VIRUS SEROLOGY

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The external quality assessment programme of Virus Serology of the Hong Kong Institute of Medical Laboratory Science Quality Assurance Programme Limited was launched in 1991. The testing involved anti-HIV, HBsAg/Ab, and anti-HCV. Totally there were four surveys in 2009. With each survey, five anti-HIV, five HBsAg/Ab and five anti-HCV specimens were distributed. Participants were invited to record anti-HBs results for those specimens negative for HBsAg. The performance of anti-HBs was optional and not scored.

I. Participants

The overall number of participants and types of laboratories participating in the programme in 2009 are shown in Table 1. Distribution of laboratories returning anti-HIV, HBsAg/Ab and anti-HCV is shown in Table 2.

Table 1: Types of laboratories

Types	No.	Percent
Hospitals under Hospital Authority	7	19.0
Government Institutes*	2	5.4
Private Laboratories	18	48.6
Private Hospitals	10	27.0
Total	37	100.0

Note: *One from Hong Kong and the other from Macau

Table 2: Number of laboratories returning results in 2009

Test items	Survey				Total
	1st	2nd	3rd	4th	
Anti-HIV	35 / 36	34 / 36	35 / 36	35 / 36	139 / 144 (96.5%)
HBsAg	35 / 36	34 / 36	36 / 36	35 / 36	140 / 144 (97.2%)
Anti-HBs	35 / 36	34 / 36	36 / 36	35 / 36	140 / 144 (97.2%)
Anti-HCV	26 / 27	27 / 29	29 / 29	28 / 29	110 / 114 (96.5%)

II. Results

Results were scored according to the following table.

Table 3: Scoring scheme for participants' results:

	Intended Result	
Participant's report	**Positive**	**Negative**
Positive, to be confirmed or referred	2	0
Positive, not confirmed or referred	1	-1
Equivocal, to be confirmed or referred	1	2
Equivocal, not confirmed or referred	0	0
Negative	-1	2

Scores of two were given to those correct results for anti-HIV, HBsAg and anti-HCV with adequate confirmation and referral for the reactive specimens, while one for those reactive results without confirmation or indication of referral. No laboratory obtained scores below one in 2009. The percentages of participants getting full score for anti-HIV, HBsAg and anti-HCV in 2009 are shown in Table 4.

Table 4: Percentage of participants getting full score (i.e. 2) for anti-HIV, HBsAg and anti-HCV in 2009

Test item	Survey (No. getting full score / No. returning results)				Total (%)
	1st	2nd	3rd	4th	
Anti-HIV	162 / 180	162 / 180	163 / 180	167 / 180	654 / 720 (90.8%)
HBsAg	157 / 180	150 / 180	157 / 180	155 / 180	619 / 720 (86.0%)
Anti-HCV	112 / 135	110 / 145	113 / 145	110 / 145	445 / 570 (78.1%)

Intended results and scoring for all the specimens for anti-HIV, HBsAg and anti-HCV in 2009 are summarized in Table 5. The intended Western blot results of all the specimens in 2009 are shown in Table 6.

