

methods are developed to create synergies between public health laboratories and academic, research or private institution staff in Member States and to leverage those complementarities.

7.4 Equipment

The provision of diagnostic and public health laboratories is dependent on the availability of necessary laboratory equipment. Member States must ensure the following:

- the equipment is available in adequate quantities and meets quality standards;
- there are mechanisms in place to service the equipment. (The current practice of engaging biomedical engineers who specialize in hospital equipment may not be ideal in view of the complexity of modern laboratory equipment. Lack of skilled staff and high workloads are associated with inordinate delays in equipment servicing. This, however, can be addressed through a review of acquisition practices to incorporate service contracts.);
- implementation of additional capacity to train laboratory equipment maintenance engineers and technicians;
- modalities for the servicing of biosafety cabinets, microscopes and pipettes are in place;
- an adequate budget to cover requisite reagents and consumables if the equipment is to be kept operational throughout the budget cycles.
7.5 Sample collection and storage

Sample collection and storage is a core function of public health laboratories and it is therefore essential that Member States evolve a comprehensive policy on sample collection procedures, sample storage and retention time. The essential requirements for sample collection and storage should encompass the following aspects:

- list of samples to be collected for investigation
- records of sample collection
- sample collection procedures outlined in a sample collection manual
- transport requirements for the sample before it reaches the testing laboratory
- sample storage condition before and after testing
- sample retention time
- sample inventory maintenance

7.6 Quality control and quality assurance requirements

Laboratory testing in any public health laboratory is incomplete unless adequate emphasis is given to quality control (QC) and quality assurance (QA) requirements. Furthermore, QC and QA are two crucial parameters that enable an objective evaluation of the performance of a laboratory. Member States should evolve a comprehensive document outlining QC and QA standards for their own laboratories depending on the level and functions of the public health laboratory. The essential requirements for QC and QA are provided below.

Essential QC requirements

- assay and equipment calibration
- ensuring availability of standard operating procedures (SOPs)
- availability of documents and records such as assay worksheets, validity of tests performed, kit used, expiry dates of reagents and kits, whether positive and negative controls were used for the assay, whether test results were released after supervision by qualified personnel, whether test result records are filed and retrievable.

Essential QA requirements

- regular participation in proficiency testing
- corrective actions if proficiency testing scores are not satisfactory
- a proportion of samples tested to be sent to a referral laboratory for verification of test results.
Accreditation

All public health laboratories must be encouraged to seek external accreditation. The process for accreditation will provide the public health laboratory opportunities to:

- identify areas for improvement in their performance
- enhance management and leadership skills
- review roles and responsibilities
- implement quality standards in the laboratory.

7.7 Supply chain management

Procurement and supply management is another key component of laboratory services that requires appropriate capacity. The selection of laboratory tests and methods (as outlined in the national laboratory plan) should correctly reflect the country’s capacity to manage the supply chain. Procurement decisions should be based on the quality of supplies and equipment, e.g. pre-validation, expiry dates and shelf life. Supply decisions should take into account issues such as centralized or decentralized purchasing and bulk or small purchases. These decisions also apply to donated equipment and supplies. Decisions on procurement and supply management cannot be overruled without adequate consultation between suppliers and end users. Expected standards and approaches to building capacity in procurement and supply management can be outlined in the national laboratory plan using WHO guidelines where applicable.

The key considerations for supply chain management are:

- selection and standardization of reagents, test kits, controls, calibrators, chemicals and consumables based on specifications appropriate for each tier of public health laboratories, taking into consideration equipment, test methods, costs, availability, shelf life and storage conditions;
- utilization of pre-qualification guidance provided by international organizations in selection of specific reagents and test kits;
- establishment of a national procurement unit or a technical working group with a procurement and supplies management system guided by national protocols, policies, procedures and checklists, addressing: quantification; supply planning; selection/qualification of vendors; procurement procedures; storage and distribution; pre- and post-market quality monitoring; inventory management at both central and local levels; pipeline monitoring; supervision and evaluation; accurate annual or biannual national forecasting of laboratory commodities; redistribution of surplus reagents and chemicals, disposal of expired reagents/kits.
• establishment of a laboratory logistics management system for supplies;
• establishment of a regulatory mechanism for inspecting and approving suppliers of laboratory commodities; identification of qualified, competent laboratories as national centres for independent quality assurance and pre-qualification of consumables and reagents;
• establishment of a fair and transparent tender system for bulk procurement to minimize costs;
• establishment of a dedicated budget at the central level for the purchase and supply of laboratory commodities, and,
• establishment of national guidelines for the acceptance of donated laboratory supplies to ensure that they meet the required specifications and are appropriate for the laboratory.

7.8 Information management

The management of information should be integral to the provision of public health laboratory services. Member States should strengthen their capacity to collate accurate and complete data in order to improve disease management and allocate adequate human, material and financial resources towards this end. Member States should, therefore, ensure that:

• information management guidelines are incorporated in laboratory policies;
• adequate budgets are allocated to provide information management logistics; and
• electronic information management systems are established to improve data accuracy and expedite information sharing.

7.9 Biosafety

Public health laboratory management is responsible for the safety of all employees and visitors to the laboratory. The primary responsibility shall rest with the laboratory director, although individual staff members must follow documented safety procedures to ensure both personal and institutional safety.

• A safety officer may be appointed to assist the laboratory director in overseeing laboratory safety, giving advice to the management and assisting in the design and maintenance of the safety programme. If warranted, a safety committee with well-defined terms of reference should be set up.
• A programme shall be in place, with regular monitoring and review, to ensure a safe work environment and safe work practices in the laboratory, encompassing the following elements:
• provision for training to promote appropriate safety measures
• implementation of practices in accordance with the safety manual
• management of accidents and incidents
• management of staff health
• monitoring of safety systems
• maintenance of various safety records.

• A biological waste management programme should be established, which includes cleaning, disinfection, sterilization, segregation and disposal of sharps and contaminated material. Standard procedures for the safe disposal of chemicals and supplies must also be put in place; the disposal of laboratory waste must be in accordance with national environmental protection regulations and staff training.

7.10 Transportation of samples

The transportation of infectious and potentially infectious materials is subject to strict national and international regulations. These regulations call for the proper use of packaging materials, as well as other shipping requirements, in accordance with the basic triple packaging system (Fig. 7.2). The public health laboratory should have mechanisms, human resources and a budget to enable the transportation of samples within and between Member States.

![Fig. 7.2. Triple packaging system for transportation of samples](image)
Key considerations with regard to the transportation of samples are:

- developing a plan for the packaging and shipping of infectious and potentially biohazardous substances/specimens, which includes the determination, documentation and dissemination of applicable international (International Air Transport Association or IATA), national, local and shipping company requirements;
- developing the process and detailing the instructions for the safe collection and transportation of samples to another laboratory;
- communicating laboratory reports back to the originating facility or to the public health authorities in a timely manner;
- adequate transportation systems covering all necessary routes need to be defined; other existing logistics systems within the laboratory network, broader health system or private sector should be explored.
- adequate tracking and chain of custody systems must exist along with standard operating procedures for all specimens being referred;
- training programmes for all the staff involved in packaging and shipping processes must be conducted and must include instructions on completing the Shipper’s Declaration;
- resources must be allocated for the collection, packaging and transportation of specimens and communication of test reports.

### 7.11 Coordination with the national programme and field staff

At present, some Member States have disease-/programme-specific laboratories that primarily provide diagnostic services. Unfortunately, there is often weak collaboration between the laboratory components of these programmes and other laboratories (e.g. national referral laboratories, clinic- and hospital-based laboratories, private laboratories). Global financing instruments and disease-specific bilateral projects have increased the “verticality” of some laboratory systems, thus contributing to their fragmentation. Each has its own budget, human resources, procurement and supply chain, information network and technical programme, which often leads to duplication of efforts, omission of locally required essential components and waste of resources. The aim is to ensure that all laboratories can work together in an effective, practical and functional way, with clear patterns for referral, confirmation of certain types of results, and efficient provision of supplies and procurement.

Public health laboratories should strive to collaborate with laboratories in other sectors such as animal health, agriculture, environment and human health. This would ensure fulfilling the goal of “One Health approach” by providing surge capacity and a coordinated response to human communicable diseases.
The expertise available with specialized laboratories supporting vertical disease programmes (e.g. TB, HIV/AIDS) should be harnessed to support public health laboratories in the country. One of the roles of the national focal point for public health laboratories would be to explicitly define both the vertical (between levels) and horizontal (across programmes) connections between health laboratory services to strengthen the network. Even when laboratories remain separate, functional integration can improve efficiency, quality and health outcomes. In many settings, improved information technology, such as the internet and mobile phones, can make this functional integration more feasible.

In order to help Member States evaluate their public health laboratories in an objective manner, as well as to monitor improvements in their performance, a simplified checklist can be used to assess the functioning of laboratories. This simplified checklist is given in Annex 1 to this document and covers the essential requirements required for assessing the status of public health laboratories.
Laboratory personnel working inside a BSL-3 laboratory
(Source: National public health laboratory, Nepal)
WHO has defined the six building blocks of a public health system, one of which is the health workforce (Fig. 8.1). Health in a community is largely dependent on access to preventive and curative services, as well as public health services such as monitoring quality of air and water, environmental sanitation and nutrition. Towards this end, the health sector depends on people to carry out its mission. Outcomes and achievements are directly related to the human resource density in this sector. Adequate and skilled human resources – health professionals, technicians and support staff – are required for implementation of increasing number of health programmes, preventive and promotive interventions, and confronting existing and emerging public health challenges.

