GUIDELINES FOR LABORATORY PERFORMING HIV TESTING

GENERAL

1 A clinical laboratory intending to perform HIV testing must obtain prior approval from the Ministry of Health (MOH) and the institution must first be licensed by MOH under the Private Hospitals and Medical Clinics Act .

2 Application for approval of clinical laboratory for HIV Testing shall be made to the Director of Medical Services, Ministry of Health (Attention: Regulatory Compliance Division, Health Regulation Group, 16 College Road Singapore 169854) on the Application Form prescribed. The application form must be submitted to the Director not less than 90 days before the intended commencement of the service.

3 Clinical laboratory approved to perform HIV testing shall be subjected to regular inspections by appointed MOH assessors. The Director may in his discretion refuse to issue or withdraw the approval to perform HIV testing as he may think fit to impose.

PERSONNEL

4 The laboratory manager shall be

a a person with a degree in medicine or a basic degree in a relevant science subject that is acceptable to the Director; and

b at least 5 years' relevant working experience in a clinical laboratory acceptable to the Director.

5 There shall be at least one trained person who satisfies one of the following requirements:

a A degree in medical laboratory technology acceptable to the Ministry of Health and 3 years relevant working experience in a clinical laboratory acceptable to the Ministry of Health, **OR**

b A pass in the Departmental Qualifying Examination of the Ministry of Health acceptable to the Ministry of Health and 3 years relevant working experience in a clinical laboratory acceptable to the Ministry of Health **OR**

c A diploma in Medical Laboratory Technology acceptable to the Ministry of Health and 3 years relevant working experience in a clinical laboratory acceptable to the Ministry of Health

FACILITIES AND EQUIPMENT

6 All facilities and equipment shall be adequate for the proper and efficient performance of the tests provided. Maintenance manuals for all laboratory equipment shall be available in the laboratory. These shall include regular maintenance to be performed on each piece of equipment, documentation of maintenance completed and corrective action taken, if any.

LABORATORY SAFETY

7 Procedures and policies on laboratory safety must be available to all laboratory personnel, and shall be reviewed annually. Laboratory personnel are required to comply with existing guidelines for laboratories and guidelines on infection control in Singapore (e.g "Guidelines For Preventing Transmission Of Bloodborne Infections In A Health Care Setting 2000").

8 Every clinical laboratory shall ensure that all infectious waste materials are properly disinfected and disposed of in accordance with laws such as those administered by the National Environment Agency and the Ministry of Health, and any other existing laws.

PRACTICES

9 Laboratory shall ensure that only properly labelled blood samples obtained at licensed healthcare institutions, including hospitals and medical clinics are accepted for testing. Laboratory shall not accept samples directly from employer or employment agency.

10 Accredited laboratories for HIV testing must not carry out HIV tests on walk-in patients who have not seen a doctor, unless the medical laboratory is staffed with a registered medical practitioner who can conduct the pre and post HIV test counselling and obtain the necessary consent. This is to ensure that all persons undergoing a HIV test are fully aware of the implications of the test results.

11 If blood is taken at the laboratory, there shall be in place a system for verification of identity of the person undergoing HIV testing. The policy and procedure for such verification must be available to all laboratory personnel.

12 All blood samples for HIV test must be properly labelled and securely covered and placed in a plastic biohazard labelled bag.

13 Samples reactive for HIV screening test must be repeated and repeated reactive samples and those with equivocal results must be referred to the

National HIV Reference Laboratory, Department of Pathology, Singapore General Hospital for confirmation. The reactive results of the HIV screening test are not to be released to the patient or the referring doctor before they are confirmed by the National HIV Reference Laboratory. Laboratories shall also ensure that a sufficient amount of blood is taken for the HIV screening test so that there is a sufficient amount of the blood sample **(at least 1.5 cc of serum/plasma)** to be sent to the National HIV Reference Laboratory for confirmatory tests should the HIV screening test produce reactive results.

14 The laboratory shall not pool sera for HIV testing.

QUALITY ASSURANCE

15 The laboratory shall have a Quality Assurance Programme which shall include:

a Quality control activities
b Written test protocol
c Evaluation of new reagents and test methods. (e.g to run parallel testing of 100 samples to permit a comparison of the performance of the proposed methodology to that of the one it is designed to replace)
d Maintenance of equipment and instruments.

16 A volume of some 100 tests per quarter is necessary to ensure consistency in competence.

17 The laboratory must participate in the Proficiency Testing for HIV programme conducted by the National HIV Reference Laboratory.

REQUEST FORM

18 Laboratories must ensure that all blood samples sent to the National HIV Reference Laboratory (NHRL) for confirmatory test are properly labelled. The accompanying Laboratory Request Form shall have the following information: (i) the name of the person from whom the specimen was taken, (ii) age, (iii) national registration identity card number/passport number and address.

RECORDS

19 The laboratory shall maintain a record of all specimens received (with NRIC/Passport numbers) and the results of all tests shall be retained for an appropriate period of time.

20 The laboratory shall submit quarterly returns on the HIV tests done via the online National Public Health Unit Registry System (NPHURS). Such returns shall be in the format prescribed in Annex A.

NOTIFICATION

21 All confirmed HIV positive cases must be notified to MOH on the MD131 form via the online Communicable Diseases Live and Enhanced Surveillance System (CD-LENS) (www.cdlens.moh.gov.sg) or by fax (6221 5528, 6221 5538 or 6221 5567).

22 The clinical laboratory shall abide by all guidelines and policies as required by the Director of Medical Services, MOH.

Annex A

APPROVAL OF LABORATORY FOR HIV TESTING
QUARTERLY RETURNS

Name of Laboratory .....

Months/Year .....

Table 1 **Countries**	**Sex**	**Total Number of HIV Tests Done**	**Total Number Reactive (Screening Tests)**	**Total Number Confirmed by National HIV Reference Laboratory (Dept of Pathology, SGH)**
SINGAPOREANS	M			
	F			
BANGALDESH	M			
	F			
BRUNEI	M			
	F			
CHINA PR	M			
	F			
HONG KONG	M			
	F			
INDIA	M			
	F			
MALAYSIA	M			
	F			
PHILIPINES	M			
	F			
SRI LANKA	M			
	F			
THAILAND	M			
	F			
OTHERS (SPECIFY)	M			
	F			

This is to confirm that the above information is correct to the best of my knowledge and that my laboratory does not pool sera for HIV antibody testing, and that HIV reactive sera are not reported as non-reactive.

Name & Signature of Laboratory Director/Manager .....

Date .....

Submission of HIV Quarterly Returns

Please submit the HIV quarterly returns online via the National Public Health Unit Registry System (NPHURS). Should you require any clarifications, please contact the following persons:

NPHEU, MOH

Mr Patrick Sim Zhi Wei (sim_zhi_wei@moh.gov.sg), Tel: 6359 6939
Ms Amanda Li Jia Hui (Li_Jiahui@moh.gov.sg)
Ms Nilufer Banu (Nilufer_BANU@moh.gov.sg)
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eLIS@moh.gov.sg