VIRUS SEROLOGY

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The Hong Kong Medical Technology Association Quality Assurance Programme in Virus Serology was launched in 1991. The format of the programme in 1997 and 1998 was the same as that in the previous years. Totally there were four dispatches in each year. With each dispatch, 5 HBsAg and 5 anti-HIV specimens were distributed. Participants were also invited to record results for anti-HBs. However, the performance on anti-HBs was not scored.

The overall numbers of participants and types of laboratories participating in the programme in 1997 and 1998 are shown in Table 1. In 1997, 23 participants took part in HIV and HBsAg testing and 4 took part in HBsAg only; in 1998, 23 participants took part in HIV and HBsAg testing and 5 took part in HBsAg only (Table 2).

Table 1. Types of laboratories

	1997		1998	
Types	No.	%	No.	%
A. Hospitals of Hospital Authority	5	18.5	6	21.4
B. Government Institutes / Clinics	1	3.7	1	3.6
C. University Hospital	1	3.7	1	3.6
D. Private Laboratories	13	48.2	13	46.4
E. Private Hospitals	7	25.9	7	25.0
Total	27	100	28	100

Table 2. Distribution of participants in Virus Serology in 1997 & 1998

Year	Maximum no. of participants involved in testing of HIV and HBsAg serology	Maximum no. of participants involved in testing of HBsAg serology only	Total
1997	23	4	27
1998	23	5	28

The overall percentage of returns for HIV antibody and HBsAg testing in 1997 were 95.5% and 96.2% respectively. The numbers in 1998 were 93.5% and 94.6% respectively (Table 3). The percentage of correct answers for HIV and HBsAg testing in 1997 were 99.8% and 100% respectively, the ones in 1998 were 97.7% and 99.6% (Table 4).

Table 3. Comparison of responses in 1997 and 1998

	1997			1998		
Testing	Expected	Actual	Percent	Expected	Actual	Percent
HIV	88	84	**95. 5**	92	86	**93. 5**
HBsAg	104	100	**96. 2**	112	106	**94. 6**

Table 4. Comparison of the percentage of participants getting full score for anti-HIV and HBsAg in 1997 and 1998

	1997			1998		
Testing	Expected	Actual	Percent	Expected	Actual	Percent
HIV	420	419	**99.8**	430	420	**97.7**
HBsAg	500	500	**100**	530	528	**99.6**

HIV Serology

Tables 5 and 6 summarize the intended results and the overall responses in 1997 and 1998. In 1997 and 1998, discrepant results were found for specimens VS703, VS722, VS802, VS815, VS831 and VS835. They were associated with one particular EIA kit. Transcriptional errors were also found for VS723, VS724, VS725 and VS803.

Table 5. HIV Specimen Data in 1997

Survey	Intended	Western blot result	Number	Returned results		
Sample	result		returned	+	-	Ind.
VS 701	+	p24, p31, gp41, p51, p55, p66, gp120/160	20	20	0	0
VS 702	-	Nil	20	0	20	0
VS 703	-	Nil	20	2	15	3
VS 704	+	p31, gp41, p51, p55, p66, gp120/160	20	20	0	0
VS 705	+	p24, p31, gp41, p51, p55, p66, gp120/160	20	20	0	0
VS 711	+	p24, p31, gp41, p51, p55, p66, gp120/160	19	19	0	0
VS 712	+	gp41, p51, p55, p66, gp120/160	19	19	0	0
VS 713	-	Nil	19	0	19	0
VS 714	+	p24, gp41, gp120/160	19	19	0	0
VS 715	+	p31, gp41, p51, p55, gp120/160	19	19	0	0
VS 721	+	p31, gp41, p55, gp120/160	23	23	0	0
VS 722	-	Nil	23	4	19	0
VS 723	-	Nil	23	0	22*	0
VS 724	+	p24, p31, gp41, p51, p55, p66, gp120/160	23	22	1	0
VS 725	+	p31, gp41, p66, gp120/160	23	22	1	0
VS 731	-	Nil	22	0	22	0
VS 732	+	p24, gp120/160	22	22	0	0
VS 733	+	p24, p31, gp41, p51, p66, gp120/160	22	22	0	0
VS 734	+	p31, gp41, p66, gp120/160	22	22	0	0
VS 735	+	p24, p31, gp41, p51, p66, gp120/160	22	22	0	0

Remarks: * One laboratory forgot to fill in the result for VS723.

'Ind.' denotes indeterminate result.