**Fig. 8.1. WHO Health Systems Framework: the six building blocks of a health system**

*Establishment of Public Health Laboratories in South East Asia*
Public health laboratories play a vital role in disease surveillance and response. Over time, with increasing health demands and changing disease dynamics, the functions of these laboratories have evolved, requiring a specialized workforce. Public health laboratory personnel now include specialists with knowledge of one or more scientific disciplines, with basic and advanced skills in laboratory practice. The professional cadres include public health medical officers, scientists, scientific officers and laboratory technicians with specialization in microbiology, clinical pathology, biochemistry, life sciences and laboratory medical technology. This workforce provides clinical diagnostic testing, disease surveillance, environmental testing and emergency response support, and also executes a wide range of functions to support national public health demands. The availability of a full-time epidemiologist on the staff of the state/provincial laboratory ensures close cooperation and coordination between the public health and clinical medical laboratory network in the region.

Public health laboratory training is not developed as specialized training in the South-East Asia (SEA) Region. Most laboratory courses are designed with a focus on diagnostics and are neglectful of public health aspects while studying diseases and pathogens. Short-term training programmes exist in some countries for specific diseases, however, the need to integrate these to provide a broader understanding of public health is necessary.

The roles of local public health laboratories in supporting state health departments vary according to the size of the community served, the relationship with the state public health department and the community’s needs. The projections for laboratory manpower should ensure that the different categories of public health laboratory staff are in adequate numbers to fill vacant positions and make up for loss of staff either through attrition or retirement and also meet the potential for future expansion. The following should be considered when projecting the need for laboratory staffing:

- total number of public health laboratories in the country/state
- core functions of the laboratories at various levels
- workload
- future developments and expansion of laboratories
- loss due to retirement or other reasons.

The number and cadre of staff required to meet the demands of each tier of the public health laboratory need to be defined for:

- laboratory technologists, phlebotomists and medical officers;
- non-laboratory cadres including equipment maintenance engineers, information technologists and data managers.
It is also essential to ensure the development of appropriate cadres of service providers and distribute them according to the workload as well as equity and geographical access. The laboratory need for staff training and continuing education should be identified and periodically addressed. This will allow laboratory staff to be abreast with available technologies.

Human resource management is gaining a lot of attention as emergency response strategies advance and require highly skilled and cross-trained staff dedicated to the public health laboratory mission. To sustain excellence in laboratory performance and ensure continuous improvements, long-term and quality employees are essential.

The success of the laboratory regardless of the design depends upon its human resource (Fig. 8.2). Qualified, trained and motivated personnel are the backbone of the quality management system (QMS) in the laboratory. The laboratory policy recognizes that human resource management skills are critical to the public health system. The human resource development action plan must be developed and should incorporate certain aspects (discussed ahead) for strengthening the performance of public health laboratories.

8.1 Education and capacity development

This component should address the following issues:

- To build capacity and skills development of the laboratory workforce, countries should upgrade and strengthen medical laboratory training institutions by providing resources (qualified teachers, equipment and supplies) to meet the minimum standards.
- The curriculum of laboratory medicine and technology courses in the country should be reviewed periodically to ensure alignment with national needs and advanced technologies.
• Training programmes should be reviewed and updated for their content to include public health laboratory training, emerging diseases, newer technologies, laboratory quality management systems and advances in biomedical sciences in alignment with national needs.
• The country should encourage and support the establishment of graduate and postgraduate programmes in public health and biomedical sciences.
• In-service short-term courses can also serve to sensitize the staff on public health perspectives.

8.2 Human resource plan and improvement in management

Following are the essential features of human resource planning and bringing about improvement in management:

• A human resource development plan for laboratory staff should be prepared in alignment with the national human resource plan for health workers.
• The human resource development plan should focus on continuous professional development.
• An electronic database of the laboratory workforce should be prepared.
• Foreseeing of necessary laboratory personnel should be predicted and required budgets, teaching programmes and resource development included in annual planning.
• A laboratory career structure and promotion opportunities for continuing education to support the implementation of laboratory standards and policies need to be in place.
• Skill levels of testing personnel must be in conformance with the complexity of instrumentation and methods in use at each tier of the public health laboratory.
• Periodic competency assessments of staff must be carried out to verify individual demonstration of necessary skills, knowledge and correct work practices (in areas including quality processes, safety, procurement and supply management, and reporting of results).
• Annual performance appraisals by the immediate supervisor, using a standard appraisal tool to provide feedback to individual staff on work performance and to guide career development, must be conducted.
• There must be a staff record of each laboratory worker. It must include personal and employment details, resume, posts held and
dates, authorized areas of testing, terms and conditions of employment, job description, continuing professional development, competency assessments, disciplinary actions, vaccination and work injury records.

- Induction training, on-site training, e-learning and continuous professional development should be ensured as part of the human resource development plan for laboratory staff.
- A code of professional ethics in laboratory practice, including observing patient and information confidentiality, needs to be emphasized.
- Oversea training for motivated and meritorious candidates needs to be encouraged to ensure career satisfaction.
- Identification of champion laboratory personnel should be encouraged and they should be provided additional training on laboratory management to create a pool of master trainers. Such a pool could in turn train personnel at different levels of the laboratory network.
- Provide the required technical and administrative oversight of the laboratory network by developing effective supervisory systems to monitor work performance and quality using a structured checklist. Supervision should be of sufficient duration and frequency and include on-site evaluation, teaching, mentoring, monitoring, quality assurance and supportive feedback.
- Efforts should be made to facilitate a review of staff remunerations and incentives to ensure professional and personal satisfaction for better retention of health personnel at all levels of laboratory services.
- Review/revise job descriptions of laboratory staff to include the quality component and performance management.
- Evaluate training needs and develop a training plan for all categories of staff which would include:
  - leadership management
  - quality management training
  - testing
  - information management.
- Training must be provided to laboratory personnel to address the increasing sophistication of diagnostic procedures (Fig. 8.3). Skilled biomedical engineering support within the country is essential as there has been a rapid change in diagnostic technology with an increasing number of automated and sophisticated laboratory equipment that requires training of biomedical engineering personnel for preventive maintenance and small repairs.

Establishment of Public Health Laboratories in South East Asia
8.3 Certification

The health department should ensure the certification of public health laboratory personnel and encourage their enrolment in professional laboratory associations. All medical laboratory professionals need to be registered and certified by a body authorized by the Member States. National and regional public health laboratories should be represented at all meetings for the planning and development of health sector budgets and policy-making to foster ownership in the programmes.

In summary, capacity-building initiatives for public health laboratories acquired increased significance since the introduction of the International Health Regulations (2005) (1). Article 5 of the regulations specifies that all countries be able to detect, assess, notify and report on public health issues of international importance. To achieve this, capacity building of public health laboratory manpower is of paramount importance.
Inter-sectoral networking meeting in progress at Yangon, Myanmar (Source: NIMHANS, India)
Public health laboratories provide their services to the entire country. Not all laboratory investigations can be available at every facility or at every level of the health system. No single institution and no developing country has all the capacity to provide comprehensive services to support efficient public health actions. Interdependence and collaboration with different institutions/laboratories is thus essential. This is the essence of a network.

A network is a type of partnership of like-minded institutes undertaking interdependent activities to deliver high quality products or services in an area of common interest, e.g. public health services. The structure of a network is flexible and roles are loosely defined.

For a public health laboratory network, it can be a combination of formal arrangements between government-funded laboratories, supplemented by informal arrangements with laboratories outside the government-owned health sector.

9.1 Goal of networking

The primary goal of a network of public health laboratories is to provide strategic advice. The network also provides technical support for diagnosis and sharing of expertise for the efficient implementation of public health actions and strategies against communicable diseases.

9.2 Types of laboratory networks

The laboratory networks can be of two broad types: geographic networks and disease-specific networks. Some of the examples are as follows (Table 9.1):
### Table 9.1: Types of laboratory networks

<table>
<thead>
<tr>
<th>Geographic networks</th>
<th>Disease-specific global networks</th>
</tr>
</thead>
<tbody>
<tr>
<td>National lab networks</td>
<td>Vaccine preventable disease networks</td>
</tr>
<tr>
<td>Subregional lab networks</td>
<td>Poliomyelitis</td>
</tr>
<tr>
<td>Regional lab networks</td>
<td>Measles</td>
</tr>
<tr>
<td>Global lab networks</td>
<td>Influenza (Global Influenza Surveillance and Response System)</td>
</tr>
<tr>
<td></td>
<td>Rabies</td>
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<tr>
<td></td>
<td>Salmonellosis</td>
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<tr>
<td></td>
<td>Antimicrobial resistance (Global Antimicrobial Resistance Surveillance System – GLASS)</td>
</tr>
</tbody>
</table>

International agencies like WHO, Food and Agriculture Organization (FAO), World Organisation for Animal Health (OIE) have been coordinating several global/international disease-specific networks of public health laboratories with substantial and sustained contribution to global health. The Global Influenza Surveillance and Response System (GISRS) is the oldest disease-specific network in the world that has been detecting novel influenza viruses, generating information on composition of influenza vaccines, understanding the emergence of antiviral resistance in influenza viruses and enhancing capacity of developing countries in diagnosing influenza and undertaking its surveillance.

