ORIGINAL ARTICLE VIROLOGY

The current status of HIV screening laboratories in Korea assessed by a questionnaire survey of participants in the KCDC HIV EQAS (2006)

J-S. Wang[1,2], M. K. Kee[1], H-S. Kim[3], B-S. Choi[1], S-D. Suh[1], E-J. Kim[1], C-W. Kim[2] and S. S. Kim[1]

1) *Division of AIDS, Centre for Immunology and Pathology, Korea National Institute of Health, Nok-bun, dong Eunpyung-Gu,* 2) *Graduate school of Biotechnology, Korea University, Anam-dong seongbuk-Gu and* 3) *The Korean Society for Laboratory Medicine, Quality assurance committee, Seoul, South Korea*

Abstract

Using a questionnaire, we assessed the current status of the quality management systems at HIV screening laboratories in Korea. The Korea Centres for Disease Control and Prevention HIV external quality assurance scheme (EQAS) questionnaire includes 18 items divided into five groups related to HIV testing: personnel, HIV test processes, participation in the Quality Assurance programme and HIV testing equipment. Five hundred and sixty-one HIV screening laboratories participated in this questionnaire investigation; data were collected from 233 public health centres, 309 hospitals or clinics, eight blood centres and 11 commercial laboratories. The total number of HIV screening tests was about 5.5 million in 2005. The average number of HIV tests per institution was highest in blood centres (308 561), followed by commercial laboratories (56 084), hospital or clinic laboratories (6756), and public health centres (1751). Equipment and HIV test methods varied between HIV screening laboratories, and, to manage the quality of their HIV testing, most laboratories participated in several evaluation programmes such as EQAS or a laboratory accreditation programme. This study is the first questionnaire survey of HIV testing laboratories in Korea. The results could be used to evaluate and promote the quality management of HIV testing laboratories.

Keywords: HIV EQAS programme, HIV testing laboratory, questionnaire survey
Original Submission: 8 September 2008; **Revised Submission:** 1 December 2008; **Accepted:** 2 December 2008
Editor: E. Gould
Article published online: 27 May 2009
Clin Microbiol Infect 2010; **16:** 482–487
10.1111/j.1469-0691.2009.02835.x

Corresponding author and reprint requests: S.-S. Kim, Division of AIDS, Centre for Immunology and Pathology, NIH Korea, National Institute of Health, 5 Nok-bun, dong, Eunpyung-Gu, Seoul 122-701, Korea
E-mail: sungskim@nih.go.kr

Introduction

Since the US Food and Drug Administration approved ELISA diagnosis kits for donor screening in 1985 [1], various types of test kits and equipment have been developed for detecting and quantifying HIV and adopted according to each laboratory's conditions and requirements. These HIV test methods have been developed rapidly compared with other diagnostic testing kits. Screening tests have been conducted for high-risk groups in Korea since the first case of HIV infection was identified in 1985 [2]. Blood centres have tested all donated blood since 1987, and public health centres have tested all blood since 1992 [3,4]. The number of HIV screening tests conducted at hospitals or clinics has been increasing gradually, and five to six million tests are estimated to be performed each year in Korea. The number of HIV cases has also increased gradually, and the accumulated number up to 2006 stands at 4580 [5].

Until 2005, the HIV testing strategy in Korea was a three-step process, in which positive results at public health centres, private medical centres such as hospitals or clinics, and blood centres (which collect and test blood for donations) were checked by the Local Institutes of Public Health and Environment (LIHEs) for public health centres and hospitals and the Blood Transfusion Research Institute (BTRI) for blood centres and finally confirmed by the Korea Centres for Disease Control and Prevention (KCDC). This was reduced to two steps from 2006 by empowering LIHEs to make the final decision on HIV test results [6].