Table 6. HIV Specimen Data in 1998

Survey Sample	Intended result	Western blot result	Number returned	Returned results +	-	Ind.
VS 701	+	p24, p31, gp41, p51, p55, p66, gp120/160	20	20	0	0
VS 801	+	p24, p31, gp41, p51, p66, gp120/160	20	20	0	0
VS 802	-	Nil	20	5	13	2
VS 803	-	Nil	20	1	19	0
VS 804	+	gp41, gp120/160	20	20	0	0
VS 805	+	p24, p31, gp41, p51, p66, gp120/160	20	20	0	0
VS 811	+	p24, p31, gp41, p51, p66, gp120/160	23	23	0	0
VS 812	+	gp41, p51, p55, p66, gp120/160	23	23	0	0
VS 813	-	Nil	23	0	23	0
VS 814	+	p24, p31, gp41, p51, p66, gp120/160	23	23	0	0
VS 815	-	Nil	23	4	14	5
VS 821	+	p24, p31, gp41, p51, p66, gp120/160	22	22	0	0
VS 822	-	Nil	22	0	22	0
VS 823	+	p24, p31, gp41, p51, p66, gp120/160	22	22	0	0
VS 824	+	p24, p31, gp41, p51, p66, gp120/160	22	22	0	0
VS 825	+	p24, p31, gp41, p51, p66, gp120/160	22	22	0	0
VS 831	Ind.	gp120/160	21	19	0	2
VS 832	+	p31, gp41, p51, p66, gp120/160	21	21	0	0
VS 833	-	Nil	21	0	21	0
VS 834	+	p24, p51, p66, gp120/160	21	21	0	0
VS 835	Ind.	gp120/160	21	19	0	2

Remark: 'Ind.' denotes indeterminate result.

HBsAg Serology

Tables 7 and 8 summarize the intended results and the overall responses for hepatitis B serology in 1997 and 1998 respectively. Errors were found for the specimens VS 807, VS 808, VS 810 and VS 826. They were apparently due to transcriptional errors occurred during reporting for the specimens. The results for anti-HBs were not scored. However, the responded rates for all the participants for this testing in each of the dispatches in 1997 and 1998 were very high (Table 9). The concentrations of HBsAg in the positive samples dispatched in 1997 and 1998 were shown in table 10. The titres for the the positive anti-HBs samples were listed in tables 11a and 11b for 1997 and 1998 respectively.

Table 7. HBsAg Specimen data in 1997

Survey sample	Intended result	No. returned	Returned results +	-	Ind.
VS 706	-	24	0	24	0
VS 707	+	24	24	0	0
VS 708	-	24	0	24	0
VS 709	+	24	24	0	0
VS 710	-	24	0	24	0
VS 716	-	23	0	23	0
VS 717	-	23	0	23	0
VS 718	+	23	23	0	0

Survey sample	Intended result	No. returned	Returned results +	-	Ind.
VS 719	+	23	23	0	0
VS 720	+	23	23	0	0
VS 726	+	27	27	0	0
VS 727	+	27	27	0	0
VS 728	-	27	0	27	0
VS 729	-	27	0	27	0
VS 730	+	27	27	0	0
VS 736	-	26	0	26	0
VS 737	+	26	26	0	0
VS 738	+	26	26	0	0
VS 739	-	26	0	26	0
VS 740	-	26	0	26	0

Remark: 'Ind.' denotes indeterminate result.

Table 8. HBsAg Specimen data in 1998

Survey sample	Intended result	No. returned	Returned results +	-	Ind.
VS 806	+	25	25	0	0
VS 807	-	25	1	24	0
VS 808	+	25	24	1	0
VS 809	+	25	25	0	0
VS 810	-	25	0	24	1
VS 816	-	28	0	28	0
VS 817	+	28	28	0	0
VS 818	B+	28	28	0	0
VS 819	-	28	0	28	0
VS 820	+	28	28	0	0
VS 826	-	27	0	26	1
VS 827	-	27	0	27	0
VS 828	-	27	0	27	0
VS 829	+	27	27	0	0
VS 830	B+	27	27	0	0
VS 836	-	26	0	26	0
VS 837	+	26	26	0	0
VS 838	+	26	26	0	0
VS 839	+	26	26	0	0
VS 840	+	26	26	0	0

Remarks: 'B+' denotes borderline positive; 'Ind.' denotes indeterminate result.

Table 9. Participation rates of anti-HBs in each of the dispatches in 1997 and 1998

1997				1998			
1st	2nd	3rd	4th	1st	2nd	3rd	4th
100%	95.7%	96.3%	100%	100%	100%	100%	96.2%

Table 10. Concentrations of HBsAg in the reactive specimens in 1997 and 1998

1997		1998	
Specimen	Concentration	Specimen	Concentration
VS 707	550 ng/mL	VS 806	1570 ng/mL
VS 709	90 ng/mL	VS 808	1 ng/mL
VS 718	14 ng/mL	VS 809	2 ng/mL
VS 719	110 ng/mL	VS 817	1375 ng/mL
VS 720	1 ng/mL	VS 818	1 ng/mL
VS 726	5 ng/mL	VS 820	164 ng/mL
VS 727	12 ng/mL	VS 829	500 ng/mL
VS 730	3562 ng/mL	VS 830	1 ng/mL
VS 737	9 ng/mL	VS 837	63 ng/mL
VS 738	15 ng/mL	VS 838	133 ng/mL
		VS 839	290 ng/mL
		VS 840	6 ng/mL