WHO has designated several institutions of excellence as WHO collaborating centres (CCs). Many of these are laboratory based and have the mandate to provide referral, training or research support to all Member States. These WHO CCs provide excellent technical support to countries in accordance with their terms of reference.

### 9.3 Functions of a laboratory network

Although a public health laboratory network performs all the functions described in Chapter 2, given below are the expected outcomes of a functional network in the context of communicable diseases.

- provision of referral and diagnostic services along with characterization of pathogens;
- information collation, analyses and dissemination in a transparent number;
- exchange and sharing of clinical samples, pathogens and other biological material;
• knowledge creation through analysis and research;
• capacity building, especially of peripheral and intermediate laboratories, to facilitate generation of reliable results;
• development of new tools/interventions and their evaluation;
• provision of surge capacity as and when needed.

9.4 Requirements of a laboratory network

The most important interlinked requirements for any successful network are its sustainability and availability of adequate financial support. In addition, laboratory networks should have the willingness of its members to participate in it and contribute towards the overall goal of the network. Mapping expertise and infrastructure available with each member should be done and made accessible to everyone to make use of, as and when needed. The members of the network should also be keen, willing and ready to cope with additional workload from partners, especially during outbreaks of new, emerging or re-emerging infections.

9.5 Prerequisites for establishing a laboratory network

Several factors influence the establishment and management of public health laboratories in developing countries. Some of these are:

• Technical
• Administrative
• Legal
• Ethical
• Behavioural
• Financial

Technical expertise according to the mandate of the laboratory depending upon its location and position within the network, administrative approval from its top management to support it financially on a sustainable basis to perform the mandated tasks, compliance with local regulations and laws, operating in a transparent and ethical way with a keen desire to support national public health activities, all of these are salient factors that influence the outcome of support from a laboratory network. It is hence essential that all these factors are addressed before the network becomes operational.

An organized network ensures that complex test methods are referred to the appropriate level. The transport of specimens or referral of patients is usually more cost-effective than developing sophisticated capacity in every facility. Every laboratory service should know where it stands within the national or regional laboratory network, and to whom to refer specimens or patients for different specialized investigations. A formalized
network facilitates the exchange of knowledge and expertise among experienced laboratory specialists and practitioners, thus facilitating timely and appropriate laboratory support for patient management, surveillance, disease prevention and control.

The aim is to ensure that all laboratories can work together in an effective, practical and functional way, with clear patterns for referral, confirmation of certain types of results, and efficient provision of supplies and procurement. The expertise available with the specialized laboratories supporting the vertical disease programmes (e.g. TB, HIV/AIDS) should be harnessed to support other laboratories in the country.

9.6 Composition of a national public health laboratory network

A national public health laboratory network is primarily composed of laboratories at each level of the national health system (peripheral/district, intermediate/provincial and central/national) that are mandated to perform the functions of public health laboratories as elaborated in Chapter 2. Within the network are communication channels for exchange of information, formal and informal ways to interact and sharing of biological material according to the agreed mechanism.

Many other laboratories in any country (viz. those of the animal health sector, environment, academia, private sector, research institutes) may also have competence, infrastructure and the mandate to undertake work that can influence public health. These laboratories can also be linked to the national public health laboratory network.

The national laboratory network may also communicate and interact as necessary with subregional, regional and international networks. The national public health laboratory or any other national laboratory with expertise in a specific area may also become part of an international network to contribute to global public health and health security.

9.7 A step-wise approach to establishing a national laboratory network

Several leading institutions and experts have suggested following a step-wise approach to establishing a national laboratory network. The process should include the following steps:

1. Advocate with national policy-makers the need for a network of public health laboratories and its potential benefits to the main task of supporting the public health response to emerging, re-emerging and new infectious diseases.

2. Designate a national focal point or assign this task to the national laboratory manager. Provide him with sufficient administrative and
technical support in the form of human resources and access to adequate finances.

3. Define the vision, mission, goal, objectives, strategic activities and composition of this laboratory network. Obtain administrative approval from competent authorities.

4. Develop a broad operational plan to establish the network with clear milestones, targets and indicators.

5. Convene meeting(s) of proposed members, orient them and seek their ownership through extensive consultation and dialogue. Repeat the process till everyone is on board.

6. Undertake a situation analyses and need assessment of each proposed member of the network. Identify the mechanism to meet their needs and ensure smooth operations on long-term basis.

7. Initiate network operations with a smaller number of members. With the passage of time, increase the membership and widen the scope of activities.

8. Organize training courses for different categories of laboratory staff and certify their competence in technical, quality management and communication areas as well as in the shipment of infectious materials according to current international norms and practices.

9. Organize or facilitate participation of all members of the network in a national External Quality Assessment Scheme (NEQAS).

10. Institute a system for regular two-way information exchange. If feasible, organize face-to-face meetings at least once a year.

11. Document the activities undertaken by the network and share these extensively, especially with policy-makers and public health professionals to sustain its relevance.

12. Undertake an annual review of operations of the network, identify gaps and take steps to strengthen both infrastructure and capacity of the members of the laboratory network.

The establishment and operationalization of a laboratory network can multiply manyfold the efforts of an individual laboratory and provide comprehensive as well as critical support to national public health efforts in combating new, emerging and re-emerging diseases. It must be kept in mind, however, that a network is only as strong as individual members. It is therefore essential that all laboratories in the network should be strengthened to fulfil their individual mandates as well as the mandate of the network.
Elements of data management for a public health laboratory

(Source: NIMHANS, India)
Public health Laboratories are key stakeholders in providing critical data to local, state and national health agencies to investigate individual cases of communicable and noncommunicable diseases, as well as to characterize and mitigate population-based public health threats. In addition, public health laboratories provide specialized testing surveillance and surge capacity during disasters. Therefore, these laboratories need to be supported by a robust data management system that can provide quality and timely information to:

- support appropriate patient information
- support laboratory management
- contribute to disease surveillance, prevention and control on a broader scale.

10.1 Importance of data management in public health laboratories:

Data management is crucial in improving the operational efficiency of public health laboratories. It provides the direction on how data is collected, stored, analysed and disseminated. Incorporating standardized procedures for management of laboratory data facilitates preparation of reports, presentations and publications, helps in sharing of scientific information amongst different networks, and promotes data security. More importantly, it minimizes the risk of error and duplication of work. Good data management will enable public health laboratories to organize and ensure the authenticity, reliability and completeness of the data and allow for a quick and convenient means for accessing data. A proper data management plan cannot always ensure that the data produced is of good quality; however, continuous monitoring and review of the data will. Consequently, it is essential to keep track of the changes in data patterns and keep the data management strategy updated in tune with the types...
of data being gathered. This is especially important in a public health laboratory set-up where data management deals with a large number of people. The absence of a proper data management strategy can not only compromise the quality of the public health laboratory but could also jeopardize the health outcome of communities.

10.2 Methods of data management currently available

Prior to the advancement in technology, laboratories relied upon the traditional method of data management using pen and paper and manually storing the data in its concrete form. This method of data management is very slow, erratic and time-consuming. The current modern technique of data management widely adopted is electronic data management that facilitates a more accurate and efficient technique for data processing. The Excel spreadsheet is among the most commonly used electronic data management tools within the context of public health. However, with the advancement in information technology, there is a substantial shift towards the health management information system/health informatics. The use of a laboratory management information system has significantly improved data entry, tracking and analysis, and also the dissemination of reports.

10.3 Information technology

Information technology (IT) is a key component of today’s state-of-the-art public health laboratory, being essential for data management and transfer. Health information technology (HIT), on the other hand, refers to the application of computerized information processing for the storage, retrieval, exchange and utilization of health-care information. HIT also involves the exchange of health information in an electronic environment. The use of HIT within the health-care industry is aimed at improving the quality of health-care delivery, minimizing errors, increasing administrative efficiencies, decreasing paperwork, improving accessibility of health data and ensuring data privacy and security since the data is being transmitted electronically. Utilization of information technology in the health-care industry is substantial and increasing with time, though it is not routinely practiced in the majority of health-care sectors. HIT has contributed to the development of strategic and efficient data management, from data entry to the analysis and dissemination of reports. It has helped improve the flow of data exchange with ease. From a public health perspective, where one is often subjected to deal with big complex data, it makes more sense to integrate HIT as a data management platform. It is essential to establish a robust IT system for data management and in doing so address the following questions:
• What technology will align with given architecture?
• What bidding processes are used by the state?
• Who are the vendors?

