

# **National Laboratory System**

## 8. National Laboratory System

### Notes:

- The indicators refer to national laboratory capacity for the country.
- The national laboratory system should include:
  - Ability to conduct at least five of the ten core tests identified by the International Health Regulations;
  - Ability to transport specimens safely and quickly from 80% or more of intermediate levels/districts to national laboratory facilities for advanced diagnostics;
  - Ability to conduct higher level diagnostic testing at national laboratories or agreements with regional networks to ensure testing is available.
- Core tests can include local priority tests determined by country-selected indicator pathogens on the basis of major national public health concern.

Questions	Responses	Documents Required
<b>Contextual Questions:</b>		
1. Which of the ten core tests is the country capable of conducting?	1) Influenza-PCR 2) Polio-Virus culture 3) HIV-Serology 4) TB-Microscopy 5) Plasmodium-Rapid test (Thick film) 6) Salmonella typhi & enteritidis-culture 7) Ebola-PCR 8) Dengue-Rapid test 9) Leptospirosis, Rapid test 10) Melioidosis, Rapid test (IHA for antibody) Thailand has capacity to detect wide ranges of infectious diseases. Thailand has capacity to set up new test methods	2016, Handbook of Specimen collection and Laboratory services. National Institute of Health. ( <a href="http://nih.dmsc.moph.go.th/lab_nih/labnih60.pdf">http://nih.dmsc.moph.go.th/lab_nih/labnih60.pdf</a> ) 2015, EID-Lab Network ( <a href="http://nih.dmsc.moph.go.th/login/filedata/media2559_2.pdf">http://nih.dmsc.moph.go.th/login/filedata/media2559_2.pdf</a> )

Questions	Responses	Documents Required
	<p>in response to outbreak.</p> <p>Animal Health sector</p> <ol style="list-style-type: none"> <li>1. Flu (highly pathogenic avian influenza): virus isolation, antigen detection, real time RT-PCR/Seq. HA/HI</li> <li>2. Mycobacterium in animals: bacterial culture, PCR and immunohistochemistry (IHC)</li> <li>3. Salmonella enteritidis serotype Typhi: bacterial culture and PCR</li> <li>4. Brucellosis: PCR, bacterial culture and IHC</li> <li>5. Rabies: fluorescent antibody technique (FAT), RT-PCR and real time RT-PCR</li> <li>6. Leptospira 24 serova: microscopic agglutination test (MAT), isolation and real time PCR</li> <li>7. <i>Burkholderia pseudomallei</i>: bacterial culture and PCR</li> <li>8. Nipah encephalitis virus: PCR, ELISA and IHC</li> <li>9. Bovine spongiform encephalopathy (BSE): IHC</li> <li>10. Japanese encephalitis virus : PCR, HI and ELISA</li> </ol> <p>Anthrax PCR/Seq MERS- CoV PCR/Seq Ebola- PCR/Seq</p>	
2. Please describe structure of the laboratory system, including number of labs, at local,	The laboratory system consists of diagnostic laboratories, public health laboratories, public health reference laboratory and national	MOPH Standard

Questions	Responses	Documents Required
<p>intermediate levels/district, and national level.</p>	<p>laboratories. Ministry of public health classifies health service provider by number of bed. There are 896 MoPH hospitals. Among 896, 116 hospitals with <math>\geq 150</math> beds (33 Tertiary care, 83 secondary care, and ) have laboratories that can perform public health function. There are 119 hospitals belong to non MoPH, 347 private hospitals and 23 university hospitals.</p> <p>Department of Medical Sciences (DMSc) is national reference laboratories for diseases and consumer protection by mandate under royal decree. Under DMSc NIH is national reference laboratory for infectious diseases. There are 14 Regional Medical Sciences centers, sub-national laboratories located across the country. All of them have capacities to perform diagnostic tests as well as to refer the specimen to NIH if need. Bamrasnaradura Infectious disease Institute is an excellent center on infectious disease.</p> <p>University Hospitals can perform most of complicate diagnosis. They are under ministry of education.</p> <p>AH There are 9 veterinary diagnostic labs under Department of Livestock Development (DLD),</p>	<p><a href="http://niah.dld.go.th/en/index.php?option=com_content&amp;view=article&amp;id=7&amp;Itemid=109">http://niah.dld.go.th/en/index.php?option=com_content&amp;view=article&amp;id=7&amp;Itemid=109</a></p>

