



RCPA Serology QAP

SQAP Updates & Case Studies

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RCPA Serology QAP



PART 1 SQAP Updates

- Website & Guest Login
- Questionnaires & Reports
- Clinical Notes & Result Sheets

- Participant Assessment Reports
- Participant Survey Reports
- Cumulative Reports
- Reviewer Reports
- Results by Disease

Website



RCPA Quality Assurance Programs Pty Limited  Serology QAP

Home | About Serology QAP | Programs/Enrolment | Login/Member Services | Resources | Committees | Contact Us

blood-based Quality Assurance for Infectious Diseases using both Serological and Molecular Techniques

This website is up-to-date as at 18 September 2009 (AEST)

Our Services

- Sole focus is Quality Assurance
- Timely and friendly customer service
- Offering the most comprehensive and cost-effective range of Serology based QA in the World - [View Tests](#)
- Almost 700 participants in 26 countries (every continent except Antarctica)
- Pioneered Internet data entry of results
- Prompt report issue - [View Generic Report](#)
- Dynamic Graphs of Results via Internet after due date
- Frequent surveys to facilitate trend analysis
- Confidential analysis of results
- Internationally respected report reviewers
- Choice of result submissions via Internet, email or mail
- Enrolment for laboratories, manufacturers and suppliers
- Material available for validation studies
- Search the [Manufacturers Database](#)
- View the latest issue of SQAP News - [Read Here](#)

Latest News for Enrolled Participants

26 Aug 2009 - The August issue of SQAP News is now available. Select the link underneath to view.
[SQAP News V8 Issue 3 \(August 2009\)](#)

21 May 2009 - The May issue of SQAP News is now available. Select the link underneath to view.
[SQAP News V8 Issue 2 \(May 2009\)](#)

13 Jun 2008 - If you are authorised and would like to become a Subgroup Coordinator for a group of laboratories within your organisation, please print and coordinate return of signed Subgroup Coordinator Report Authorisation forms to the Serology QAP.
[Subgroup Coordinator Report Authorisation Form](#)