10.4 Laboratory information management system (LIMS)

Laboratory test results are a vital part of a patient’s health record and provide health-care professionals with data to support decision-making and case management at the point of care. The implementation of an appropriate laboratory information management system (LIMS) should therefore be considered by all Member States. LIMS is a software-based solution which supports the automation of a modern laboratory’s operations. The key features of LIMS can be broadly classified into project management, laboratory management, data reporting and quality assurance. Over the years, LIMS has evolved from simple sample tracking to an enterprise resource planning tool that manages multiple aspects of laboratory informatics. Since the public health laboratory’s requirements are rapidly evolving and different laboratories often have different needs, it is necessary to have a customized LIMS. One of the important needs for customization is the user interface of the system. In order for LIMS to improve productivity, an easy to use, specific front end needs to be provided. A user interface must be intuitive, flexible and robust. Specific screens for various parts of the system should be developed in LIMS thereby reflecting the specificity of the system’s domain.

Quite often, the laboratory information system (LIS) must interface with instruments as well as other national information systems. Integration of LIMS with the national surveillance system would facilitate early detection of an outbreak, unusual disease activity, and also help in periodic epidemiological disease surveys that could facilitate policy changes. Systematically engaging national public health institutions and centres of excellence, as well as private-sector laboratories, with national laboratory systems and integrated surveillances systems would enhance utilization of available laboratory and research capacities, and management of resources. This can be achieved partly by laying down guidelines for adopting LIMS in any laboratory. The first step would be to adopt a national guideline to develop LIMS in public health laboratories using predefined outputs that would help in uninterrupted, uniform integration with the national disease surveillance system. Subsequently, the same guidelines could also be applied to the private sector, thereby converging laboratory data to a uniform database which could be used for better public health management and action.
10.5 Software available

There are several data management software solutions to choose from. A few that are relevant to public health laboratories include the following: WinWedge, CloudLIMS Lite, Sample Manager LIMS™ and WHONET. WHONET is a free Windows-based database software developed for the management and analysis of microbiology laboratory data with a special focus on the analysis of antimicrobial susceptibility test results.

There are several agencies that provide assistance for procuring, installing and training public health laboratories in the use of software. The Association of Public Health Laboratories (APHL) is one such organization that assists resource-constrained countries to develop systems to capture and exchange laboratory data. It provides guidelines, toolkits and software provider report along with other resources for developing an efficient LIMS. This initiative is known as the Global Lab Information Management System Initiatives.

10.6 Challenges to data integration

The challenges faced in data integration include the following:

- absence of predefined output criteria;
- multiple specific disease surveillance systems in place which makes data integration to the designated disease surveillance system difficult;
- the scope of the majority of public health laboratories includes testing for multiple pathogens that may fall under different surveillance systems;
- coordinating among multiple agencies/institutions where automation systems may be defined for data security and sharing;
- working with different generations of LIMS or automation systems means the computer language used in the older generation computers may not be compatible with the newer ones thus hampering data integration; and,
- if the development of the user interface between LIMS and the automation system is not well defined, data integration is a challenge.

10.7 Use of data within the laboratory

Laboratory data, apart from giving information on the etiology of a disease, is also helpful in many other ways. Analysis and comparison of the data can aid quality assurance of the laboratory, intra- and inter-laboratory comparisons, and assessments of the equipment/personnel performance over a period of time. Data within the laboratory can also be used to
determine the circulating serotypes of pathogens, seasonal trends in the community, and time series analysis.

10.8 Dissemination of data

One of the major duties of the public health laboratory is to disseminate data to public health authorities, policy-makers and all stakeholders in a timely manner so that data on the disease prevalence can be consolidated and analysed, and appropriate public health action and policy changes can be made. Indeed, data dissemination is the cornerstone of rapid detection of potential outbreaks. Data flow should follow a hierarchy so that data duplication is avoided. In many countries, data dissemination on notifiable diseases is made mandatory by law for both public health laboratories and private laboratories. A hierarchical approach to data dissemination makes it easier for data analysis and interpretation which in turn can be shared with policy-makers and international agencies to bring about policy changes and newer guidelines/regulations for public health action.

10.9 Annual reports

The preparation and circulation of annual reports is among the key mechanisms available for disseminating the work carried out by a public health laboratory. The annual reports must be based on the guidelines issued by the respective Member States. These reports are the medium through which accurate scientific data is provided to support and guide public health surveillance and response system. Further, they offer insights into the activities of the laboratory as well as fiscal information. The status of ongoing activities and plans for the subsequent year are also elaborated in the reports. The annual reports contain sections on the data generated, its analysis and interpretation. Action taken, based on the data generated, is usually mentioned in the report. Often the public health laboratory function ceases at reporting of the data and further action is taken up by the concerned public health agency. In order to fulfil the criterion of true sense of surveillance, action based on the data is of utmost importance.

While preparing annual reports, the public health laboratory should ensure that the following key elements are incorporated in the report:

- vision
- mission
- goals and objectives
- core functions
- services
- staff and budget
- annual specimen testing volume and type of tests performed
• shared commitments/partnerships
• highlights and accomplishments
• opportunities and challenges
• strategic directions
• audited financial statement.

In summary, the need for robust data management systems for public health is growing because of new challenges related to antibiotic resistance, emerging infections, and chemical and biological terrorism. The confluence of improved information systems presents a unique opportunity to improve the efficiency and effectiveness of public health laboratories. It is in this context that the new and evolving discipline of public health informatics is being exploited for the benefit of the public’s health. This new discipline needs to be fostered by all Member States in order to retain the importance and relevance of public health laboratory data in the overall context of health care itself.
Establishment of Public Health Laboratories in South East Asia

Source: NIMHANS, India
Health laboratories provide cross-cutting support to all health programmes. Health laboratories are increasingly being recognized as a vital component of the public health team, as they provide wide-ranging laboratory expertise and services using state-of-the-art technologies. Chapter 2 describes the diverse functions that public health laboratories perform to protect and promote human health. One of the critical functions of public health laboratories is to promote, encourage, support and undertake basic research, operational research and translational research.

11.1 Research objectives of public health laboratories

Laboratories can contribute considerably to research in the following areas:

- to develop better strategies for disease control and prevention
- to develop and update disease management guidelines
- to evaluate different treatments for a disease
- to improve disease detection and response capabilities
- to develop health risk management policies
- to improve programme implementation and monitoring.

The potential of public health laboratories in undertaking quality research to improve public health services is yet to be fully realized and effectively explored in developing countries. There are still major gaps and limitations that hamper progress in this area.

11.2 Research gaps

All the components of the communicable diseases control programme benefit from efficient health laboratories. These components include early detection and confirmation of the etiology of outbreaks, monitoring the
trends and spread of infections, identification of new infectious agents or agents with novel characteristics, detection of agents of biological warfare/bioterrorism, verification of elimination and eradication of diseases, development and evaluation of new diagnostic tools/technologies, and environmental monitoring.

Laboratory diagnosis of almost all communicable diseases is done by isolation and identification of the causative agent, enzyme-linked immunosorbent assay (ELISA) or immunochromatographic assays, direct detection by immunofluorescence and/or identification through molecular biological tools, especially the polymerase chain reaction (PCR) test and nucleic acid characterization. While the equipment, physical infrastructure and competent human resource team to run these tests remain the same and are now widely available in select laboratories of Member States, disease-specific reagents or kits essential for confirming diagnoses are not easily available, especially for diseases that have a low prevalence in developed countries. Isolation of new organisms requires comprehensive genetic characterization and comparison with existing species.

At the peripheral level, where sophisticated laboratory infrastructure and expertise are not available, field-friendly tests can play a vital role in rapid diagnosis and early containment of a disease. Rapid diagnostic tests (RDTs) can make a considerable difference in managing an outbreak in developing countries. These are now becoming available for infections such as HIV, hepatitis B, influenza, dengue, malaria, Japanese encephalitis, etc. Most RDTs are still produced in developed countries and are expensive. Their ability to establish a reliable diagnosis also suffers because the antigens used in these RDTs are obtained from strains not prevalent in South-East Asia. For several emerging infectious diseases (EIDs), these are not available at all or those that are available have an unacceptable sensitivity or specificity. There is an urgent need to undertake research in developing countries in several areas so that solutions to locally prevalent problems can be designed, developed and disseminated locally.

11.3 Research potential of public health laboratories at different levels

It is an erroneous belief that research can be conducted only in highly sophisticated and modern laboratories. Research relating to public health can be undertaken even in the most peripheral areas of the country to solve public health issues faced by the local population. Even a peripheral (or district public health laboratory) can provide substantial support in improving the health of the people by undertaking research and providing solutions that are acceptable and applicable in a local context. As mentioned in

Establishment of Public Health Laboratories in South East Asia
Chapter 2, the research mandate varies amongst the different levels of public health laboratories (Table 11.1).

**Table 11.1. Research functions at different levels of public health laboratories**

<table>
<thead>
<tr>
<th>Research function</th>
<th>Central/national lab</th>
<th>Intermediate/provincial lab</th>
<th>Peripheral/district lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of new technologies</td>
<td>++++</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Evaluation of new technologies/reagents</td>
<td>++++</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Isolation/confirmation of new pathogens</td>
<td>++++</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Coordinate multicentric studies</td>
<td>++++</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Operational research</td>
<td>++++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Clinical and translational research</td>
<td>++++</td>
<td>++</td>
<td>–</td>
</tr>
<tr>
<td>Supply standard strains/isolates</td>
<td>++++</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

++++: Mandatory research function  
++: Essential research function  
+: Desirable research function

### 11.4 Priority research areas

#### 11.4.1 Enhancing the detection of causative agents

Advances in laboratory sciences have helped in identifying almost 40 new microorganisms in the past four decades. Without laboratory tools, the world would not have been able to identify many viruses such as human immunodeficiency virus (HIV), hepatitis C, severe acute respiratory syndrome (SARS), Middle East respiratory syndrome coronavirus (MERS-CoV), Nipah and many other viruses of public health importance. The continual discovery of new pathogens has highlighted that there may be a large number of organisms causing diseases in humans and animals which are yet to be discovered. These need to be identified to be able to respond to the potential challenges to public health they might pose in future.