Questions	Responses	Documents Required
	<p>Ministry of Agriculture and Cooperatives (MOAC) include National Institute of Animal Health (NIAH) in Bangkok and 8 Regional Research and Development Centers (RVRDC). In addition, there are OIE Regional Reference Laboratory for Foot and Mouth Disease in Southeast Asia (RRL) and Veterinary Biologics Assay and Research Center (VBAC) which are NIAH network.</p>	
<p>a. How many reference labs exist and for which microbes?</p>	<p>The Department of Medical Sciences functions as national laboratory for Public health. There are reference laboratories classified by group of pathogens cover the ranges of EIDs.  <a href="http://nih.dmsc.moph.go.th/index.php">http://nih.dmsc.moph.go.th/index.php</a> DMSc has 14 regional medical sciences centers that can provide services for the whole country.</p> <p>Disease specific reference laboratories. DMSc laboratories designated as reference laboratories are as follow:</p> <ul style="list-style-type: none"> <li>• WHO Regional Influenza Reference Laboratory for the South-East Asia Region : WHO RIRL</li> <li>• WHO regional reference laboratory for Polio in SEAR</li> <li>• WHO regional reference laboratory for Measles and Rubella in SEAR</li> <li>• WHO CC for AMR Surveillance and Training</li> <li>• National HIVDR Laboratory (WHO</li> </ul>	<p>DMSc organization chart.  <a href="http://www.dmsc.moph.go.th">www.dmsc.moph.go.th</a>  <a href="http://nih.dmsc.moph.go.th/index.php">http://nih.dmsc.moph.go.th/index.php</a></p> <p>list of tests  HH  <a href="http://www.dmsc.moph.go.th/dmscnew/userfiles/files/dmsc2559.pdf">http://www.dmsc.moph.go.th/dmscnew/userfiles/files/dmsc2559.pdf</a></p> <p>TB : Bureau of tuberculosis, DDC.  <a href="https://www.tbthailand.org/chart.html">https://www.tbthailand.org/chart.html</a>  STD:</p>

Questions	Responses	Documents Required
	<p>designation)</p> <p>There are also the pathogen specific laboratories belong to Department of Disease Control such as TB, Malaria and STD.</p> <p>Bamrasnaradura hospital laboratory is a reference laboratory for many infection diseases such as EIDs.</p> <p>AFRIMS are WHO Collaborating Centre for Diagnostic Reference, Training and Investigation of Emerging Infectious Diseases</p> <p>King Chulalongkorn Memorial Hospital is designated as WHO CC for Research and Training in Viral Zoonoses.</p> <ol style="list-style-type: none"> <li>1. OIE Regional Reference Laboratory for Foot and Mouth Disease in Southeast Asia</li> <li>2. OIE Reference Laboratory for Brucellosis (at NIAH)</li> </ol>	<p>AH</p> <p><a href="http://niah.dld.go.th/th/index.php?option=com_content&amp;view=article&amp;id=913&amp;Itemid=366">http://niah.dld.go.th/th/index.php?option=com_content&amp;view=article&amp;id=913&amp;Itemid=366</a></p>

Questions	Responses	Documents Required
<p>b. Do local clinicians have the custom of using the laboratory system? Are there national guidelines for clinicians on which microbiological tests should be taken in specific syndromes like severe pneumonia, severe diarrhoea or suspected meningitis (for example)</p>	<p>Yes, lab test algorithms for priority infectious diseases are documented in disease specific guidelines.</p> <p>Accessibility to essential lab services is good . The expense covers by one of 3 types of health insurance: universal health coverage system for general public, government health insurance for government officials, and social security for private organization..</p> <p>Under outbreak situation Department of Disease Control will take responsibility on the cost of laboratory services. This activity is done under communicable disease acts.</p> <p>Yes. Guideline for Diagnosis and specimen transportation for Vet lab. (Ebola, AI, Rabies, etc.)</p> <p>Yes. Guideline for Diagnosis and specimen transportation for Vet lab. (Ebola, AI, Rabies, etc.)</p>	<ol style="list-style-type: none"> <li>1) Disease specific guideline such as Practice Guideline on Avian Influenza for Medical and Public Health Personnel, 2016 (Revised version) <a href="http://beid.ddc.moph.go.th/beid_2014/sites/default/files/AI_manual59_291259.pdf">http://beid.ddc.moph.go.th/beid_2014/sites/default/files/AI_manual59_291259.pdf</a></li> <li>2) Dengue (Bureau of vector borne diseases, DDC)</li> <li>3) TB (Guideline for Programmatic management of drug-resistant tuberculosis, 2015) <a href="http://www.tbnfmthailand.org/Download/DR-TB%20Proof%202023%20FINAL.pdf">http://www.tbnfmthailand.org/Download/DR-TB%20Proof%202023%20FINAL.pdf</a></li> <li>4) Guideline for Laboratory diagnosis of EID, <b>2013</b></li> <li>5) Guideline for EID laboratory network <b>2015</b> <a href="http://nih.dmsc.moph.go.th/login/filedata/meda2559_2.pdf">http://nih.dmsc.moph.go.th/login/filedata/meda2559_2.pdf</a></li> <li>6) Zika, <a href="http://nih.dmsc.moph.go.th/data/data/59/zika_virus010959.pdf">http://nih.dmsc.moph.go.th/data/data/59/zika_virus010959.pdf</a></li> </ol> <p>Etc.</p>
<p>c. What systems exist for getting laboratory results back to practitioners?</p>	<p>94% of the hospitals have electronic information systems. Provincial and regional hospital laboratories can report results electronically or paper based within a day the tests finish.</p>	