World Wide Program with World Class Service and International Accreditation

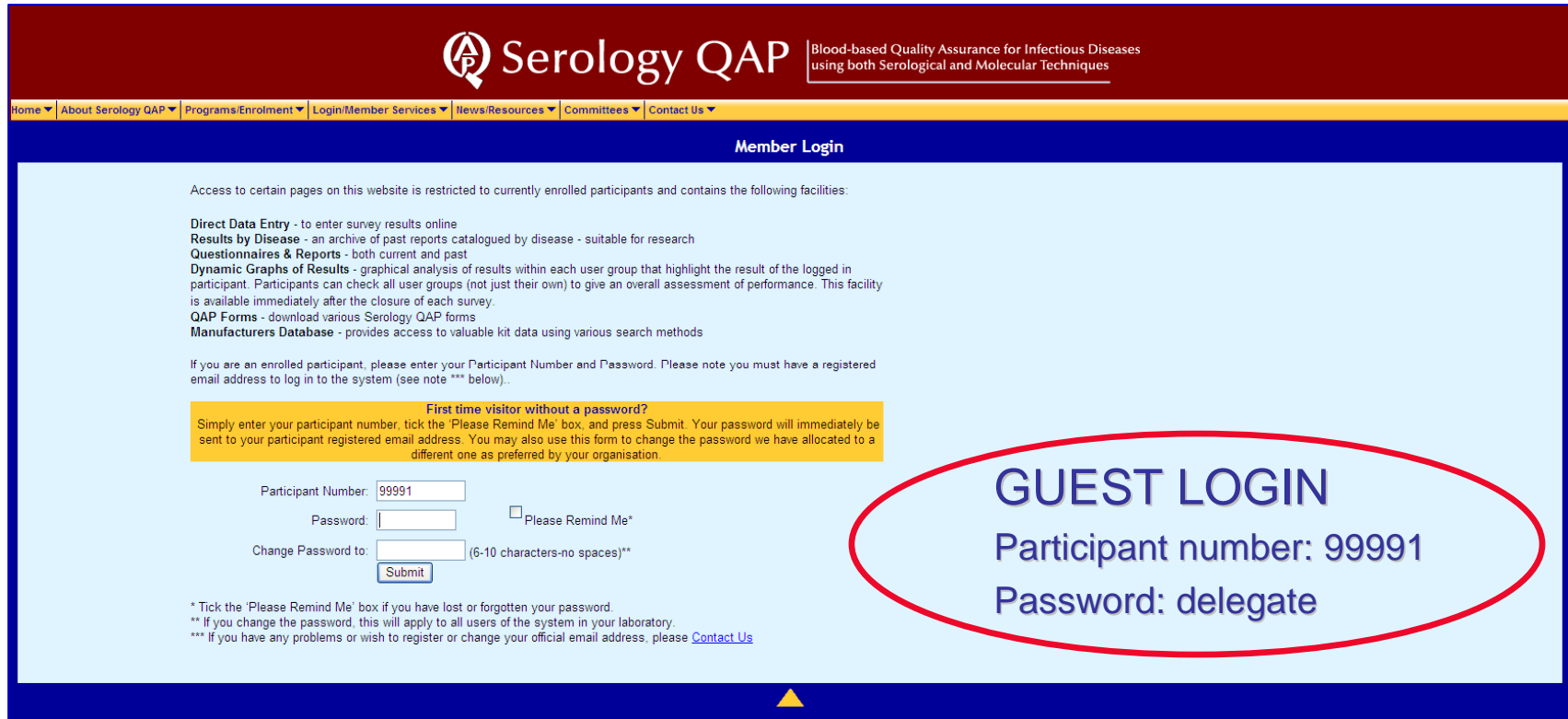



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www.rcpaqap.com.au/serology

Website

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Member Login

Access to certain pages on this website is restricted to currently enrolled participants and contains the following facilities:

- Direct Data Entry** - to enter survey results online
- Results by Disease** - an archive of past reports catalogued by disease - suitable for research
- Questionnaires & Reports** - both current and past
- Dynamic Graphs of Results** - graphical analysis of results within each user group that highlight the result of the logged in participant. Participants can check all user groups (not just their own) to give an overall assessment of performance. This facility is available immediately after the closure of each survey.
- QAP Forms** - download various Serology QAP forms
- Manufacturers Database** - provides access to valuable kit data using various search methods

If you are an enrolled participant, please enter your Participant Number and Password. Please note you must have a registered email address to log in to the system (see note *** below)..

First time visitor without a password?
Simply enter your participant number, tick the 'Please Remind Me' box, and press Submit. Your password will immediately be sent to your participant registered email address. You may also use this form to change the password we have allocated to a different one as preferred by your organisation.

Participant Number:

Password: Please Remind Me*

Change Password to: (6-10 characters-no spaces)**

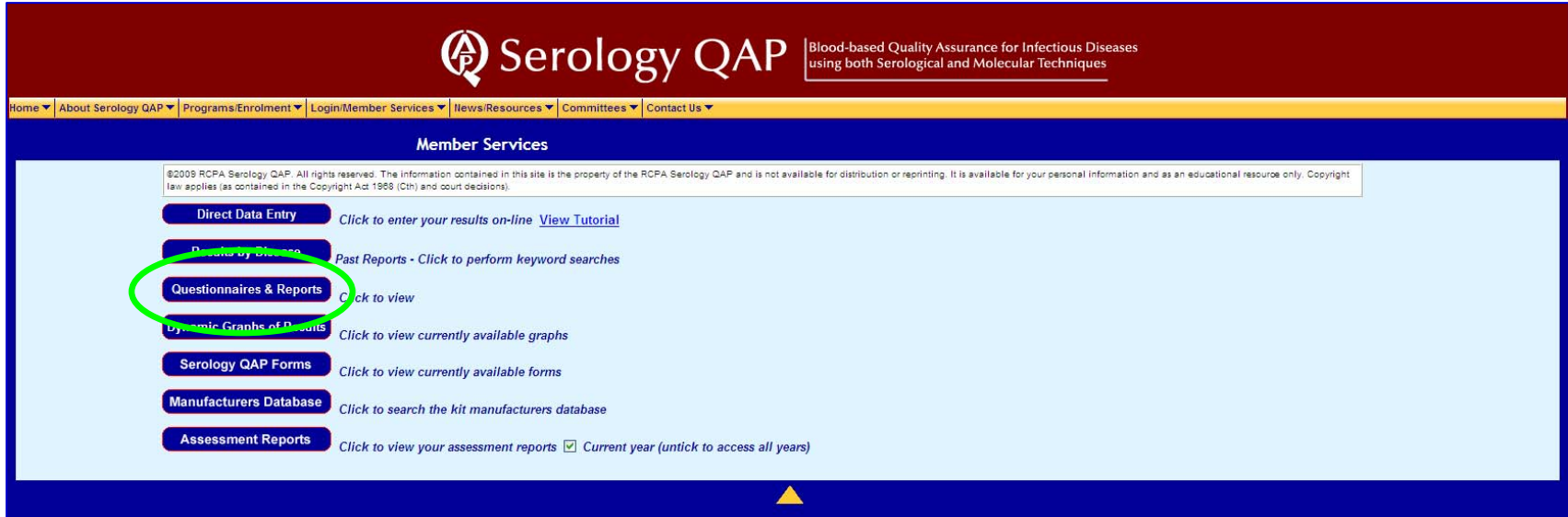
* Tick the 'Please Remind Me' box if you have lost or forgotten your password.
** If you change the password, this will apply to all users of the system in your laboratory.
*** If you have any problems or wish to register or change your official email address, please [Contact Us](#)


GUEST LOGIN

Participant number: 99991

Password: delegate

Questionnaires & Reports



 Serology QAP Blood-based Quality Assurance for Infectious Diseases using both Serological and Molecular Techniques

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Member Services

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- Direct Data Entry** Click to enter your results on-line [View Tutorial](#)
- Results by Disease** Past Reports - Click to perform keyword searches
- Questionnaires & Reports** Click to view
- Dynamic Graphs of Results** Click to view currently available graphs
- Serology QAP Forms** