# 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 dispatches in 2008. With each dispatch, five anti-HIV, five HBsAg 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 2008 are shown in Table 1. Distribution of laboratories returning anti-HIV, HBsAg/Ab and anti-HCV is shown in Table 2.

Types	No.	Percent
Hospitals under Hospital Authority	7	20.0
Government Institutes*	2	5.7
Private Laboratories	16	45.7
Private Hospitals	10	28.6
Total	35	100.0

#### **Table 1: Types of laboratories**

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

Tost itoms		Sur	vey	Total	
Test items	1st	2nd	3rd	4th	- 10tai
Anti-HIV	32 / 34	32 / 34	34 / 35	34 / 35	132 / 138 (95.7%)
HBsAg	32 / 34	33 / 34	34 / 34	34 / 34	133 / 136 (97.8%)
Anti-HBs	32 / 34	33 / 34	34 / 34	33 / 34	132 / 136 (97.1%)
Anti-HCV	26 / 26	26 / 26	28 / 28	28 / 28	108 / 108 (100%)

## **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 2008. The percentages of participants getting full score for anti-HIV, HBsAg and anti-HCV in 2008 are shown in Table 4.

# Table 4: Percentage of participants getting full score (i.e. 2) for anti-HIV, HBsAg and anti-HCV in 2008

Test item _	– Total (%)				
	1st	2nd	3rd	4th	
Anti-HIV	156 / 160	152 / 160	162 / 170	162 / 170	632 / 660 (95.8%)
HBsAg	139 / 160	150 / 165	158 / 170	150 / 170	597 / 665 (89.8%)
Anti-HCV	103 / 130	111 / 130	108 / 140	109 / 140	431 / 540 (79.8%)

Intended results and scoring for all the specimens for anti-HIV, HBsAg and anti-HCV in 2008 are summarized in Table 5.

			Scores				
Specimen	Testing requested	Intended result	2	1	0	-1	- Total
VS 0801	Anti-HIV	POS	31	1	0	0	32
VS 0802	Anti-HIV	POS	31	1	0	0	32
VS 0803	Anti-HIV	POS	31	1	0	0	32
VS 0804	Anti-HIV	POS	31	1	0	0	32
VS 0805	Anti-HIV	NEG	32	0	0	0	32
VS 0806	HBsAg	POS	27	5	0	0	32
VS 0807	HBsAg	NEG	32	0	0	0	32
VS 0808	HBsAg	POS	27	5	0	0	32
VS 0809	HBsAg	POS	27	5	0	0	32
VS 0810	HBsAg	POS	26	6	0	0	32
VS 0811	Anti-HCV	POS	19	7	0	0	26
VS 0812	Anti-HCV	POS	20	6	0	0	26
VS 0813	Anti-HCV	NEG	26	0	0	0	26
VS 0814	Anti-HCV	POS	19	7	0	0	26
VS 0815	Anti-HCV	POS	19	7	0	0	26
VS 0816	Anti-HIV	NEG	32	0	0	0	32
VS 0817	Anti-HIV	POS	30	2	0	0	32
VS 0818	Anti-HIV	POS	30	2	õ	Õ	32
VS 0819	Anti-HIV	POS	30	2	0	0	32
VS 0820	Anti-HIV	POS	30	2	Ő	Õ	32
VS 0821	HBsAg	POS	28	5	Ő	Ő	33
VS 0822	HBsAg	POS	28	5	Ő	Ő	33
VS 0823	HBsAg	NEG	33	0	Ő	0	33
VS 0824	HBsAg	POS	28	5	0	0	33
VS 0825	HBsAg	NEG	20	0	0	0	33
VS 0826	Anti HCV	POS	21	5	0	0	26
VS 0820	Anti HCV	POS	21	5	0	0	20
VS 0827	Anti HCV	POS	21	5	0	0	20
VS 0820	Anti HCV	rus NEC	21	5	0	0	20
VS 0829	Anti HCV	NEU	20	0	0	0	20
VS 0830	Anti-HUV	POS	22	4	0	0	20
VS 0831		POS	32	2	0	0	34
VS 0832		POS	32	2	0	0	34
VS 0833		POS	32	2	0	0	34
VS 0834	Anti-HIV	POS	32	2	0	0	34
VS 0835	Anti-HIV	NEG	32	0	0	0	34
VS 0836	HBSAg	POS	30	4	0	0	34
VS 0837	HBsAg	POS	30	4	0	0	34
VS 0838	HBsAg	NEG	34	0	0	0	34
VS 0839	HBsAg	POS	30	4	0	0	34
VS 0840	HBsAg	NEG	34	0	0	0	34
VS 0841	Anti-HCV	POS	22	8	0	0	28
VS 0842	Anti-HCV	NEG	28	0	0	0	28
VS 0843	Anti-HCV	POS	20	8	0	0	28
VS 0844	Anti-HCV	POS	20	8	0	0	28
VS 0845	Anti-HCV	POS	20	8	0	0	28
VS 0846	Anti-HIV	POS	32	2	0	0	34
VS 0847	Anti-HIV	POS	32	2	0	0	34
VS 0848	Anti-HIV	POS	32	2	0	0	34
VS 0849	Anti-HIV	POS	32	2	0	0	34
VS 0850	Anti-HIV	NEG	32	0	0	0	34
VS 0851	HBsAg	POS	29	5	0	0	34
VS 0852	HBsAg	POS	29	5	0	0	34
VS 0853	HBsAg	NEG	34	0	0	0	34
VS 0854	HBsAg	POS	29	5	0	0	34
VS 0855	HBsAg	POS	29	5	0	0	34
VS 0856	Anti-HCV	POS	20	8	0	0	28
VS 0857	Anti-HCV	POS	21	7	0	1	28
VS 0858	Anti-HCV	POS	20	8	0	0	28
VS 0859	Anti-HCV	NEG	28	0	0	0	28
VS 0860	Anti-HCV	POS	20	8	0	0	28