Questions	Responses	Documents Required
	<p>Private contact laboratories can report results online.</p> <p>NIH laboratories has in-house LIMS. The results are report by Fax for urgent cases and paper based for normal cases. Due to government regulations official letters are still required in some cases.</p> <p>Initial results are reported by phone or email during outbreak situation, follow by official document.</p> <p>Gaps  Linking data from LIMS to HIS  Linking microbiological data to LIMS  No standard data set for laboratory tests.</p> <p>By post, phone or e-mail</p> <p>Initial report by phone or email during outbreak situation, follow by official document</p>	
<p>d. What percentage of the population has access to laboratory services for the ten priority diseases?</p>	<p>100 %.</p> <p>For routine laboratory service, every Thai people can access to free healthcare services.</p> <p>Thailand has 3 types of health insurances.</p> <p>Thailand has universal health coverage system that Thai people can access to healthcare. Government officials can use government health insurance. The</p>	

Questions	Responses	Documents Required
	<p>private company staff can use social security. Under outbreak situation Department of Disease Control will take responsibility on the cost of laboratory services. This activity is done under communicable disease acts.</p> <p>Laboratory service is accessible throughout the country. The referral system is available if complicate laboratory tests are required.</p> <p>100% of reported cases.</p>	
3. Have national laboratories been accredited?	Yes (AH+HH)	
a. If yes, to what standard?	<p>ISO 15189:2012  ISO 17025:2005  ISO 17043:2010  ISO 9001;2015  AAALAC  ISO 15190;2003</p> <p>ISO/IEC 17025:2005  ISO 9001:2008</p>	
b. Are guidelines and protocols for quality management system enforced and in use by public and animal health laboratories?	<p>Yes, National policy on laboratory quality system is available for public health sectors. MoPH standard, LA, JCI and ISO 15189 are the quality standards adopted in Thailand.</p> <p>Though the national policy on laboratory quality</p>	<p>Copies of certificates</p> <p>DLD Policy on Quality system</p>

Questions	Responses	Documents Required
	standard does not exist in animal health sector, the NIAH laboratories and every affiliate are accredited by ISO 17025.	
c. Is there a national body that oversees Internal Quality Controls and External Quality Assessment schemes for public health laboratories at all levels?	Yes (AH+HH), Bureau of laboratory quality standards is the organization that oversees the IQA and EQA for public health laboratories. Some PT schemes on infectious diseases are operated by NIH and RMsC.	DMSc PT website. <a href="http://www.dmsc.moph.go.th/nihexpert/home.php">http://www.dmsc.moph.go.th/nihexpert/home.php</a>
d. Are all laboratories enrolled in EQA program for the tests they perform to detect any of the ten priority diseases?	<p>Influenza-PCR : yes NIH is EQA provider for RMsC laboratories.</p> <p>Polio-Virus culture : no</p> <p>HIV-Serology: yes, DMSc is PT provider.</p> <p>TB-Microscopy: DMSc/DDC are provider</p> <p>Plasmodium-Rapid test : Yes, DMSc is provider</p> <p>Salmonella typhi &amp; enteritidis-culture: Yes, DMSc participate PT with EU. DMSc is provider for bacterial culture</p> <p>Ebola-PCR : yes, DMSc participate with WHO EQAS</p> <p>Dengue- test : Yes, DMSc is provider</p> <p>Lepto-Rapid test :no</p> <p>Melioidosis- Rapid test: no</p> <p>NIAH performs PT as follows</p> <ol style="list-style-type: none"> <li>1. Highly pathogenic avian influenza with Australian Animal Health Laboratory (AAHL) and OFFLU</li> <li>2. Brucellosis with EU PT (ANSES/ French Agency for Food, Environmental and Occupational Health</li> </ol>	Reports

Questions	Responses	Documents Required
	<p>&amp; Safety)</p> <p>3. Leptospira 24 serovas with Leptospirosis Reference Centre (The Netherlands), National Serology Reference Laboratory (Australia), International Leptospirosis Society and Animal Health and Veterinary Laboratories Agency (England)</p> <p>4. Salmonella spp. (8 species), Shigella spp. (4 species), Campylobacter spp. (2 species) with WHO external quality assurance system.</p> <p>For accredited tests regional laboratories participate in interlaboratory comparison with NIAH.</p>	<p>AI</p> <p>Rabies</p> <p>Bru.</p>
<p>4. How is laboratory data on zoonotic diseases shared between human and animal health laboratories? Are the two data systems interoperable? (please see related questions for Prevent 2- Zoonotic Disease)</p>	<p>There are no common platform for information sharing between human and animal health. Some selected diseases such as influenza, the surveillance data is shared on website.</p> <p>NIAH sends lab results of zoonotic diseases to Bureau of Disease Control and Veterinary Services, Department of Livestock Development. Then Bureau of Disease Control and Veterinary Services communicate to related organizations such as Department of Disease Control.</p>	<p>ThaiRabiesnet</p> <p>AI</p>
<p>5. Is Personal Protective Equipment available for laboratory staff?</p>	<p>Yes (both)</p>	