The reliability of an HIV test result is essential because of the implications for the individual and for society. HIV testing laboratories are actively involved in the HIV external quality assurance scheme (EQAS), begun in 1989 [7], which provides the opportunity to review every stage of the testing process: receiving samples, analysis, laboratory testing strategies,

and reporting of test results. By comparing results between laboratories, EQAS shares information on diagnostic kits and laboratory environments, and allows the laboratories themselves to assess their procedures. Because HIV prevalence is relatively low [8], HIV-positive results are rare in Korean laboratories. Therefore, laboratories can improve their testing skills and abilities by participating in the EQAS programme for testing various samples for anti-HIV or antigen titre. From 2005, 620 public and private HIV testing laboratories have participated in EQAS programmes twice a year [6].

This study analysed the results of a survey that participants completed during a 2006 HIV EQAS programme, to assess the current state of HIV testing laboratories. In addition, it can provide reference data for future EQAS programmes and development of a national HIV testing policy in Korea.

Materials and Methods

Data collection and participating laboratories

The survey included 615 HIV laboratories that participated in the 2006 HIV EQAS Programme. The survey was conducted from 12 June to 14 July and was co-sponsored by the KCDC and the Korean Society for Laboratory Medicine (KSLM). The survey was conducted online through the HIV laboratory quality assurance website (http://hivqa.nih.go.kr). Responses were received from 561 out of 583 screening laboratories: 233 public health centres, 309 hospitals or clinics, eight blood centres and 11 commercial laboratories. Four HIV counselling services, 17 LIHEs and one BTRI were excluded because this study was aimed at primary HIV testing laboratories.

Questionnaire survey

The survey asked questions about five main HIV-related topics: (i) the number of HIV tests, methods and positivity rate; (ii) the status, training and experience of the personnel in charge of the HIV testing and their participation in the quality assurance (QA) programme; (iii) HIV testing equipment, automation and monitoring; (iv) practicalities of HIV testing procedures, including retesting of positive and borderline results, external confirmation of positive results, and reporting results; and (v) internal quality control (IQC).

Results

The number of HIV tests and methods

The average number of HIV screening tests per year and the testing methods of each laboratory are shown in Table 1. The average annual number of HIV tests was 308 561 at blood centres, 56 056 at commercial laboratories, 6756 at hospitals or clinics, and 1751 at public health centres. Each laboratory adopted a testing method suitable to its particular conditions. The highest rate of HIV-positive results came from hospitals or clinics, at 0.22%.

The personnel in charge of the HIV testing and participation in the QA programme

Nearly all (99.1%) of those in charge of HIV testing in the laboratories were medical technologists. In public health centres they had an average of 7.7 years of experience, which was greater than that seen in the other organizations. The average job rotation duration was longest at public health centres (4.1 years). More than half of all staff at public health centres participated in HIV-related training (education). Also, 57.9% of all HIV laboratories participated in the EQAS Programme of the Korean Association of Quality Assurance of Clinical Laboratories, while 43.3% of all HIV laboratories participated in the laboratory certification programme of the KSLM. Ten laboratories were enrolled in the College of American Pathology, eight in the ISO 9002, and one in the ISO 9000 certification programmes (Table 2).

TABLE 1. Average number of HIV tests and preliminary results according to the test method used in HIV screening laboratories in 2005

Test method	Public health centres			Hospital or clinic laboratories			Blood centres			Commercial laboratories		
	No. laboratories (%)[a]	Average no. HIV tests[b]	Preliminary positive % (mean ± SD)[c]	No. laboratories (%)[a]	Average no. HIV tests[b]	Preliminary positive % (mean ± SD)[c]	No. laboratories (%)[a]	Average no. HIV tests[b]	Preliminary positive % (mean ± SD)[c]	No. laboratories (%)[a]	Average no. HIV tests[b]	Preliminary positive % (mean ± SD)[c]
Total	233	1751	0.16 ± 0.70	309	6756	0.22 ± 1.56	8	308 561	0.09 ± 0.04	11	56 056	0.04 ± 0.03
ELISA	147 (63)	1990	0.21 ± 0.86	235 (76)	8434	0.24 ± 1.76	8 (100)	308 561	0.09 ± 0.04	10 (90)	60 462	0.04 ± 0.09
PA	56 (24)	1422	0.04 ± 0.08	9 (3)	2481	0.21 ± 0.43	–	–	–	–	–	–
RT	30 (13)	1193	0.13 ± 0.37	65 (21)	1283	0.14 ± 0.48	–	–	–	1 (10)	12 000	0.01 ± 0.00