Some life-threatening viruses are not detectable with current technologies during the early phase of an infection. These include HIV, hepatitis B and hepatitis C. Apart from the progression of a disease, the inability to detect
it may be a pitfall in blood safety and instituting curative treatments. Antibodies to HIV are usually detectable approximately 3–4 weeks after exposure using sensitive antibody immunoassays. Use of nucleic acid technology can reduce this window period significantly.

The window period for the hepatitis C virus (HCV) is greatly reduced using nucleic acid testing (NAT) methodology. HCV antibody assays have a window period of around 70 days, which can be reduced to 8–12 days using HCV NAT assays.

The window period for diagnosing hepatitis B virus (HBV) by detecting the hepatitis B surface antigen (HBsAg) is highly dependent on the performance of the HBsAg assay. Some of the newer HBsAg assays detect infection within a time frame similar to that of some NAT tests. The window period for detection of HBV infection can be shortened from approximately 51 days to 31 days (depending on the tests used) using NAT methodologies instead of HBsAg assays. Diagnostic tools need to be developed to further reduce or eliminate the window period.

A persistent challenge to control efforts for some diseases is the inability of the currently used tests to diagnose the condition of interest. It is estimated that as many as 3 million individuals who present every year with suspected tuberculosis actually have sputum smear-negative pulmonary disease or extrapulmonary disease. Currently available tools, especially those that are widely used in disease control programmes, need improvement. The availability of modern nucleic acid technology and enzyme detection processes can detect these cases which used to remain undetected hitherto thus causing harm to the health of the individual as well as being a source of infection to many others. This is an area that needs to be explored urgently by the public health laboratories in close collaboration with other laboratories, research institutes and health-care industry.

Laboratory tests have limitations in detecting organisms that are present in small numbers. The currently used sputum smear microscopy examination can detect mycobacteria only if these are present in concentrations higher than 10000/ml. The low sensitivity of the technology, which detects only roughly half of the active cases, is further compounded by its complexity. It is estimated that less than 45% of predicted incident smear-positive cases of tuberculosis are detected and notified to WHO. This is true for several other diseases where the existing technologies are not able to detect causative agents present in small numbers.

Areas where research should be targeted include:

- detection of new pathogens that cause outbreaks and remain undiagnosed;
• identification of HIV, hepatitis B and hepatitis C during the window period and dengue antibody during the early days of clinical disease;
• increasing the sensitivity and specificity of detection by rapid or conventional methods and refining the existing diagnostic tools;
• detection of organisms that are present in small numbers in the clinical material;
• increasing stability of the organisms in the clinical material through cost-effective methods of sample collection, storage and shipment;
• developing combo tests for use in diagnosis of common syndromes to confirm/exclude the common causes of disease syndrome; and,
• formulating tests/diagnostic algorithms for genetically modified pathogens where the organisms have been deliberately modified to make them amenable to diagnosis by the currently available tests.

11.4.2 Development of quality diagnostic tools for neglected diseases

Several diseases with considerable public health importance do not have diagnostic tools that can either differentiate these from diseases with similar clinical features or identify the presence of their causative agents in the clinical material. Some of these diseases fall under the broad group of “neglected tropical diseases” (NTDs) and include, among others, yaws, schistosomiasis, lymphatic filariasis, Chagas disease, leishmaniasis. The development of specific diagnostic tools for these will facilitate early and specific public health interventions for their prevention and control, as well as to confirm their elimination from any geographical area. These tools shall be particularly useful in remote areas which are predominantly affected by diseases such as malaria, Japanese encephalitis, Nipah virus, avian influenza and acute encephalitis syndrome (AES).

Research should be targeted at:

• developing diagnostic tools that can rapidly and reliably establish the diagnosis of NTDs;
• developing reliable diagnostics for use in field settings;
• evaluation/development of rapid, user-friendly diagnostics that are stable in diverse environmental conditions;
• developing RDTs for epidemic-prone diseases that can be used in peripheral health facilities by minimally skilled health functionaries;
• development and evaluation of point-of-care molecular diagnostic assays to support the rapid outbreak response at remote and border locations.

11.4.3 Tools to monitor the environment

The detection of microorganisms in the environment or their unique metabolic/biochemical characteristics can yield critical information for
understanding the epidemiology of EIDs. Several organisms such as Yersinia pestis and Bacillus anthracis can survive in the environment for years and their detection can help to control these diseases during the early phase. Technologies to detect organisms or their products are also of immense use in the defence against biological warfare.

Several diseases are being targeted for elimination/eradication. Eradication calls for evidence that the organisms causing these diseases are no longer surviving in the environment. Persistence of the poliovirus in the environment is an indication that this disease requires additional efforts for its elimination.

11.4.4 Expanding the characterization of pathogens

Genetic sequence-based identification and typing of microorganisms not only helps in confirming an etiological diagnosis but also assists in epidemiological tracing of the infection, its virulence profile, pathogenic genes, antibiogram and typing of isolates. Complete genetic profiling of the organisms also helps in understanding their evolutionary profile and thus the disease. Understanding genomic characters of pathogens is a critical step in the development of diagnostics, vaccines and therapeutic tools.

Research should be aimed at full characterization of local isolates and correlation of the genetic composition with the phylogenetic and epidemiological features of microorganisms and diseases caused by them.

11.4.5 Increase the stability of diagnostic reagents

The environmental conditions required for the storage and shipment of diagnostic reagents/kits are usually exacting, leading to their deterioration if these conditions are breached or not met or whenever there is exposure to adverse conditions. In peripheral areas in developing countries, environmental conditions are not conducive to retaining the essential characteristics of diagnostic reagents/kits.

Research should address the modification of existing diagnostic kits/reagents to enhance their stability so that they can withstand wide fluctuations in environmental parameters (temperature, humidity, light) and have a longer shelf life. This would go a long way in strengthening diagnostic capacity in remote and peripheral areas.

11.4.6 Development of diagnostics using locally prevalent microorganisms

The majority of diagnostic reagents/kits are produced in developed countries using antigens that are prevalent in those countries. The kits are even sold in areas where the specific subtype of the pathogen that the test kit aims to detect is not in circulation. This has been observed to be the case with regard to HIV, hepatitis B, Japanese encephalitis and dengue, and may sometimes lead to false-negative results. Either the antigenic
epitope that is common to all subtypes of the pathogen should be used or geographical area-specific diagnostic reagents need to be developed.

Research is required:

- to develop tools for testing new vaccines and drugs in a given setting to analyse their context-specific efficacy and safety;
- to develop diagnostic reagents/kits based on antigens available locally.

11.4.7 Determination of antimicrobial resistance patterns using rapid and real-time tests

Specific antimicrobial therapy plays a critical role in the clinical management of a patient. In addition, it is an effective public health tool to cut short the transmission of disease. Determining the susceptibility of organisms, especially viruses, to the available drugs can provide a powerful intervention for the public health system. Currently, these analyses take a long time and are restricted to a few laboratories. This hinders the wide application of this tool.

Antimicrobial resistance (AMR) has become a major global public health concern. The surveillance of AMR is an integral part of National Action Plans to combat AMR which have been developed in alignment with the WHO global action plan on antimicrobial resistance. All levels of public health laboratories have to take part in this surveillance for which quality tools are needed.

There is a need for development of bedside technologies that can rapidly identify the causative agent(s) of disease as well as provide information on the types of antimicrobial agents that would be effective against the isolated agent.

11.4.8 Development of environment-friendly technologies

Laboratories handle a large amount of material that can contaminate the environment. Several inexpensive and effective systems for proper disposal of infectious waste have been developed.

Research should address the need for redesigning diagnostic technologies to make these more environment-friendly by using less toxic chemicals and reducing, refining and replacing the use of animals in toxicity and diagnostic tests.

11.4.9 Animal–human interface

Zoonotic diseases have assumed great importance because of the emergence of several important communicable diseases from animals. The human–animal interface is becoming intense and complex because
of several factors, including deforestation, industrialization, expansion of human habitations, and greater dependence of human beings on animals. These factors are causing close and continuous contact between animals and humans thus facilitating the transmission of diseases between them. To prevent these diseases it is essential to understand the complexity of this interface and the factors influencing it. Public health laboratories need to collaborate with epidemiologists and veterinary public health experts to elucidate the dynamics of human–animal interactions and devise interventions that can reduce the transmission of infections between them.

Research should address the:
- elucidation of factors that facilitate the transmission of pathogens between humans and animals
- development of interventions that can minimize their impact on human health.

11.4.10 Detection of pathogens, especially viruses from wildlife

Wildlife is full of large numbers of viruses and other pathogens that have been inhabiting these areas for ages. With environmental changes and increasing proximity of wildlife to human habitations, the likelihood of viruses and other pathogens attacking humans has increased significantly. In the absence of diagnostic, preventive and therapeutic tools, such transmissions to a susceptible population can lead to outbreaks, epidemics or even pandemics. It is increasingly important to stay alert and map all the pathogens in the wild.

Research is needed for the isolation, identification and characterization of wildlife pathogens and the development of diagnostic, preventive and therapeutic tools for their early detection and surveillance, and for the protection and management of affected cases.

To undertake the above-mentioned research priorities, there is a strong and urgent need to encourage research and development (R&D) institutes in developing countries to make a need-based plan on research priorities, collaborate with other institutions/agencies, develop reagents/kits/RDTs for communicable diseases, facilitate transfers of technology to the private sector, and ensure the availability of these reagents to other countries at an affordable cost.

It is important to institute a mechanism for developing regular dialogue with diagnostic technology and test developers for accelerated diagnostic tool development, evaluation, demonstration and sustainable adoption of the test. The national network of public health laboratories is mandated to play a critical role in all these areas to preserve, protect and promote human health.
Line-listing: An important component of data management
(Source: NIMHANS, India)
The national laboratory policy and plan should systematically outline the major issues that need to be addressed, including: organizational and management structure; human resource; laboratory infrastructure, care and maintenance of equipment, provision of laboratory supplies; a functional information management system; a quality management system; adequate sustained financial support; and, an efficient monitoring and evaluation (M&E) component for effective oversight and course correction.

12.1 Monitoring and evaluation

Monitoring and evaluation (M&E) is a process that helps improve performance and achieve results. The goal is to improve current and future management of outputs, outcomes and impact. The implementation of the national public health laboratory annual operational plan requires regular and careful monitoring to ensure that agreed activities are properly implemented and financial expenditures are accounted for. The M&E system refers to all the indicators, tools and processes that we use to measure if a programme has been implemented according to the plan (monitoring) and is having the desired result (evaluation).

The following M&E points should be considered:

- Establish mechanisms for monitoring the implementation of activities, including identifying responsible persons, establishing regular reporting mechanisms, and holding regular review meetings with stakeholders to assess progress.
• Review progress through the measurement of indicators, as follows:
  o activity indicators: measurement of activities conducted
  o outcome indicators: measurement of outcomes and performances.
• Prepare timely reports addressing the review of indicators as well as challenges and constraints.
• Adjust activities, objectives and timelines according to the results of the review.
• Conduct periodic audits, both internal and external, to evaluate performance and activities, based on the essential elements.

The acronym “SMART” is useful to remember when developing objectives/indicators. Laboratory professionals should ask themselves the following questions while developing objectives and indicators.

• **Specific**: Is the objective specific? Does it cover only one activity rather than multiple activities?
• **Measurable**: Is the objective measurable? Can it be measured or counted in some way?
• **Appropriate/attainable**: How important is this objective to the work that we do? How relevant is it to achieving our goal?
• **Realistic/relevant**: Is the objective actually doable? Can we achieve this goal?
• **Time-based**: Does the objective give a time frame by when it will be achieved, or a time frame during which the activity will occur?

Given ahead are action points for the various components of the M&E plan.

12.1.1 Monitoring the creation of a national public health laboratory leadership framework

The following questions must be addressed:

• Is there a national steering group identified for the accreditation of local public health laboratory networks? If yes, does it advise the national focal point in preparing the strategic plan, and facilitate the mobilization of political and material resources?
• Does the national regulatory agency licence health-care providers, set minimum standards for human resources, materials, kits, machines and methodologies, and monitor and enforce standards?
• Does the national focal point for laboratories advise national authorities, guide all laboratory initiatives in line with national policies and plans, and respond to rapid changes in all areas of laboratory services including public health?
• Does the national public health laboratory network provide referral laboratory testing services to affiliate laboratories, transmit test result
information to a central database for epidemiological analysis (information network), and bring together health-care practitioners to facilitate storing, sharing and adoption of their “tacit” and “explicit” knowledge (knowledge management network)?

12.1.2 Monitoring essential components of public health laboratories

Evidenced by the fact that public health laboratory services are recognized as vital and integral to quality health services at all levels of the health system, all stakeholders must undertake operational planning and allocate adequate and sustainable resources. Monitoring the process can be facilitated using the following questionnaire:

- Is there a detailed countrywide situational analysis to determine the current status of public health laboratory services and requirements based on clinical and public health activities?
- Is a national health laboratory policy, outlining the structure and function of laboratory services including the structure of laboratory management and support systems for both clinical and public health laboratories, being formulated?
- Is a long-term (5–10 years) national public health laboratory plan outlining priorities, timelines and indicative budgets being developed along with annual operational plans detailing clear timelines, costs and responsibilities of implementing partners, including the contribution of the private sector?
- Does the national health laboratory policy provide the overall direction for establishing and strengthening national laboratory services including public health laboratory services?
- Are annual operational plans drawn up, detailing activities, time frames, implementing partners, budgetary allocations and annual funding sources, taking into consideration the contribution of the private sector?
- Do the national health laboratory policy and national public health laboratory plan include the following?
  - laboratory organizational and management structure
  - national standards for infrastructure, tests, techniques and equipment
  - human resource management
  - quality management systems (QMS)
  - procurement and supplies management
  - laboratory equipment management
  - laboratory information management system (LIMS)
  - safety and waste management.
• Are the national standards for infrastructure, tests, techniques and equipment clearly defined?

National standards for competence, essential infrastructure, equipment, tests and techniques should be established for laboratories at each level of the public health network.

12.1.3 Monitoring human resource management is an essential component and it can be achieved using the following:

• Are the number and types of health workers required – from peripheral to reference and/or national laboratory levels – defined and arrangements made for their training?
• Are public health laboratory services provided only by staff with recognized qualifications or relevant training?
• Are job descriptions for all laboratory personnel working at different levels of the health system developed?
• Are opportunities for career advancement of human resource identified?
• Are periodic competency assessments of staff to verify individual demonstration of necessary skills, knowledge and correct work practices undertaken?
• Are appropriate in-service training programmes for all categories of staff defined and practiced?
• Are effective supervisory systems to monitor work performance and quality using a structured checklist in place?
• Are there national and/or regional professional associations to promote professional development and ethical practices in public health laboratories?

12.1.4 Monitoring quality management systems is crucial in all health care laboratories and can be carried using the following indicators.

• Has a national laboratory quality statement been developed which reflects the intention and commitment of the national authorities to ensure that quality laboratory services are provided at all levels of health-care facilities?
• Is there a provision for adequate and sustainable financial resources for establishing and maintaining quality laboratory systems?
• Has a quality manager been designated?
• Has a network of quality managers among the various institutional laboratories under the office of the national laboratory focal point to coordinate all activities relating to the quality system been created?
• Is there a mechanism in place for the development, implementation and monitoring of quality standards in all laboratories?
• Is there a training plan in place for all laboratory staff on all aspects of the quality system?
• Is the development, maintenance and updating of standard operating procedures (SOPs) in place or not?
• Is internal quality control (IQC) practiced in all laboratory procedures?
• Is there a mechanism in place for the organization of an appropriate External Quality Assessment Scheme (EQAS) at each level of the laboratory? Does it ensure mandatory participation and also document any corrective actions taken?
• Are assessments of laboratory performance through audits (internal or external) undertaken? Are periodic well-structured and well-documented internal audits undertaken by the laboratories?
• Are quality indicators (including pre-analytic, analytic and post-analytic aspects) being developed to consistently monitor and evaluate laboratory performance?
• Is a national system of step-wise accreditation being developed that also helps laboratories achieve accreditation to a defined standard?
• Is there a functional mechanism that ensures effective communication between laboratories and all other related stakeholders?

12.1.5 Monitoring the selection and standardization of supplies and reagents.

Consumables and reagents of good quality are essential for obtaining accurate and reliable results in the laboratory. The selection and standardization can be monitored using the following questionnaire:

• Has an effective national laboratory procurement and supplies management system, with appropriate storage facilities and timely distribution systems, been developed?
• Is the evaluation and validation of laboratory consumables and reagents conducted by qualified, competent laboratories using standard guidelines or by referring to reliable evaluations and validations?
• Is there a system in place for the identification of a national centre for independent quality assurance and pre-qualification of consumables and reagents?
• Have clear guidelines been developed for accepting and receiving donated laboratory supplies to ensure that they meet the required specifications and are appropriate for the laboratory?
• Is there a standardized system in place for inventory and stock control in every laboratory, including the development of appropriate systems for receipt, quality checking and storage of consumables and supplies by the laboratory?
• Does training of laboratory managers include the following: procurement, supply management and logistics; planning; quantification, costing, budgeting; storage, stock-keeping, inventory control; and, rational use of supplies?
• Are standard procedures in place to identify laboratory chemicals and supplies for safe disposal?