Questions	Responses	Documents Required
<p>a. How is availability of PPE tracked for laboratories?</p>	<p>The laboratories have to purchase the PPEs by themselves. There is an official procurement system.</p> <p>During pandemic outbreak PPE stockpiles are organized by DDC and Department of health service support.</p> <p>NIAH's PPE are financial supported by Thai government. There are general PPE central stock on NIAH website available for all lab staff, meanwhile, each lab is able to find the appropriate or particular PPE.</p>	<p>EID Strategies (Stockpiles)</p>
<p>b. Please describe training procedures for PPE use in national laboratories</p>	<p>The biosafety training is scheduled once a year. The guideline and video for training of PPE used are available on NIH website</p> <p>Biosafety and Biosecurity training is organized by NIAH for staff every year.</p>	<p>NIH.dmsc.moph.go.th Training programs and records (see AP: Biosafety and Biosecurity)</p>
<p>6. What biosecurity/biosafety training is provided to laboratory workers? (please see related technical questions for Prevent - Biosafety and Biosecurity)</p>	<p>Biosafety and Biosecurity training is organized by NIH for DMSc staff every year. The training course and train-the-trainer course is available. DMSc staff are trained to be trainer and provide training for hospital laboratory staff in regional areas.</p> <p>BRM toolkit is used for training, including BSC .</p>	<p>Training course content. Work plan and report.</p>

Questions	Responses	Documents Required
	In-house training and attend external course hold by the Biosafety Association (Thailand) and others.	
<b>Technical Questions:</b>		
<b>D.1.1 Laboratory testing for detection of priority diseases</b>		
<p>1. Is there a set of national diagnostic algorithms for performance of core laboratory tests that has been aligned with international standards (i.e. WHO, CLSI, OIE)?</p>	<p>The national algorithms are developed for priority diseases in line with international standards such as TB, HIV, Influenza, MERs-COV, dengue, Zika. There is a mechanism to develop national algorithm in response to the outbreak. For example, national guideline for Ebola virus detection and zika virus detection are developed by DMSc.</p> <p>Yes, there is. Most of our ten core tests have been aligned with OIE standard</p>	<p>Example of national guidelines  Influenza  TB  MERS-COV</p> <p>Influenza-PCR  คู่มือแนวทางการตรวจวินิจฉัย โรคติดเชื้ออุบัติใหม่ ทางห้องปฏิบัติการ ปี 2556, , ISBN 978-616-11-0311-8 หน้า 97-101,  Polio-Virus culture คู่มือการเก็บตัวอย่างและการส่งตรวจ สถาบันวิจัยวิทยาศาสตร์สาธารณสุข ปี 2558, หน้า 32-33,  HIV-Serology คู่มือแนวทางการตรวจวินิจฉัย โรคติดเชื้ออุบัติใหม่ ทางห้องปฏิบัติการ ปี 2556, , ISBN 978-616-11-0311-8 หน้า 119-124  TB-Microscopy คู่มือแนวทางการตรวจวินิจฉัย โรคติดเชื้ออุบัติใหม่ ทางห้องปฏิบัติการ ปี 2556, , ISBN 978-616-11-0311-8 หน้า 62-68  Plasmodium-Rapid test คู่มือแนวทางการตรวจวินิจฉัย โรคติดเชื้ออุบัติใหม่ ทางห้องปฏิบัติการ ปี 2556, , ISBN 978-616-11-0311-8 หน้า 91-96,  Salmonella typhi &amp; enteritidis-culture มีคู่มือ ประกอบการตรวจวินิจฉัยซัลโมเนลลา และ ชิเกลลา ปี 2536</p>