# Table 5: Specimen data

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The intended results of Western blot of all specimens in 2008 are shown in Table 6.

Specimen	Western blot result	Intended result
VS 0801	p24, p31, gp41, p51, p55, p66, gp120/160	POS
VS 0802	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0803	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0804	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0805	No bands	NEG
VS 0816	No bands	NEG
VS 0817	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0818	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0819	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0820	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0831	p24, p31, gp41, p51, p55, p66, gp120/160	POS
VS 0832	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0833	p24, p31, gp41, p51, p55, p66, gp120/160	POS
VS 0834	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0835	No bands	NEG
VS 0846	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0847	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0848	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0849	p24, p31, gp41, p51, p66, gp120/160	POS
VS 0850	No bands	NEG

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

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.

Specimen	Intended result	Concentration (IU/mL)	Specimen	Intended result	Concentration (IU/mL)
VS 0806	POS	>250	VS 0836	POS	>250
VS 0807	NEG	Not detected	VS 0837	POS	23
VS 0808	POS	>250	VS 0838	NEG	Not detected
VS 0809	POS	3	VS 0839	POS	141
VS 0810	POS	>250	VS 0840	NEG	Not detected
VS 0821	POS	30	VS 0856	POS	>250
VS 0822	POS	>250	VS 0857	POS	Not detected
VS 0823	NEG	Not detected	VS 0858	NEG	Not detected
VS 0824	POS	4	VS 0859	POS	4
VS 0825	NEG	Not detected	VS 0860	POS	83

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

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

Specimen	Concentration (mIU/mL)	Range of reported concentration (mIU/mL)
VS 0807	100	66 - 237
VS 0823	550	186 - 824
VS 0838	40	18.9 - 49.9
VS 0853	>1000	>500->1000

# III. Methods and assay kits

The commercial kits used by the participants in 2008 for the testing of anti-HIV; HBsAg/Ab and anti-HCV are summarized in Tables 9 -12.