12.1.6 Monitoring specimen collection and transportation.

Appropriate specimen collection and transport are crucial factors that determine the quality of a the laboratory result. Hence they need to be monitored regularly using the following questions:

• Have the sample types and quantities been defined for various diagnostic tests? Where do the specimens go for laboratory testing? Is the destination clearly defined? The transport mechanism must be clear and must support sending samples across the different laboratory levels – from the peripheral level to the district level, and then the provincial/regional and central levels. Is the process for sending feedback to the health centre, district and regional/provincial health centre clearly defined and supported by the programme?
• Does packaging and shipping of infectious material follow International Air Transport Association (IATA) guidelines?
• Is there a system of training in place for technical staff on sample collection and transportation using standard SOPs?
• Are the materials for collection and transportation of clinical samples defined and available, including triple packaging of infectious material?

12.1.7 Monitoring laboratory safety (biosafety/biosecurity).

Implementing best practices for biosafety and biosecurity in the public health laboratory is mandatory. It can be monitored by using the following check-list:

• Have laboratory safety procedures been developed in line with national health and safety guidelines?
• Has a laboratory safety officer been designated? Is there a provision for adequate protection of laboratory personnel to prevent occupationally acquired diseases, and also for managing such incidents in the case of exposure, including post-exposure prophylaxis (PEP)?
• Has a biological waste management programme been established?
• Is the disposal of laboratory waste in accordance with national environmental protection regulations?
12.1.8 Monitoring laboratory financing

- Is the financing of health laboratory services part of the overall health financing plan and all national, subnational and institutional budgeting processes?

12.1.9 Monitoring the laboratory information management system (LIMS)

- Is the national LIMS, in line with the national health information management system (HIMS), which may be electronic or paper-based, in place?

12.2 Independent review of the public health laboratory system

To improve the public health laboratory set-up and functioning, it is of vital importance that an independent in-depth review of all aspects of the laboratory system is periodically carried out if feasible, but definitely once at the start of setting up a public health laboratory system. The review should be carried out by senior laboratory professionals who are well versed with the functioning of various types of available public health laboratory facilities, but they should not be part of the system. The focus of the in-depth review should be the following:

- structural configuration of laboratory services
- functional configuration of laboratory services
- type of mandates of various types of laboratories
- quality systems
- status of laboratory accreditation and preparedness
- laboratory biosafety and biosecurity practices
- technology evaluation of laboratory equipment, diagnostic kits, reagents and consumables
- role of private diagnostic laboratories in delivering public health services
- networking of laboratories and inter-sectoral coordination
- list gaps in public health laboratory functions
- list gaps in the public health laboratory structure
- suggest a way forward/road map/phased approach/strategies for strengthening public health laboratory services.
Further Reading


Establishment of Public Health Laboratories in South East Asia


Suggested checklist

Introduction

It is advisable that public health laboratories may be reviewed for their performance during the immediate preceding 12 months by Member States (health laboratories, regulatory authorities or equivalent) annually.

Five suggested areas for assessment of a public health laboratory:

1. **Test results are reported by the laboratory on at least 80% samples within the defined turnaround time of receipt of samples.**

2. **The accuracy of test results is at least 90% (concordance)**
   
   Samples for validation should be representative of all results (positive, negative and equivocal) and for all tests, and should be sent to the linked reference laboratory at defined regular intervals.

3. **The score on the most recent approved proficiency test is at least 90%.**
   
   All public health laboratories should participate in proficiency testing wherever available. Where proficiency testing is not available, the public health laboratory should participate in inter-laboratory comparison with another public health laboratory within the country/region. All proficiency test results are to be reported within 14 days of panel receipt to the proficiency test provider.

4. **Laboratory tests are performed on at least 50 specimens annually.**
   
   To maintain skills in performing assays, public health laboratories should maintain appropriate reagents and assay kits to have the capacity to test continually through the year. To maintain expertise, it is required that laboratories test a minimum of 50 specimens annually, spread across the year. See Section 2, Part II.
5. The score from the annual on-site review of laboratory operating procedures and practices is at least 80/100.

A public health laboratory that achieves less than the acceptable score on any one of the applicable criteria will work with the national public health laboratory to:

- identify areas where improvement is needed
- develop and implement a work plan
- monitor laboratory improvement progress.

The checklist consists of four parts:

**Part I** summarizes the findings of the review and the data on which the assessment is based and is to be filled out by the assessor.

**Part II** provides a profile of the laboratory and serves to identify resource needs.

**Part III** provides a worksheet to calculate and record laboratory performance for criteria 1 through 4 for the immediately preceding 12 months where data are complete. (Selection of the most recent 12-month period, rather than the most recent calendar year as a basis for calculation, provides an assessment of current performance and permits review of laboratories at any time during the calendar year.)

**Part IV** is a checklist for the evaluation of laboratory operating procedures and practices.

All public health laboratories may preferably be assessed annually by the Member State.

Note: The assessor is expected to be experienced in the field of public health laboratory services and can make additional suggestions as appropriate to assure high-quality laboratory performance.

**Disclaimer:** This checklist does not include all laboratory activities or cover all situations. It is intended to serve ONLY as a guide. Member States may modify the checklist according to their defined requirements to capture the required data on laboratory performance and assign scores they deem appropriate.
# Suggested checklist for public health laboratories

<table>
<thead>
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<td>Fax:</td>
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<tr>
<td>Laboratory in-charge:</td>
<td>Head technician:</td>
</tr>
<tr>
<td>Name of referral laboratory:</td>
<td></td>
</tr>
<tr>
<td>Name and designation of reviewer(s):</td>
<td></td>
</tr>
</tbody>
</table>

## Part I: Summary of review (assessor to complete)

**Recommendations (check one):**

- [ ] Laboratory meets all criteria
- [ ] Laboratory needs improvement

**Findings:**

1. **Test results reported by the laboratory within defined turnaround time**
2. **The accuracy of detection (≥90%):**
3. **Samples referred to the Reference Laboratory within 30 days: (≥80%)**
4. **The overall score on the most recent proficiency tests is ≥ 80%:**
5. **Number of samples tested per year is greater than 50**
6. **The score from the annual on-site review of laboratory operating procedures and practices is ≥ 80% as determined by Part II, Part III and Part IV of the checklist.**

---

*Establishment of Public Health Laboratories in South East Asia*
### SUMMARY, COMMENTS AND RECOMMENDATIONS:

**Summary**

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
</table>
## Part II

### Laboratory Profile
*(To be completed by the laboratory)*

1. **Human Resource**

<table>
<thead>
<tr>
<th>Names of staff</th>
<th>Qualification/designation</th>
<th>Permanent staff/contract staff</th>
<th>Percentage of time spent working in the laboratory</th>
<th>Undergone training (month/year)</th>
<th>Years of experience in laboratory testing</th>
<th>Experience with other public health programmes</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

**Comments** *(Please comment on adequacy, training and experience):*
2. Tests performed (please tabulate results for the past 12 months):

<table>
<thead>
<tr>
<th>Test performed</th>
<th>Number of specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Received</td>
</tr>
<tr>
<td>Serological Tests</td>
<td></td>
</tr>
<tr>
<td>Microscopy</td>
<td></td>
</tr>
<tr>
<td>Point-of-care tests (Rapid)</td>
<td></td>
</tr>
<tr>
<td>Bacterial culture</td>
<td></td>
</tr>
<tr>
<td>Biochemical tests</td>
<td></td>
</tr>
<tr>
<td>Hematology tests</td>
<td></td>
</tr>
<tr>
<td>Chemical analysis</td>
<td></td>
</tr>
<tr>
<td>Water testing</td>
<td></td>
</tr>
<tr>
<td>Food testing</td>
<td></td>
</tr>
<tr>
<td>Any others (specify)</td>
<td></td>
</tr>
</tbody>
</table>

3. Space: Describe the space available

<table>
<thead>
<tr>
<th>Space available (area) for laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean area for sample receipt</td>
</tr>
<tr>
<td>Clean workspace for serological tests</td>
</tr>
<tr>
<td>Clean room for bacterial culture</td>
</tr>
<tr>
<td>Washing and sterilization area</td>
</tr>
<tr>
<td>Separate area for documentation &amp; report writing</td>
</tr>
<tr>
<td>Staff room</td>
</tr>
<tr>
<td>Other (Specify: e.g. molecular testing)</td>
</tr>
</tbody>
</table>

Comments (Please comment on adequacy of space, layout, etc.):
4. List of equipment available in the public health laboratory:

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Equipment name</th>
<th>Brand/catalogue no.</th>
<th>Date of receipt</th>
<th>Working condition Y/N</th>
<th>AMC Y/N</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

5. Laboratory support from public health programmes in the country:
(tick those applicable)

<table>
<thead>
<tr>
<th>Support</th>
<th>Government</th>
<th>Donor Support</th>
<th>Any other agency (Specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample collection</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sample shipment</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Training</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Manpower</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Test kits</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Consumables</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Quality assurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proficiency testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Specify)</td>
<td></td>
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</tbody>
</table>
### Part III: Laboratory performance in the previous 12 months
(to be completed by the laboratory)

Dates from: __/__/____  to  __/__/____

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Percentage of results reported within defined turnaround time:</strong></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.1 Total number of samples received for testing:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.2 Total number of samples where results were reported within defined turnaround of receipt:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>1.3 Mean time for reporting:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.4 Number of samples received for:</td>
<td></td>
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</tr>
</tbody>
</table>