Table 5: Specimen data

Specimen	Testing requested	Intended result	Scores				Total
			2	1	0	-1	
VS 0901	Anti-HIV	POS	32	3	0	0	35
VS 0902	Anti-HIV	POS	32	3	0	0	35
VS 0903	Anti-HIV	POS	31	4	0	0	35
VS 0904	Anti-HIV	POS	32	3	0	0	35
VS 0905	Anti-HIV	NEG	35	0	0	0	35
VS 0906	HBsAg	POS	29	6	0	0	35
VS 0907	HBsAg	POS	29	6	0	0	35
VS 0908	HBsAg	NEG	35	0	0	0	35
VS 0909	HBsAg	NEG	35	0	0	0	35
VS 0910	HBsAg	POS	29	6	0	0	35
VS 0911	Anti-HCV	POS	18	8	0	0	26
VS 0912	Anti-HCV	NEG	25	0	0	1	26
VS 0913	Anti-HCV	NEG	26	0	0	0	26
VS 0914	Anti-HCV	POS	17	9	0	0	26
VS 0915	Anti-HCV	NEG	26	0	0	0	26
VS 0916	Anti-HIV	NEG	34	0	0	0	34
VS 0917	Anti-HIV	POS	32	2	0	0	34
VS 0918	Anti-HIV	POS	32	2	0	0	34
VS 0919	Anti-HIV	POS	32	2	0	0	34
VS 0920	Anti-HIV	POS	32	2	0	0	34
VS 0921	HBsAg	POS	29	5	0	0	34
VS 0922	HBsAg	POS	29	5	0	0	34
VS 0923	HBsAg	NEG	34	0	0	0	34
VS 0924	HBsAg	POS	29	5	0	0	34
VS 0925	HBsAg	POS	29	5	0	0	34
VS 0926	Anti-HCV	POS	20	7	0	0	27
VS 0927	Anti-HCV	POS	20	6	0	1	27
VS 0928	Anti-HCV	NEG	25	0	1	1	27
VS 0929	Anti-HCV	NEG	25	0	1	1	27
VS 0930	Anti-HCV	POS	20	7	0	0	27
VS 0931	Anti-HIV	POS	32	3	0	0	35
VS 0932	Anti-HIV	NEG	35	0	0	0	35
VS 0933	Anti-HIV	POS	32	3	0	0	35
VS 0934	Anti-HIV	POS	32	3	0	0	35
VS 0935	Anti-HIV	POS	32	3	0	0	35
VS 0936	HBsAg	POS	29	6	0	1	36
VS 0937	HBsAg	NEG	35	0	1	0	36
VS 0938	HBsAg	POS	29	6	0	1	36
VS 0939	HBsAg	NEG	34	0	1	1	36
VS 0940	HBsAg	POS	30	6	0	0	36
VS 0941	Anti-HCV	POS	21	8	0	0	29
VS 0942	Anti-HCV	NEG	28	0	0	1	29
VS 0943	Anti-HCV	POS	21	8	0	0	29
VS 0944	Anti-HCV	POS	22	7	0	0	29
VS 0945	Anti-HCV	POS	21	8	0	0	29
VS 0946	Anti-HIV	POS	33	2	0	0	35
VS 0947	Anti-HIV	POS	33	2	0	0	35
VS 0948	Anti-HIV	NEG	35	0	0	0	35
VS 0949	Anti-HIV	POS	33	2	0	0	35
VS 0950	Anti-HIV	POS	33	2	0	0	35
VS 0951	HBsAg	POS	29	6	0	0	35
VS 0952	HBsAg	NEG	35	0	0	0	35
VS 0953	HBsAg	POS	29	6	0	0	35
VS 0954	HBsAg	POS	29	6	0	0	35
VS 0955	HBsAg	NEG	33	0	0	2	35
VS 0956	Anti-HCV	NEG	28	0	0	0	28
VS 0957	Anti-HCV	POS	20	8	0	0	28
VS 0958	Anti-HCV	POS	20	8	0	0	28
VS 0959	Anti-HCV	POS	21	7	0	0	28
VS 0960	Anti-HCV	POS	21	7	0	0	28

Remarks: POS: positive; NEG: negative

Table 6: Western blot results (anti-HIV-1) of survey specimens

Specimen	Western blot result	Intended result
VS 0901	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0902	p24, p31, gp41, p66, gp120/160	POS
VS 0903	p24, p31, gp41, p51, p55, p66, gp120/160	POS
VS 0904	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0905	No bands	NEG
VS 0916	No bands	NEG
VS 0917	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0918	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0919	p24, p31, gp41, p51, p55, p66, gp120/160	POS
VS 0920	p24, p31, gp41, p66, gp120/160	POS
VS 0931	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0932	No bands	NEG
VS 0933	p24, p31, gp41, gp120/160	POS
VS 0934	p24, gp41, p51, p66, gp120/160	POS
VS 0935	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0946	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0947	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0948	No bands	NEG
VS 0949	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0950	p24, p31, gp41, p51, p66, gp120/160	POS

Remarks: POS: positive; NEG: negative

The intended results and concentrations of HBsAg in 2008 are summarized in Table 7. The concentrations of anti-HBs in 2008 are shown in Table 8.

Table 7: Intended results and concentrations of HBsAg in the reactive specimens

Specimen	Intended result	Concentration (IU/mL)	Specimen	Intended result	Concentration (IU/mL)
VS 0906	POS	17	VS 0936	POS	>250
VS 0907	POS	>250	VS 0937	NEG	Not detected
VS 0908	NEG	Not detected	VS 0938	POS	60
VS 0909	NEG	Not detected	VS 0939	NEG	Not detected
VS 0910	POS	>250	VS 0940	POS	30
VS 0921	POS	>250	VS 0951	POS	25
VS 0922	POS	4.3	VS 0952	NEG	Not detected
VS 0923	NEG	Not detected	VS 0953	POS	3
VS 0924	POS	>250	VS 0954	POS	>250
VS 0925	POS	76	VS 0955	NEG	Not detected

Table 8: Concentrations of the anti-HBs in the specimens negative for HBsAg

Specimen	Concentration (mIU/mL)	Range of reported concentration (mIU/mL)
VS 0908	130	88.6 – 476.4
VS 0909	390	259.9 - >1000
VS 0923	97	72 – 191
VS 0939	208.3	126 - 484
VS 0952	>1000	21.2[@] - >1000

[@]outlying result

III. Methods and assay kits

The commercial kits used by the participants in 2009 for the testing of anti-HIV; HBsAg/Ab and anti-HCV are summarized in Tables 9 -12.