Questions	Responses	Documents Required
		<p>Ebola-PCR มี คู่มือการตรวจวินิจฉัย โรคติดเชื้อไวรัส อีโบล่า และ ไวรัสทางเดินหายใจตะวันออกกลาง ทางห้องปฏิบัติการ ปี 2558, ISBN 978-616-11-2710-7 หน้า 4-9</p> <p>Dengue- test มี คู่มือแนวทางการตรวจวินิจฉัย โรคติดเชื้ออูบตีใหม่ ทางห้องปฏิบัติการ ปี 2556, ISBN 978-616-11-0311-8 หน้า 135-140</p> <p>Lepto-Rapid test Yes คู่มือวิชาการโรคเลปโตสไปโรสิส , ISBN 978-616-11-2536-3 หน้า 55-63 , คู่มือแนวทางการตรวจวินิจฉัย โรคติดเชื้ออูบตีใหม่ ทางห้องปฏิบัติการ ปี 2556, ISBN 978-616-11-0311-8 หน้า 69-74</p> <p>Melioidosis - test มี</p> <p>OIE guidelines do not cover all selected diseases. The algorithms are developed in line with Australian animal health laboratory/CDC</p>
2. How many of the core tests for ten priority diseases are implemented effectively across the tiered laboratory network?	10	<p>Flu, HIV, Dengue, Salmonella typhi, TB, Mellioidosis, Leptospirosis, Malaria, Polio, Ebola (2016 questionnaire)</p> <p>*4 tests including Salmonella typhi, Lepto, Ebola, Dengue (2015 questionnaire for EID network)</p>
a. Of the tests that cannot be conducted, are there plans and timelines in place to gain this capacity within the next year?	- No. Since primary antibodies and control samples of the remaining 2 core tests (Nipah encephalitis virus and BSE) are limited.	Plan for yellow fever detection
b. Are there official agreements with labs outside of the country	Yes	Thai-US CDC MOU TOR (Thai-WHO) for WHO CC

Questions	Responses	Documents Required
for specialized testing not available in country?		Australian Animal Health Laboratory (AAHL).
3. Do labs have required equipment (based on the testing appropriate for the level in the tiered lab network) to support performance of core laboratory tests? No; Are maintenance contracts in place for key equipment and preventive maintenance implemented regularly?	<p>Yes, the laboratory is equipped according to the size and level of function. The preventive maintenance is usually performed regularly according to the laboratory quality standard. The maintenance usually done by company. Reference laboratories under DMSc is well equipped. All labs can perform molecular testing. Equipment maintenance is performed on regular basis.</p> <p>- Yes, RVRDCs have required equipment (based on the testing appropriate for the level in the tiered lab network) to support performance of core laboratory tests.</p> <p>- Yes, there are maintenance contracts in place for key equipment and preventive maintenance implemented regularly</p>	SOPs and records
4. How does the country ensure standardization of testing? Do national laboratories send out samples for testing validation of more local/regional labs?	<p>The laboratories has to participate in PT scheme. In case of new testing service DMSc will send out the sample for testing validation.</p> <p>Reference laboratories participate in international PT/EQA programs if available.</p> <p>Reference materials/ strains /specimens are available for test validation.</p>	<p>Records.</p> <p>(polio, EV71,Ebola)</p> <p>NIH Specimen Repository</p>

Questions	Responses	Documents Required
	<p>National lab. send specimen to CDC, WHO reference lab for testing validation when need.</p> <p>NIH has WHO reference labs, sending and receiving specimen is one of routine activities.</p> <p>Shipping are usually done by World Courier.</p> <ul style="list-style-type: none"> <li>- NIAH as inter-laboratory comparison provider send samples such as brucellosis, Salmonella spp., and H5N1 antigen and positive serum to RVRDCs to ensure standardization of testing.</li> <li>- Yes. OIE Regional Reference Laboratory for Foot and Mouth Disease in Southeast Asia</li> </ul> <p>And OIE Reference Laboratory for Brucellosis send samples to neighbouring countries for inter-laboratory proficiency testing.</p>	
<b>D.1.2 Specimen referral and transport system</b>		
<p>1. Is the specimen referral network documented for each of the tests necessary to detect and confirm etiologies of ten priority diseases?</p>	<p>Yes, the tier laboratory is documented in MoPH standard. The referral system is explained in Guideline for EID laboratory network, 2015, ISBN 978-616-11-2099-3 ).</p>	<p>MoPH standard</p> <p>Guideline for EID laboratory network, 2015.  <a href="http://nih.dmsc.moph.go.th/login/filedata/media2559_2.pdf">http://nih.dmsc.moph.go.th/login/filedata/media2559_2.pdf</a></p>
<p>2. Is there proof of functioning referral system available? For example, data on the number of</p>	<p>Yes.</p> <p>For example, the no. of sample submitted for dengue confirmation is 2.26/100,000 population.</p>	