**COMMENTS AND RECOMMENDATIONS:**

<p>| | | | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>2.</td>
<td><strong>Percentage accuracy of tests</strong> : (≥90%)</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.1 Number of samples tested:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.2 Number of samples forwarded to referral lab:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.3 Number confirmed accurate by referral lab:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**COMMENTS AND RECOMMENDATIONS:**
### 3. **Samples referred to the reference laboratory within specified time: (≥80%)**

<table>
<thead>
<tr>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.1 Number of samples referred:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.2 Number forwarded to Regional Reference Laboratory within specified time:</strong></td>
<td></td>
</tr>
</tbody>
</table>

### COMMENTS AND RECOMMENDATIONS:


### 4. **Result of most recent proficiency testing: (≥ 90%)**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serology</td>
<td></td>
</tr>
<tr>
<td>Biochemistry</td>
<td></td>
</tr>
<tr>
<td>Bacterial culture</td>
<td></td>
</tr>
<tr>
<td>Haematology</td>
<td></td>
</tr>
<tr>
<td>Water testing</td>
<td></td>
</tr>
<tr>
<td>Food testing</td>
<td></td>
</tr>
<tr>
<td>Others (Specify)</td>
<td></td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>4.1 Date of panel receipt:</strong></td>
<td>/</td>
</tr>
<tr>
<td><strong>4.2 Date of reporting proficiency test results:</strong></td>
<td>/</td>
</tr>
<tr>
<td><strong>4.3 Timeliness of reporting within specified time:</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Nature of deficiency, if any, and corrective action taken:*


*Establishment of Public Health Laboratories in South East Asia*
Part IV: Laboratory operating procedures and work practices
(to be completed during on-site review)

<table>
<thead>
<tr>
<th>1. Infrastructure (4)</th>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Space is used efficiently with appropriate equipment placement: (Y/N):</td>
<td></td>
</tr>
<tr>
<td>1.2 Space configuration is consistent with good laboratory practices (Y/N):</td>
<td></td>
</tr>
<tr>
<td>1.3 Space is clean and well kept (Y/N)</td>
<td></td>
</tr>
<tr>
<td>1.4 Does the lab have adequate water supply and electricity (Y/N):</td>
<td></td>
</tr>
</tbody>
</table>

COMMENTS AND RECOMMENDATIONS:

<table>
<thead>
<tr>
<th>2. Staff (4)</th>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Adequately and effectively assigned (Y/N):</td>
<td></td>
</tr>
<tr>
<td>2.2 Adequately trained (Y/N):</td>
<td></td>
</tr>
<tr>
<td>2.3 Lines of supervision are clear (Y/N):</td>
<td></td>
</tr>
<tr>
<td>2.4 Supervisor reviews results before reports are dispatched (Y/N):</td>
<td></td>
</tr>
</tbody>
</table>

COMMENTS AND RECOMMENDATIONS:
### 3. Equipment (10)

<table>
<thead>
<tr>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Inventory of equipment maintained (Y/N):</td>
</tr>
<tr>
<td>3.2 Equipment in good functioning condition (Y/N):</td>
</tr>
<tr>
<td>3.3 Record of maintenance and repair available (Y/N):</td>
</tr>
<tr>
<td>3.4 Placement of equipment is conducive to Good Laboratory Practices (Y/N):</td>
</tr>
<tr>
<td>3.5 SOP available for use and maintenance of equipment (Y/N):</td>
</tr>
</tbody>
</table>

**COMMENTS AND RECOMMENDATIONS:**

### 4. Sample receipt and storage (10)

<table>
<thead>
<tr>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Record of samples received:</td>
</tr>
<tr>
<td>4.2 Record of quality of sample received:</td>
</tr>
<tr>
<td>4.3 Samples are appropriately labelled and stored (Y/N):</td>
</tr>
<tr>
<td>4.4 Samples are stored for the duration specified by the national guidelines (Y/N):</td>
</tr>
<tr>
<td>4.5 Inventory of stored samples available (Y/N):</td>
</tr>
</tbody>
</table>

**COMMENTS AND RECOMMENDATIONS:**
### 5. Quality Control (30) Score

<table>
<thead>
<tr>
<th>Score</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 In-house and kit controls are used (5) (Y/N)</td>
<td></td>
</tr>
<tr>
<td>5.2 Pipettes are regularly calibrated (5) (Y/N)</td>
<td></td>
</tr>
<tr>
<td>5.3 Temperature of incubators, freezers and refrigerators are monitored (5) (Y/N)</td>
<td></td>
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<tr>
<td>5.4 SOPs available (5) (Y/N)</td>
<td></td>
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<tr>
<td>5.5 Staff are familiar with SOP (2) (Y/N)</td>
<td></td>
</tr>
<tr>
<td>5.6 Worksheets available (2)</td>
<td></td>
</tr>
<tr>
<td>5.7 Validity of test recorded (1) (Y/N)</td>
<td></td>
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<tr>
<td>5.8 Kit manufacturer and batch number recorded (1) (Y/N)</td>
<td></td>
</tr>
<tr>
<td>5.9 Kits/reagents used within expiry date (1) (Y/N)</td>
<td></td>
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<tr>
<td>5.10 Supervisor reviews the test (2) (Y/N)</td>
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<tr>
<td>5.11 Records easily retrievable (1) (Y/N)</td>
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</table>

### COMMENTS AND RECOMMENDATIONS:

### 6. Supplies (8) Score:

<table>
<thead>
<tr>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>6.1 Inventory of supplies maintained (2) (Y/N):</td>
<td></td>
</tr>
<tr>
<td>6.2 Adequate time allowed for replenishment (at least 3 months) (1) (Y/N):</td>
<td></td>
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<tr>
<td>6.3 Interruption of testing due to stock out of kits (1) (Y/N):</td>
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<tr>
<td>6.4 Kits are stored at appropriate temperature (2) (Y/N) Yes</td>
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<tr>
<td>6.5 Test kits/reagents are verified before they are put to use (2) (Y/N):</td>
<td></td>
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</table>

### COMMENTS AND RECOMMENDATIONS:
### 7. Information management (10)  

<table>
<thead>
<tr>
<th>Score:</th>
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<tbody>
<tr>
<td>7.1 Sample and test records maintained and updated (2) (Y/N):</td>
</tr>
<tr>
<td>7.2 Monthly report submitted on time (2) (Y/N):</td>
</tr>
<tr>
<td>7.3 SOP available for reporting (2) (Y/N):</td>
</tr>
<tr>
<td>7.4 Back up of data made periodically (monthly) (2) (Y/N):</td>
</tr>
<tr>
<td>7.5 Time frame for reporting (2) (hours/days/weeks):</td>
</tr>
</tbody>
</table>

**COMMENTS AND RECOMMENDATIONS:**

### 8. Biosafety and waste disposal (8)  

<table>
<thead>
<tr>
<th>Score:</th>
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</thead>
<tbody>
<tr>
<td>8.1 Staff have been instructed in biosafety (2) (Y/N):</td>
</tr>
<tr>
<td>8.2 Personal protective equipment is available and used (gloves and lab coat) (1) (Y/N):</td>
</tr>
<tr>
<td>8.3 Used gloves and consumables are decontaminated before disposal (1) (Y/N):</td>
</tr>
<tr>
<td>8.4 Staff immunized against hepatitis (1) (Y/N):</td>
</tr>
<tr>
<td>8.5 Plan for needlestick injury management available (1) (Y/N):</td>
</tr>
<tr>
<td>8.6 Availability of first aid kit and eye wash solution (1) (Y/N):</td>
</tr>
<tr>
<td>8.7 Protocols for spills management and accidents available (1) (Y/N):</td>
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</tbody>
</table>

**COMMENTS AND RECOMMENDATIONS:**
### 9. Shipment of samples (6) | Score:

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<thead>
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<tbody>
<tr>
<td>9.1 Appropriate cold boxes, vials, ice packs are available and used (2) (Y/N):</td>
<td></td>
</tr>
<tr>
<td>9.2 Sample referral forms are available (1) (Y/N):</td>
<td></td>
</tr>
<tr>
<td>9.3 Record maintained of samples referred and remarks of the referral laboratory (1) (Y/N):</td>
<td></td>
</tr>
<tr>
<td>9.4 IATA regulations for shipping are followed (2) (Y/N):</td>
<td></td>
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</tbody>
</table>

### COMMENTS AND RECOMMENDATIONS:


### 10. Communication (10) | Score:

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<table>
<thead>
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<tbody>
<tr>
<td>10.1 Laboratory and public health authorities communicate regularly (5 points)</td>
<td></td>
</tr>
<tr>
<td>10.1 Public Health Laboratory has infrastructure and mechanism for communication with linked referral laboratory (5 points)</td>
<td></td>
</tr>
</tbody>
</table>

### COMMENTS AND RECOMMENDATIONS:


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Onsite review summary score (Total of Sections 1–10):

Score out of possible 100 =

Date: [ ]

Name: [ ]

Signature: [ ]

Establishment of Public Health Laboratories in South East Asia
Public health laboratory services are an essential part of any strong and effective health system, contributing significantly to the prevention and control of diseases as well as improvement of the nation's health. This document will assist our Member States in their efforts to establish and strengthen public health laboratories and forge their network in pursuit of preventing and containing emerging, re-emerging and novel communicable diseases in the South-East Asia Region.