PA, particle agglutination test; RT, rapid test.
[a]No. labs (%): the number of laboratories (percentage).
[b]Average no. HIV tests: the average number of HIV tests performed by each laboratory in 2005.
[c]Preliminary positive % (mean ± SD): the percentage of positive results for HIV screening tests per year.

TABLE 2. Characteristics of HIV testing personnel and quality assurance programmes for HIV screening laboratories (2006)

Items	Public health centres (*n* = 233)	Hospital/clinic labs (*n* = 309)	Blood centres (*n* = 8)	Commercial laboratories[a] (*n* = 11)
Personnel status				
Number of medical technologists (%)	232 (99.6%)	305 (98.7%)	8 (100%)	11 (100%)
Period of service (years)	7.7 ± 5.47	5.0 ± 4.15	3.0 ± 1.20	3.7 ± 2.61
Period of job rotation (years)	4.1 ± 2.26	2.7 ± 1.85	3.5 ± 1.69	1.9 ± 1.04
Participation in on-the-job training (%)[b]	168 (72.1%)	140 (45.3%)	8 (100%)	9 (81.8%)
Participation in quality assurance education[c]	127 (54.5%)	123 (39.8%)	8 (100%)	5 (45.5%)
EQAS by				
KCDC (KNIH)	233 (100%)	309 (100%)	8 (100%)	11 (100%)
KAQACL	27 (11.6%)	279 (90.3%)	8 (100%)	11 (100%)
CAP in USA	–	6 (1.9%)	–	4 (36.4%)
Blood Research Institute	–	–	7 (87.5%)	–
Acquisition of certification				
Yes[d]	0	227 (73.5%)	6 (75%)	11 (100%)
No	233 (100%)	82 (26.5%)	2 (25%)	–
Certified (or accredited) by				
KSLM	–	227 (73.5%)	4 (50%)	11 (100%)
CAP in USA	–	6 (1.9%)	–	4 (36.4%)
ISO9000	–	–	1 (12.5%)	–
ISO9002	–	4 (1.3%)	4 (50%)	–

KCDC, Korea Centres for Disease Control and Prevention; KNIH, Korea National Institute of Health; KAQACL, The Korean Association of Quality Assurance for Clinical Laboratory; KSLM, The Korean Society for Laboratory Medicine; CAP, College of American Pathologists; EQAS, external quality assurance scheme.
[a]Commercial laboratory: commercial clinical laboratories.
[b]On-the-job training: HIV-related theory or practice education.
[c]Quality assurance education: HIV-related quality control or EQAS education.
[d]Some laboratories participated in more than one programme out of four programmes

HIV testing equipment

Table 3 shows the percentage of laboratories that used automated equipment: 90.9% of commercial laboratories, 75.1% of hospitals or clinics, 47.6% of public health centres, and 12.5% of blood centres. New equipment was purchased in the preceding 5 years by 72.7% of commercial laboratories, 53.7% of hospitals or clinics, 50% of blood centres, and 32.2% of public health centres. Testing equipment was not used in 31.8% of public health centres, 22.7% of hospitals or clinics, and 9.1% of commercial laboratories; these laboratories used the rapid test (RT) or particle agglutination (PA) assays.

Equipment was checked most often after failure in use. Regular equipment check-ups were performed at least three times a year at 80% of commercial laboratories, 62.5% of blood centres, 27.6% of hospitals or clinics, and 8.8% of public health centres (Table 4).