Table 9: Commercial assays for anti-HIV antibodies used by the participants

Anti-HIV assay	Method	Survey				Total
		1st	2nd	3rd	4th	
Abbott ARCHITECT HIV Ag/Ab Combo	CMIA	17	16	19	17	69
Abbott AxSYM HIV Ag/Ab Combo	MEIA	6	6	5	4	21
Abbott AxSYM HIV-1/2 gO	MEIA	0	4	4	4	12
Abbott IMx HIV-1/HIV-2 III Plus	MEIA	1	1	0	0	2
Abbott Murex HIV Ag/Ab Combination	EIA	1	1	1	1	4
ACON HIV 1/2/0	ICA	1	0	0	0	1
Bioline SD HIV-1/2 3.0	ICA	2	2	2	3	9
Bayer Centaur ADVIA EHIV	ChLIA	4	2	2	2	10
BioMerieux VIDAS HIV DUO Quick	ELFA	2	4	4	4	14
Determine Inverness Medical HIV-1/2	ICA	1	1	1	2	5
EY HIVSCAN TM 1+2 (2.1)	ICA	1	1	1	1	4
Innogenetics, INNO-LIA HIV I/II Score	LIA	1	1	1	1	4
MP Diagnostics HIV Blot 2.2	WB	1	1	1	1	4
Ortho Anti-HIV Reagent	EIA	1	2	1	1	5
Roche HIV Combi	ChLIA	4	5	5	5	19
Trinity Biotech Uni-Gold HIV	ICA	1	1	1	0	3
Vironostika HIV	EIA	1	1	1	1	4

Table 10: Commercial assays for HBsAg used by the participants

HBsAg assay	Method	Survey				Total
		1st	2nd	3rd	4th	
Abbott ARCHITECT HBsAg	CMIA	20	19	21	17	77
Abbott ARCHITECT HBsAg Quali.	CMIA	0	0	0	6	6
Abbott AxSYM HBsAg (V2)	MEIA	10	10	9	9	38
Abbott Determine HBsAg	ICA	4	4	3	3	14
Abbott Murex HBsAg Ver. 3	EIA	2	2	2	1	7
ACON Ultra HBsAg Test	ICA	1	1	1	0	3
Bayer Centaur ADVIA HBsAg	ChLIA	4	3	3	4	14
BioMerieux VIDAS HBsAg	ELFA	1	2	2	2	7
Ortho HBsAg	EIA	1	1	3	1	6
Roche Cobas Core HBsAg	ChLIA	2	4	4	4	14
Standard Diagnostics SD HBsAg	ICA	1	1	1	1	4

Table 11: Commercial assays for anti-HBs used by the participants

Anti-HBs assay	Method	Survey				Total
		1st	2nd	3rd	4th	
Abbott ARCHITECT anti-HBs	CMIA	20	19	22	22	83
Abbott AxSYM AUSAB	MEIA	10	10	7	7	34
Bayer Centaur ADVIA Anti-HBs	ChLIA	2	2	2	2	8
Ortho Anti-HBs	EIA	1	1	2	1	5
Roche Cobas Core Anti-HBs	ChLIA	3	2	2	3	10

Table 12: Commercial assays for anti-HCV used by the participants

Anti-HCV assay	Method	Survey				Total
		1st	2nd	3rd	4th	
Abbott ARCHITECT anti-HCV	CMIA	11	12	15	14	52
Abbott AxSYM MEIA anti-HCV	MEIA	6	6	4	4	20
Abbott Murex HCV ver. 4.0	EIA	1	1	1	1	4
Bayer Centaur ADVIA anti-HCV	ChLIA	4	3	3	3	13
Ortho HCV 3.0	EIA	5	1	4	3	13
Roche HCV 3.0	ChLIA	2	2	2	2	8
Standard Diagnostics SD HCV	ICA	1	1	4	4	10

Abbreviations:

(1) ChLIA: Chemiluminescence Assay
(2) CMIA: Chemiluminescent Microparticle Immunoassay
(3) ECLIA: Electrochemiluminescence Immunoassay
(4) EIA: Enzyme Linked Immunoassay
(5) ELFA: Enzyme-linked Fluorescent Assay
(6) ICA: Immunochromatographic Assay
(7) LIA: Line Immunoassay
(8) MEIA: Microparticle Enzyme Immunoassay
(9) WB: Western Blot

IV. Testing strategies used by participants

Majority of the participants (87.1%) sent their specimens to the reference laboratory for the confirmation of anti-HIV. Up to three laboratories performed a single assay without supplementary testing or referral for anti-HIV in 2009 (Table 13).