Questions	Responses	Documents Required
isolates/samples submitted to national reference lab for key disease(s) per 100 000 population.	(Data from 2015, 142,925 clinical cases, 1475 referred sample)	
3. Please describe the system for specimen transport from intermediate/district levels to reference laboratories and national laboratories.	<p>Laboratories are classified by diagnostic capacities into 4 levels. Specimen are referred to higher capacity laboratory or to national laboratory for confirmation or outbreak investigation. The process for specimen collection, packaging and transportation are described in the Guideline for Specimen collection and Biosafety, 2014</p> <p>Field veterinarians and lab staff safely collect, pack and transport to NIAH and 8 RVRDCs.</p>	<p>Guideline for Specimen collection and Biosafety, 2014 .  <a href="http://nih.dmsc.moph.go.th/login/filedata/nih58.pdf">http://nih.dmsc.moph.go.th/login/filedata/nih58.pdf</a>  Guideline for EID laboratory network, 2015</p>
a. Are standardized SOPs in place for specimen collection, packaging, and transport?	<p>Yes.  Standard SOP for specific diseases are available such as Flu, Ebola, MERS-CoV.  The auxiliary regulation for packaging and transportation as well as national SOP is scheduled to issue in 2017.</p> <p>In general the procedures are described in Guideline for Specimen collection and Biosafety, 2014</p> <p>There are in NIAH's guideline (not exactly being SOPs).</p>	<p>Guideline for Specimen collection and Biosafety, 2014</p>

Questions	Responses	Documents Required
b. Is the specimen transport, eg, courier contracts supported by MOH or partners?	Yes. MoPH will provide support in case of outbreak investigation. In general, the hospital pay for the expense.	
4. Does the host country participate in a regional (international) laboratory network?	<p>Yes.</p> <ul style="list-style-type: none"> <li>Influenza</li> <li>Polio</li> <li>Measle and rubella</li> <li>AMR</li> <li>Dengue</li> <li>HIV</li> </ul> <p>NIAH participates in regional laboratory network such as ASEAN Laboratory Director's Forum.</p>	<p>Influenza-PCR (WHO Influenza Regional Reference Laboratory in SEAR)</p> <p>Polio-Virus culture (WHO Polio Regional Reference Laboratory in SEAR)</p> <p>HIV-Serology (WHO HIV-DR)</p> <p>TB-Microscopy : no</p> <p>Plasmodium-Rapid test (IC) :no</p> <p>Salmonella typhi &amp; enteritidis-culture : no</p> <p>Ebola-PCR : no</p> <p>Dengue-Rapid test no</p> <p>Lepto-Rapid test : no</p> <p>Melioidosis- Rapid test: no</p> <p>ASEAN lab network</p>
<b>D.1.3 Effective modern point of care and laboratory based diagnostics</b>		
1. Is there a plan in place to improve the availability of point of care diagnostics at clinical sites in the country?	<p>Yes,</p> <p>MoPH 20-year master plan focuses on value based healthcare. Thus, POCT is one of the issues that support this policy.</p> <p>Actually, NIAH and RVRDCs occupy the area of the whole country which the specimens are able to send to the lab within 1 day, however, if there is an emerging dangerous unknown case NIAH has a mobile diagnostic lab (car) to perform diagnosis at</p>	Policy for POCT

Questions	Responses	Documents Required
<p>2. Does the MoH/MoA have in-country production and/or procurement processes for acquiring necessary media and reagents for performance of core laboratory tests?</p>	<p>outbreak site within 1 day.</p> <p>Procurement process is under government regulations. The procurement must be planned in advance for budget allocation. The reagent specification must be documented if the purchase order is higher than 500,000 THB.</p> <p>NIH is able to produce media and reagents for some tests such as leptospirosis.</p> <p>Yes, NIAH produce reagents compose of antigen and antiserum of H5N1 and H7N9; serum panel of brucellosis; and antigens of <i>Haemophilus paragallinarum</i> and <i>Actinobacillus pleuropneumoniae</i>.</p>	
<p><b>D.1.4 Laboratory Quality System</b></p>		
<p>1. Is there a national body in charge of laboratory licensing?</p>	<p>Department of Health service support has duty to license the private laboratories. No licensing required for government laboratories.</p> <p>Bureau of laboratory quality standard has duty to license the laboratory under Pathogen and animal toxin act.</p> <p>Gaps Licensing by technical competency is not fully applied.</p>	<p>SANATORIUMS ACT, B.E. 2541 (1998) <a href="http://web.krisdika.go.th/data/outsidedata/outside21/file/Sanatoriums Act B.E. 2541.pdf">http://web.krisdika.go.th/data/outsidedata/outside21/file/Sanatoriums Act B.E. 2541.pdf</a></p> <p>Translation version for 2016 revision is not available.</p>