HIV testing procedures

HIV testing laboratories that implemented 'grey zones' (comprising specimens that gave a result approaching but below the cut-off value for positivity) most often were blood centres, followed by commercial laboratories, hospitals or clinics, and public health centres; 32.4% of the grey zone ranges were within 5% of the cut-off and 58.3% were within 10%. Most (77.8%) grey-zone samples were tested again by the same person and with the same kit (Table 5). Nearly all participants (97%) retested an HIV-positive result using the same sample again. Most positive samples were sent to a confirmatory institute; 84% of laboratories referred the sample to a confirmatory institute and kept the original sample in their laboratory for ≥1 day. The most common way of transporting samples (71.8%) was direct delivery by staff. A positive test result was seldom reported directly to the client or patient; only 5.7% of clients received a positive result directly, and in most cases the physicians received the results immediately after the screening or confirmatory tests.

Discussion

To provide reliable test results, HIV testing laboratories should participate in a QA system that covers discipline, management, personnel, equipment, standard operating procedures, IQC, and external quality assessment [9].

HIV testing laboratories participate in domestic or international HIV EQAS programmes to enhance and maintain their testing capacities. The US CDC and Australia's National Serology Reference Laboratory conduct international HIV EQAS programmes dedicated solely to HIV testing [10,11]. According to the national HIV policies in the USA and Australia, HIV testing should be carried out by HIV testing laboratories only if they meet certain standards [12,13]. The CDC Model Performance Evaluation Program (MPEP) evaluates the annual performance of laboratories using an HIV RT, and this programme includes an HIV-related questionnaire for programme participants. The MPEP provides data about the current status and practices of HIV testing labora-

TABLE 3. HIV testing equipment used by HIV screening laboratories (2006)

Automation	Manufacturer	Equipment name	Public health centres (*n* = 233)	Hospital/clinic laboratories (*n* = 309)	Blood centres (*n* = 8)	Commercial laboratories (*n* = 11)	Number of laboratories (%)[a]	Rate of sample process (%)[b]
Auto	ABBOT	AXSYM	12	87	–	–	99 (23.80)	8.35
		ARCHITECT	–	43	–	1	44 (10.58)	13.06
		IMX	–	7	–	–	7 (1.68)	0.21
Auto	BAYER	ADVIA CENTAUR	–	19	–	–	19 (4.67)	3.89
Auto	Beckman coulter	Access	14	1	–	–	15 (3.61)	0.6
Auto	Biomerieux	VIDAS	13	2	–	1	16 (3.85)	1.9
		Mini VIDAS	4	1	–	–	5 (1.20)	0.05
Auto	Biorad	EVOLIS	–	3	–	1	4 (0.96)	2.35
		CODA	2	14	–	1	17 (4.09)	2.31
Auto	Chemilla	Labotech	6	–	–	–	6 (1.44)	0.23
Auto	Dade Behring	BEP2000	1	3	–	–	4 (0.96)	0.49
Auto	DSX	Dynex	7	1	1	–	9 (2.16)	1.02
Auto	Dynatech	Dynatech MR-7000	3	–	–	–	3 (0.72)	0.11
Auto		DIAS	3	–	–	–	3 (0.72)	0.07
Auto	Ortho	Vitros-Eci	13	8	–	–	21 (5.05)	1.38
Auto	Roche	MODULAR E170	–	14	–	–	14 (3.37)	2.52
		Elecsys 2010	5	19	–	–	24 (5.77)	1.09
		COBAS-Core	–	2	–	–	2 (0.48)	0.04
Auto	Rosys	Plato 3300	23	–	–	–	23 (5.53)	0.32
Auto	SEAC	ALISEI	3	3	–	5	11 (2.64)	7.47
		Brio	1	3	–	–	4 (0.96)	1.39
		ARIO	1	–	–	–	1 (0.24)	0.04
Semi auto	Dade Behring	BEP II	13	–	–	–	13 (3.13)	0.39
		BEP II	9	4	–	–	13 (3.13)	1.74
Semi auto	Biotek	EL808	1	–	–	–	1 (0.24)	0.02
Semi auto	TECAN	SLT-TECAN	–	–	7	–	7 (1.68)	45.41
Semi auto	Rosys	Plato 1300	16	–	–	–	16 (3.85)	1.03
Manual	Molecular device	Versamax microplate reader	–	1	–	–	1 (0.24)	0.22
	Other manufacturers	other equipments	9	4	–	1	14 (3.37)	2.32
		Total (%)	159	239	8	10	416 (100)	100

[a]Number of laboratories (%): the number of laboratories using the target equipment.
[b]Rate of sample process (%): percentage of samples processed by the target equipment for all HIV tests performed in all institutions.

TABLE 4. Maintenance schedule of testing equipment in HIV screening laboratories (2006)

Items	No. (%) public health centres	No. (%) hospital or clinic labs	No. (%) blood centres	No. (%) commercial laboratories
Periodic check-up service (per year)	38 (23.9)	119 (49.8)	7 (87.5)	9 (90)
Once	14 (8.8)	22 (9.2)	1 (12.5)	0 (0)
Twice	10 (6.3)	31 (13.0)	1 (12.5)	1 (10)
Three times	14 (8.8)	66 (27.6)	5 (62.5)	8 (80)
Service for troubleshooting only	121 (76.1)	120 (50.2)	1 (12.5)	1 (10)
Total (%)	159 (100)	239 (100)	8 (100)	10 (100)

tories internationally and includes information about personnel, testing sites, facility types, testing kits, HIV testing algorithm, quality control, EQAS, and certification or accreditation programmes [14]. Our survey results provide comprehensive information on the HIV testing laboratories in Korea, and will enhance the existing HIV policies and practices in our country.

The personnel responsible for HIV testing was rotated more frequently in the laboratories of hospitals and clinics than in other testing facilities; the average duration of working in a testing laboratory in hospitals and clinics ranged from 6 months to 3 years. Because the diagnostic kits, testing methods and QA processes change faster for HIV tests than for other tests, staff need to update their knowledge by regularly attending training courses and programmes. Staff at blood centres participated in more HIV-related training programmes than personnel at any other institution. Staff from other institutions should be provided with more opportunities for regular training in up-to-date testing programmes.

In Korea, the diagnostic laboratories in hospitals must participate in the Laboratory Inspection and Accreditation Program from the KSLM with, every 1 or 2 years, laboratory visits by medical assessors. Public health centres also are accredited by LIHEs after site inspections. Many HIV laboratories are involved in diverse EQAS and laboratory certification or accreditation programmes to enhance their quality management.

More public health centres used outdated equipment than did other medical centres. Public health centres that perform few HIV tests have adopted the PA test or RT, which do not require any testing device. Most of the automated

TABLE 5. Management strategies for preliminary positive cases in HIV screening tests (2006)

