

Laboratory system for HIV, hepatitis and syphilis in the Philippines

The National Reference Laboratory San Lazaro Hospital/STD, AIDS Cooperative Central Laboratory (NRL/SACCL) and Research Institute for Tropical Medicine (RITM) provided information on laboratory system for HIV, hepatitis and syphilis in the Philippines.

Coordination: There is a national body responsible for HIV, hepatitis and syphilis testing. The laboratories conducting HIV, hepatitis and syphilis testing are registered and licensed, and the licenses are reviewed periodically. For clinical laboratories, on-site visit is not required for registration.

Equipment and reagents: There is a national authority responsible for test kit qualification and registration for HIV, hepatitis and syphilis and an “approved” list of kits is available and the use of these kits has been monitored. Laboratories experienced difficulties in maintaining appropriate stocks of test kits partially.

Quality Management System (QMS): Quality standards for HIV, hepatitis and syphilis are in place. All clinical laboratories and over 60% of blood transfusion laboratories have quality managers and standard operating procedures (SOPs) for analytical methods, equipment maintenance and training of laboratory staff.

QMS assessment: There are national bodies to inspect/audit laboratories and for accreditation of laboratory.

External Quality Assurance Scheme (EQAS): NRL/SACCL coordinates national EQAS for clinical laboratories on HIV, hepatitis and syphilis once a year by distributing five samples. RITM coordinates national EQAS for blood service facilities on HIV, hepatitis and syphilis once a year by distributing 20 samples.

Staff education and training: Laboratory workers are licensed and/or registered and continuous access to training is possible for both clinical and blood service laboratory workers.

Area	System or activity	HIV	HBV/HCV	Syphilis
Coordination	National body responsible for laboratory activities	Yes	Yes	Yes
Licensing of laboratories	System for laboratories be registered/licensed to conduct testing	Yes	Yes	Yes
	License awarded after on-site visit	No (Yes)*	No (Yes)*	No (Yes)*
	License periodically reviewed	Yes	Yes	Yes
Equipment and reagents	National regulatory authority for test kit qualification/registration	Yes	Yes	Yes
	Donors' kits go through registration process	Yes	Yes	Yes
	List of 'approved' or 'registered' kits	Yes	Yes	Yes
	System to monitor use of 'non-approved' or 'non-registered' kits	Yes	Yes	Yes
	Kits need periodic re-qualification/re-registration	Yes	Yes	Yes
	Laboratories experience 'stock outs' of test kits or reagents	No (Private) Partial (Public)	No (Private) Partial (Public)	No (Private) Partial (Public)
National standards	National general quality norms/sets of standards established	Yes	Yes	Yes
Quality Management System (QMS)	Percentage of laboratories with quality manager	100% (85%)*	100% (85%)*	100% (85%)*
	Percentage of laboratories with SOPs for analytical methods	100% (85%)*	100% (85%)*	100% (85%)*
	Percentage of laboratories with SOPs for maintenance of equipment and reagent	100% (85%)*	100% (85%)*	100% (85%)*
	Percentage of laboratories with SOPs for employing, training and re-training staff	100% (60%)*	100% (60%)*	100% (60%)*
	Percentage of laboratories with corrective action systems	100% (60%)*	100% (60%)*	100% (60%)*
QMS assessment	National body in charge of laboratory inspection/audit	Yes	Yes	Yes
	Name of national body for inspection	Health Facilities and Services Regulatory Bureau (HFSRB)		
	National body in charge of laboratory accreditation	Yes	Yes	Yes
	Name of national body for Accreditation	Philippine Accreditation Bureau		
External Quality Assurance Scheme (EQAS)	Coordination of national EQAS	Yes	Yes	Yes
	Distribution times per year	1	1	1
	Number of samples included in each distribution	5 (20)*	5 (20)*	5 (20)*
	EQA reports reviewed at central level	Yes	Yes	Yes
	Corrective actions organized by the laboratory when EQA results are poor	Yes	Yes	Yes
Staff education and training	Licensing/registration of laboratory workers for testing	Yes	Yes	Yes
	Mandatory continuous education/training to re-new licensing/registration	Yes	Yes	Yes
	Access to suitable continuous education/training for laboratory workers	Yes	Yes	Yes

()* for blood screening laboratories