Table 11a. Concentrations of anti-HBs in the specimens in 1997

Specimens	Concentration	Range of reported titre
VS 710	925 mIU/mL	>500 - >1000
VS 717	12 mIU/mL	56.5% reported negative 17.4% reported either weakly reactive or positive 21.7% reported positive with range from 7 – 19.6 mIU/mL
VS 728	8.5 mIU/mL	8.5 – 40 mIU/mL
VS 739	12 mIU/mL	6.9 – 104 mIU/mL

Table 11b. Concentrations of anti-HBs in the specimens in 1998

Specimens	Concentration	Range of reported titre
VS 810	1140 mIU/mL	Majority reported >1000 mIU/mL
VS 819	144 mIU/mL	40 – 233 mIU/mL
VS 828	800 mIU/mL	Majority reported >1000 mIU/mL
VS 836	2340 mIU/mL	Majority reported >1000 mIU/mL

Methods and assay kits

Majority of the participants used enzyme linked immunoassays (ELISA) for screening for HIV antibodies. The commercial kits used by the participants in 1997 and 1998 are shown in table 12. The ones for HBsAg and anti-HBs are also shown in tables 13 and 14.

Table 12. Commercial assays for HIV antibodies used by the participants in 1997 and 1998

Assay	Number of participants	
	1997	1998
Abbott HIV-1/2	7	4
Abbott AxSym MEIA	3	5
Abbott IMx MEIA	9	7
Abbott Test Pack	1	1
Access HIV 1 / 2	3	2
Behring Enzygnost 1 / 2	1	1
BioMerieux HIV 1 / 2	1	1
Cambridge Capillus HIV1/ HIV2	1	0
Ey Lab HIV SCAN	1	1
Roche anti-HIV 1 / 2	5	5
Vidas HIV 1 / 2	5	6
Vironostika HIV – Uniform II	1	1
Wellcozyme Recombinant	1	1
Genelabs Diagnostics	2	2
Fujirebio Serodia- HIV	1	0
COBAS	0	1

Table 13. Commercial HBsAg assays used by the participants in 1997 and 1998

Assay	Number of participants	
	1997	1998
Abbott Daina Screen	1	2
Abbott Auszyme	6	7
Abbott IMx MEIA	15	13
Abbott AxSym MEIA	6	5
Murex HBsAg	3	2
Roche HBsAg (EIA)	5	5
Vidas – ELFA (Vitek)	2	5
COBAS Core HBsAg II	0	1

Table 14. Commercial Anti-HBs assays used by the participants in 1997 and 1998:

Assay	Number of participants	
	1997	1998
Abbott AUSAB (EIA)	5	4
Abbott IMx MEIA	14	13
Abbott AxSym MEIA	4	6
Roche anti-HBs (EIA)	2	3
Vidas – ELFA (Vitek)	5	4
COBAS Core anti-HBs	0	1

Table 15. Testing and referral in 1997

		1997							
		HIV				HBsAg			
		1st	2nd	3rd	4th	1st	2nd	3rd	4th
1.	Confirmation or referral	17	16	21	17	20	20	23	22
2.	Retested with same screening assay	0	2	2	3	0	0	0	2
3.	Tested with two different assays	0	0	0	0	0	1	0	0
4.	Performed single test without supplementary testing or referral	3	1	0	2	4	2	4	2

Table 16. Testing and referral in 1998

		1998							
		HIV				HBsAg			
		1st	2nd	3rd	4th	1st	2nd	3rd	4th
1.	Confirmation or referral	17	20	22	18	23	25	25	22
2.	Retested with same screening assay	3	3	0	0	2	3	0	0
3.	Tested with two different assays	0	0	0	0	0	0	0	0
4.	Performed single test without supplementary testing or referral	0	0	0	0	0	0	0	0

Testing strategies used by participants

Three laboratories performed single tests without supplementary testing or referral for the reactive anti-HIV survey samples in 1997. However, improvement was noticed in 1998. The numbers of laboratory having this practice decreased to zero in each of the dispatches in 1998 (Table 15 and 16). In addition, three other laboratories retested the initial reactive HIV specimens with the same screening assay in 1997 and 1998. It is recommended that these samples should be confirmed by different assays with different formats and principles. For the low prevalence of HIV in Hong Kong, at least three ELISAs with different test formats should be used or the initial reactive samples should be confirmed with Western blot. Initially reactive clinical samples in the local laboratories can be referred to Government Virus Unit at Queen Mary Hospital for confirmation. The service is free of charge.

For the HBsAg testing, 4 laboratories performed single test without supplementary testing or referral in the same period. The prevalence of HBsAg is around 10% in Hong Kong. At this high rate, the use of two different assays with different formats or principles will be sufficient for confirmation of positive results.

This virus serology quality assurance programme aims to provide recommendations to local participants concerning the testing strategies for anti-HIV and HBsAg. In order to acquire quality results for different tests, participants should review and apply quality control measures in every aspect of the testing. There is a steady increase in the number of participants in this programme from 11 participants in 1991 to 28 in 1998. More and more laboratories acknowledge the need for participation in external QAPs as means to ensure quality results.