Items	Public health centres *n* = 233 *n* (%)	Hospital/clinic laboratories *n* = 309 *n* (%)	Blood centres *n* = 8 *n* (%)	Commercial laboratories *n* = 11 *n* (%)
'Grey zone' setting institutes	68 (29.2)	133 (43.0)	8 (100)	8 (72.7)
The range of 'grey zone'				
Cut-off within 5%	23 (33.8)	46 (34.6)	–	1 (12.5)
Cut-off within 10%	43 (63.2)	76 (57.1)	2 (25.0)	5 (62.5)
Cut-off within 20%	1 (1.5)	5 (3.8)	4 (50.0)	–
Other	1 (1.5)	6 (4.5)	2 (25.0)	2 (25.0)
Test method for 'grey zone' sample				
With the same test kit by the same person	43 (63.2)	115 (86.5)	5 (62.5)	5 (62.5)
With another lot of the same test kit by the same person	6 (8.8)	5 (3.8)	–	–
With the same test kit by a different person	–	2 (1.5)	3 (37.5)	2 (25.0)
Other	19 (27.9)	11 (8.3)	–	1 (12.5)
Sample retested				
Yes	219 (94.0)	306 (99.0)	8 (100)	11 (100)
No	14 (6.0)	3 (1.0)	–	–
Retest with same sample				
With the same lot of the same test kit	179 (81.7)	251 (82.0)	7 (87.5)	10 (90.9)
With another lot of the same test kit	3 (1.4)	–	–	–
With a different kind of test kit (another assay)	20 (9.1)	8 (2.6)	–	–
By another person	1 (0.5)	2 (0.7)	–	–
Retest with re-sample	16 (7.3)	45 (14.7)	1 (1.25)	1 (9.1)
Referral institutes for HIV confirmation				
Local institute of health and environment	229 (98.3)	157 (50.8)	1 (12.5)	8 (72.7)
Public health centre	–	95 (30.7)	–	–
KCDC	3 (1.3)	22 (7.1)	1 (12.5)	1 (9.1)
Blood Research Institute	–	–	6 (75.0)	–
Commercial laboratory	–	34 (11.0)	–	1 (9.1)
Other	1 (0.4)	1 (0.3)	–	1 (9.1)
Deposit on referral sample				
Deposit	162 (69.5)	291 (94.2)	7 (87.5)	11 (100)
No deposit	71 (30.5)	18 (5.8)	1 (12.5)	–
Sample conveyance for confirmatory testing				
Personnel service directly from testing sites	185 (73.4)	204 (66.0)	3 (37.5)	11 (100)
Personnel service through commercial laboratories	–	85 (27.5)	–	–
Postal service (registered)	17 (7.3)	5 (1.6)	–	–
Door-to-door service (immediately)	2 (0.9)	15 (4.9)	–	–
Door-to-door service (via company)	29 (12.4)	–	5 (62.5)	–
Report of the test result in an HIV testing laboratory				
Provide the screening result to the doctor (medical team)	62 (26.6)	231 (74.8)	1 (12.5)	9 (81.8)
Provide the confirmatory result to the doctor	136 (58.4)	76 (24.6)	6 (75.0)	2 (8.2)
Provide the result to the patient directly	32 (13.7)	–	–	–
Other	3 (1.3)	2 (0.6)	1 (12.5)	–

diagnostic equipment currently in use is produced by a few large suppliers such as Abbot and Roche. There were no regular maintenance schedules for the equipment in some laboratories, and >50% of laboratories serviced the equipment only when it malfunctioned.

Blood centres set the 'grey zone' at a wider cut-off (>10%) to provide a safe blood supply. HIV-positive screening samples should be referred to LIHEs to confirm the test results. In practice, 30% of hospitals/clinics referred their reactive samples to public health centres or commercial laboratories for supplementary tests, which consumed additional time.

Greater attention is needed to ensure the safe transport of samples sent for confirmation. Korea adopts the standardized procedures the WHO set forth in its *Introduction to the transport of infectious substances* manual [15,16]. Overall, 87% of samples for final HIV confirmation were delivered by either personal service directly from the testing site or through a commercial laboratory and 13% were delivered by door-to-door and postal services. It is imperative to implement the international standards for transporting such samples to ensure safety.

There are some limitations to this study. First, we excluded detailed questions about the use of external quality control in this survey analysis, defining external QC as any other controls included in the test run that involved independent (separate) control of a kit's components. More than 45% of private institutions interpreted this to mean the use of internal control of a kit's components. This reflected a difference between public and private institutions, indicating the need to standardize the terminologies in future surveys. Second, answers to the questionnaire might differ from the actual performance of HIV testing because they were not confirmed by site inspection, although about 50 randomly selected HIV testing laboratories were interviewed by the HIV experts to confirm the survey response.