For hepatitis B serology, majority of the participants (82.9%) confirmed positive results. Up to seven laboratories performed a single assay without supplementary testing or referral for HBsAg (Table 14).

For anti-HCV testing, majority of participants (68.2%) indicated sending specimens with reactive results to the reference laboratory for confirmation. Up to eight laboratories performed a single assay without supplementary testing or referral for anti-HCV (Table 15).

Table 13: Anti-HIV testing

Testing strategy	Survey			
	1st	2nd	3rd	4th
1. Performed a single assay with indication of referral	22	22	22	23
2. Performed two different assays with indication of referral	8	8	8	8
3. Performed supplementary testing	2	2	2	2
4. Performed a single assay without supplementary testing or referral	3	2	3	2
Total	**35**	**34**	**35**	**35**

Table 14: HBsAg testing

Testing strategy	Survey			
	1st	2nd	3rd	4th
1. Performed at least two different assays	29	29	29	29
2. Performed a single assay without supplementary testing or referral	6	5	7	6
Total	**35**	**34**	**36**	**35**

Table 15: Anti-HCV testing

Testing strategy	Survey			
	1st	2nd	3rd	4th
1. Performed a single assay with indication of referral	17	19	20	19
2. Performed two different assays	1	1	1	1
3. Performed a single assay without supplementary testing or referral	8	7	8	8
Total	**26**	**27**	**29**	**28**

V. Common errors observed in 2009

The common mistakes observed from the returned results in the four surveys of 2009 are categorized in the following Table 16.

Table 16: Common errors observed in the surveys in 2009

No.	Category	Involved test(s)/assay(s)	No. of occurrence
1	Report equivocal results instead of confirming the initial reactive specimens with confirmatory assays or assay with different formats from the screening assay	Anti-HCV (AxSyM)	1
2	False positive results without confirmation or referral	HBsAg (ARCHITECT) Anti-HBs (Roche) Anti-HCV (Roche)	2 1 6
3	Report equivocal results for weakly reactive specimens without further confirmation or referral	HBsAg (AxSYM) Anti-HCV (AxSYM)	3 2
4	Transcription error made during the testing and reporting procedures (swap specimens swapped and/or interchanged between two whole sets of results of HBsAg and anti-HBs during reporting procedures))	Anti-HCV (AxSYM) HBsAg/Anti-HBs (Roche)	2 1
5	Contamination due to sample carry over	Anti-HBs (Roche)	2
6	False positive results related to quality control of assay	HBsAg (ARCHITECT & Advia Centaur)	2
7	Outlying result	Anti-HBs (Roche)	1
8	Instead of following the instruction of reporting test results in accordance with the kit insert, some laboratories would like to set a gray zone area and report equivocal result for the specimens with readings lay within the gray zone	HBsAg (AxSYM) Anti-HBs (Roche) Anti-HCV (AxSYM)	3 1 2
9	The use of a rapid assay with low sensitivity for initial and confirmatory testing	Anti-HCV (Standard Diagnostic)	1
10	Use of expired kits for testing	Anti-HIV Anti-HCV	1 1

VI. Recommendation

(1) For quality measures, expired assays should not be used.
(2) For those laboratories with evidence of transcription mistakes made, it is highly recommended these laboratories should review the testing and reporting procedures to identify the root cause of the mistakes.
(3) The performance of an assay should be reevaluated if incorrect results are repeated.
(4) The quality control of an assay should be investigated to find out the cause of any outlying or unexpected result.
(5) The use of a sensitive assay for initial testing and a more specific assay for the confirmation of an initial reactive specimen should be noted.
(6) For better quality control, reactive results with screening assays should not be reported. They should either be confirmed with supplementary tests or referred to reference laboratories for confirmation.

VII. Reference

(1) Immunoassays for the diagnosis of HIV: Test Quality & Laboratory Quality Assurance: http://www.medscape.com/viewarticle/715166_5

(2) HIV Testing Algorithm: A Status Report: A publication from the Association of Public Health Laboratories and the Centers for Diseases Control and Prevention. April 2009: http://www.aphl.org/aphlprograms/infectious/hiv/Documents/StatusReportExecutiveSummary.pdf

(3) Point-of-Care Repaid Tests for HIV Antibody: http://www.cdc.gov/hiv/topics/testing/resources/journal_article/J_Lab_Med_20031.htm

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End of Report