Questions	Responses	Documents Required
1. Is there a national body in charge of laboratory inspection?	Bureau of laboratory quality standard, Ministry of Public Health is in charge of laboratory inspection by MoPH standard and ISO 15189. Bureau of laboratory quality standard has duty to inspect the laboratory under the Pathogen and animal toxin act, 2558 B.E.(2015).	MoPH Policy
a. If yes, please describe the inspection mechanism (frequency, procedures, sanctions, etc.)	BLQS will perform laboratory inspection once a year by onsite audit or self-assessment report.  The inspection mechanism is voluntarily conducted through ISO/IEC 17025 every year.	
3. Is there a national body in charge of laboratory certification (e.g. using ISO 9001)?	yes	
a. If yes, please provide name(s).	Thai industrial standard Institute is an agency in charge of laboratory certification by ISO standards.	Web site
4. Is there a national body in charge of laboratory accreditation (e.g. using ISO 15189)?	yes	
a. If yes, please provide name(s).	TISI designates BLQS to be a national body in charge of ISO 15189 accreditation.	<a href="http://dmsc2.dmsc.moph.go.th/webroot/qa/webblqs/asp/qaMain.asp">http://dmsc2.dmsc.moph.go.th/webroot/qa/webblqs/asp/qaMain.asp</a>
b. If no, do laboratories use services of foreign national or regional accreditation bodies?	-	
c. If yes, please provide name(s).	-	
5. Are some laboratories accredited for disease-specific	Yes Thailand has 21 laboratories designated as WHO	<a href="http://www.newccet.org/about-us.php">http://www.newccet.org/about-us.php</a>

Questions	Responses	Documents Required
testing by WHO (e.g. polio, measles, HIV genotyping)?	<p>CCs and 40 excellence centers.</p> <p>NIH is accredited by WHO as a CC for</p> <ul style="list-style-type: none"> <li>- Poliovirus</li> <li>- MMR</li> </ul> <p>NIH is accredited by WHO as RIRL for Influenza.</p> <p>TRC-EID at King Chulalongkorn Memorial Hospital is designated as WHO CC for Research and Training in Viral Zoonoses.</p> <p>Yes, brucellosis lab of NIAH was accredited by OIE to be OIE Reference Laboratory for brucellosis.</p>	
6. Please provide number of laboratories certified or accredited and specify to which standard.	<ul style="list-style-type: none"> <li>- ISO 15189 - 156 labs</li> <li>- ISO 17025 -251 labs</li> <li>- MOPH Standard - 521 labs</li> <li>- Accredited reference material producer complying with the ISO Guide 34: 2009 - 1 lab</li> <li>- National standard on H1N1 - 6 labs</li> <li>- Health check up laboratories for Health workers 50</li> <li>- FDA border check point labs 9</li> <li>- Labs for pesticide residues in food and vegetables - 28 labs</li> </ul> <p>NIAH and 7 RVRDCs were accredited by Bureau of Laboratory Quality Standards for ISO/IEC 17025: 2005 and certified by Office of Certification body for ISO 9001: 2008</p>	<a href="http://webdb.dmsc.moph.go.th/ifc_qa/dbqa/default.asp?iID=LEDGD">http://webdb.dmsc.moph.go.th/ifc_qa/dbqa/default.asp?iID=LEDGD</a>

Questions	Responses	Documents Required
7. Is there a specific national document which describes the registration procedure for in vitro diagnostic medical devices (IVD, i.e. kits and reagents)?	<p>Medical Device Act BE 2551</p> <p>Yes, there is a Medical Device Act B.E. 2551 (2008).</p>	
8. Is there a national regulatory authority responsible for in vitro diagnostic device (e.g. reagents) qualification or registration?	<p>Yes, Thai FDA is regulatory body.</p> <p>DMSc is national reference laboratory performing validation for selected IVD, i.e., HIV and HBs.</p>	<p>FDA Circulars.</p>
a. If yes, please provide a summary of the qualification or registration mechanisms.	<p>FDA document: 3.1 Importing of General Medical Devices (10 August 2010)</p>	<p>FDA Circulars</p> <ul style="list-style-type: none"> <li>- 3.1 Importing of General Medical Devices (10 August 2010)</li> <li>- Recommendation for application of license for Production and import IVD related to detection of HIV infection. คำแนะนำการขออนุญาตผลิต นำเข้า ชุมตรวจที่เกี่ยวข้องกับการติดเชื้อเอชไอวี</li> </ul>
9. Besides the inspection, certification or accreditation detailed above is any other kind of supervision organized?	<p>Yes. Bureau of Program inspection and Evaluation set up inspection program based on situation or policy.</p> <p>Performance agreement is a mechanism used for plan implementation.</p> <p>FAO has established a tool namely Laboratory Mapping Tool (LMT) for inspection NIAH and RVRDCs in Thailand and other veterinary lab in ASEAN.</p>	