However, this is the first survey in Korea to focus on the personnel, equipment, environment, test kits, testing procedures, and quality assessment of HIV testing laboratories. Our data show a need for education by expanding training opportunities for HIV testers, regular maintenance of equipment, and development of a system to transport infectious substances safely. The results of this survey will be used in formulating a system-

atic and effective policy, and will serve as reference data for improving the quality of HIV testing in Korea.

Transparency Declaration

This study was supported by a grant for Health Promotion, Korea (No. 340-347-2430-216). The authors declare that they have no competing interests.

References

1. The US Centers for Disease Control and Prevention. Current trends update: serologic testing for antibody to human immunodeficiency virus. *MMWR* 1988; 36: 833–845.
2. Yong KH, Shin YO, Yoon JD *et al.* Study on HTLV-III (AIDS) and related virus infection. *Natl Inst Health, Korea* 1987; 24: 539–549.
3. Yong KH, Shin YO, Yoon JD *et al.* Virological and epidemiological study on acquired immunodeficiency syndrome (II). *Natl Inst Health, Korea* 1988; 25: 331–341.
4. Shin YO, Jang YS, Hur SJ *et al.* Seroepidemiological study on human immunodeficiency virus infection in Korea. *Natl Inst Health, Korea* 1993; 30: 163–172.
5. Korea Centers for Disease Control and Prevention. *The white book of KCDC in 2006 — Chapter 2. The management of STI and HIV/AIDS*. KCDC: Seoul, Korea, 2006; 103–108.
6. Korea Centers for Disease Control and Prevention. *The white book of KCDC in 2006 — Chapter 6. The management of national reference laboratory*. KCDC: Seoul, Korea, 2006; 368–376.
7. Kim SS, Suh SD, Kim OJ *et al.* External quality assessment in anti-HIV enzyme immuno assay in Korea. *J Clin Pathol Qual Control* 2000; 22: 293–301.
8. World Health Organization. *HIV/AIDS in Asia and the Pacific Region 2003*. WHO: Manila, 2004; 11–22.
9. Dybkaer R. Elements of good practice in decentralized clinical laboratories. *Ups J Med Sci* 1986; 91: 193–196.
10. The US Centers for Disease Control and Prevention, Model Performance Evaluation Program (MPEP), http://wwwn.cdc.gov/mpep/default.aspx; last accessed 8 September 2008.
11. National Serology Reference Laboratory (NRL), Australia. View Reports and information for serology, NAT, EQAS, QC and serology screening information; http://www.nrl.gov.au/hosting/serology/nrl-sec.nsf/structure/Members-JSOL-4554L7; last accessed 8 September 2008.
12. Department of Health and Human Services, the US Centers for Disease Control and Prevention. Current CLIA Regulations (including all changes through 01/24/2004) [cited 7/7/2004] Available from: URL: http://www.cms.hhs.gov/CLIA
13. The Health Connect, Australia. National HIV Testing Policy 2006. http://www.health.sa.gov.au/PEHS/PDF-files/hiv-testing-policy-2006.pdf; last accessed 8 September 2008.
14. The US Centers for Disease Control and Prevention, MPEP Questionnaire results: HIV Rapid Testing Survey 2007; http://wwwn.cdc.gov/mpep/pdf/rapid/RTSQ_0708_Results_Report_FINAL.pdf; last accessed 8 September 2008.
15. World Health Organization. *Laboratory biosafety manual*, 3rd edn. Geneva: WHO, 2004 (Introduction to the transport of infectious substances. Geneva: WHO, 2004; 94–97).
16. Ministry of Health & Welfare, Korea. Biosafety regulation for testing, transport and disposal of infectious substances (official announcement from Ministry of Health & Welfare, Korea, 2006-95: 11.28, 2006) — chapter 3. Transport of Infectious substances