Survey						
Anti-HIV assay	Method	1st	2nd	3rd	4th	Total
Abbott ARCHITECT HIV Ag/Ab Combo	CMIA	11	11	13	15	50
Abbott AxSYM HIV Ag/Ab	MEIA	7	8	8	6	29
Abbott AxSYM HIV-1/2 gO	MEIA	8	7	6	6	27
Roche Cobas HIV Combi	ChLIA	4	4	4	5	17
Bioline SD HIV-1/2 3.0	ICA	4	3	3	3	13
Bayer Centaur ADVIA EHIV	ChLIA	2	2	2	2	8
BioMerieux VIDAS HIV DUO Quick	ELFA	1	3	2	2	8
Abbott Murex HIV Ag/Ab Combination	ELISA	1	1	1	1	4
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
Trinity Biotech Uni-Gold HIV	ICA	1	1	1	1	4
Vironostika HIV	ELISA	1	1	1	1	4
Abbott IMx HIV-1/HIV-2 III Plus	MEIA	1	0	1	1	3
Determine Inverness Medical HIV-1/2	ICA	0	1	1	1	3

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

### Table 10: Commercial assays for HBsAg used by the participants

HBsAg assay	Method	1st	2nd	3rd	4th	Total
Abbott ARCHITECT HBsAg	CMIA	14	15	16	18	63
Abbott AxSYM HBsAg (V2)	MEIA	15	14	14	14	57
Bayer Centaur ADVIA HBsAg	ChLIA	4	3	4	4	15
Abbott Determine HBsAg	ICA	4	4	4	4	12
Roche Cobas Core HBsAg	ChLIA	3	3	3	3	12
Bioline SD HBsAg	ICA	2	2	2	2	8
Abbott Murex HBsAg Ver. 3	EIA	2	2	1	2	7
BioMerieux VIDAS HBsAg	ELFA	2	1	1	1	5
Immulite HBsAg	ChLIA	1	0	0	0	1

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

		Survey				_
Anti-HBs assay	Method	1st	2nd	3rd	4th	Total
Abbott ARCHITECT anti-HBs	CMIA	14	14	16	17	61
Abbott AxSYM AUSAB	MEIA	15	13	13	11	52
Roche Cobas Core Anti-HBs	ChLIA	4	4	3	3	14
Bayer Centaur ADVIA Anti-HBs	ChLIA	1	2	2	2	7
Immulite Anti-HBs	ChLIA	1	0	0	0	1

<b>Fable 12: Commerc</b>	al assays for anti-HCV	v used by the participants
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			Survey			
Anti-HCV assay	Method	1st	2nd	3rd	4th	Total
Abbott AxSYM MEIA anti-HCV	MEIA	13	12	12	10	47
Abbott ARCHITECT anti-HCV	CMIA	6	7	9	9	31
Ortho HCV 3.0	EIA	3	3	3	3	12
Bayer Centaur ADVIA anti-HCV	ChLIA	2	2	2	4	10
Roche HCV 3.0	ChLIA	0	2	2	4	8
Bioline SD HCV	ICA	2	1	1	1	5
Abbott Murex HCV ver. 4.0	EIA	1	1	1	1	4

#### 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 (87.9%) 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 2008 (Table 13).

For hepatitis B serology, majority of the participants (85.7%) confirmed positive results. Up to five laboratories performed a single assay without supplementary testing or referral for HBsAg (Table 14).

For anti-HCV testing, majority of participants (70.4%) 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).

	Survey			
Testing strategy	1st	2nd	3rd	4th
1. Performed a single assay with indication of referral	21	19	22	22
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	1	3	2	2
Total	32	32	34	34

#### Table 13: Anti-HIV testing

#### Table 14: HBsAg testing

	Survey			
Testing strategy	1st	2nd	3rd	4th
1. Performed at least two different assays	27	28	30	29
2. Performed a single assay without supplementary testing or referral	3	3	4	2
Total	32	33	34	34

#### Table 15: Anti-HCV testing

	Survey			
Testing strategy	1st	2nd	3rd	4th
1. Performed a single assay with indication of referral	18	20	19	19
2. Performed two different assays	1	1	1	1
3. Performed a single assay without supplementary testing or referral	7	5	8	8
Total	26	26	28	28

## V. Recommendation

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.

## VI. Acknowledgments

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# VI. Reference

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