Questions	Responses	Documents Required
<p>a. If yes or partial, describe the supervision plan and procedures (e.g. through specific networks like TB control programme or surveillance programmes)</p>	<p>MoPH develops regular inspection program. The inspection programs are customized as needed.</p> <p>The priority programs are selected to be KPI of high level management.</p> <p>FAO has conducted training for NIAH and RVRDCs to perform self-assessment every year</p>	
<p>10. Are there standardized supervision checklists or procedures?</p>	<p>Yes.</p> <p>BLQS develops checklist on quality management system for audi inspection and self assessment.</p> <p>Yes, it is LMT as mentioned above.</p> <p>Gaps</p>	
<p>11. When supervised, do the laboratories receive a report after each supervision?</p>	<p>Yes</p>	
<p>12. Are there indicators to measure the progress in laboratory test quality? Please list these indicators</p>	<p>No.</p> <p>However, accreditation bodies monitor the performance by IQC and PT results. The surveillance audits are performed on regular basis. There are indicators for lab accreditations.</p> <p>- NIAH has passed PT as follows: highly pathogenic avian influenza with Australian Animal Health</p>	

Questions	Responses	Documents Required
	<p>Laboratory and OFFLU : brucellosis with EU PT (ANSES/ French Agency for Food, Environmental and Occupational Health &amp; Safety): Leptospira 24 serovas with Leptospirosis Reference Centre (The Netherlands), National Serology Reference Laboratory (Australian), International Leptospirosis Society and Animal Health and Veterinary Laboratories Agency (England); and Salmonella spp. (8 species), Shigella spp. (4 species), Campylobacter spp. (2 species) with WHO external quality assurance system.</p> <ul style="list-style-type: none"> <li>- NIAH and 7 RVRDCs were accredited by Bureau of Laboratory Quality Standards for ISO/IEC 17025: 2005 and certified by Office of Certification body for ISO 9001: 2008.</li> <li>- We perform inter-laboratory comparison between NIAH and RVRDCs to ensure standardization of testing.</li> </ul>	
<p>13. Does your country have a national EQA programme (proficiency-testing or rechecking) in the following areas:</p> <ul style="list-style-type: none"> <li>a. Bacteriology?</li> <li>b. Virology?</li> <li>c. Serology?</li> <li>d. Parasitology?</li> <li>e. Biochemistry</li> </ul>	<ul style="list-style-type: none"> <li>a. Bacteriology? – yes [ AMR, (NIH) , culture, gram stain, AFB stain (BLQS)].</li> <li>b. Virology? –yes [ Measles, Dengue , HIV (DNA 13 labs, Serology ที่วปท., Seq 15 labs) , Flu + Avian flu (NIH)]</li> <li>c. Serology? – yes [HBV, HCV EQA (NIH)</li> <li>d. Parasitology–yes ( malaria thick thin film), helminths and protozoa (BLQS)</li> <li>e. Biochemistry – yes[BLQS].</li> <li>f. Haematology? – yes.[BLQS}</li> </ul>	<p>PT website</p>

Questions	Responses	Documents Required
f. Haematology? g. Anatomical pathology? h. Cytogenetic? i. Transfusion medicine?	g. Anatomical pathology? – interlab. comparison h. Cytogenetic? – interlab. comparison i. Transfusion medicine? – yes [BLQS (EQA ABO grouping , Rh(D) grouping, unexpected antibody screening test and unexpected antibody identification test)]	
14. Please describe the national EQA programme/s organization by providing for each: name of the programme, contact person/s, one line of description.	PT website  Hematology programme is organized by External quality Assessment Group, Bureau of Laboratory Quality Standards, Department of Medical Sciences.	
15. If applicable, is participation in national EQA programmes/s mandatory for public laboratories?	No. However, PT and EQA is essential element in quality system. Participation is enforced through accreditation.  It is voluntary.	
16. If applicable, is participation in national EQA programmes/s mandatory for private laboratories?	No. However, PT and EQA is essential element in quality system. Participation is enforced through accreditation. For competitiveness private laboratories participate in EQA Programs.  It is voluntary.  Gaps	

Questions	Responses	Documents Required
	No systematic monitoring and control mechanism.	
17. Percentage of public laboratories participating in the national EQA scheme (EQAS)?	70 % -	<a href="http://webdb.dmsc.moph.go.th/ifc_qa/dbqa/default.asp?iID=FFGKKJ">http://webdb.dmsc.moph.go.th/ifc_qa/dbqa/default.asp?iID=FFGKKJ</a>
18. Percentage of private laboratories participating in the national EQAS?	No data available	
19. Are corrective actions organized when assessment result is poor?	Yes. PT provider will contact the participants for corrective action if necessary as stated in ISO17043	ISO 17043 SOP from PT provider

**Key Stakeholders (list them):**

- Department of Medical Sciences, Ministry of Public Health
- Department of Disease control, Ministry of Public Health
- Department of Health Service Support, Ministry of Public Health
- Department of Medical Service, Ministry of Public Health
- Food and Drug Administration, Ministry of Public Health
- Department of livestock Development, Ministry of Agriculture
- University hospital laboratories
- WHO Collaborating Centers/Reference laboratories
- Ministry of Science and Technology
- WHO
- US CDC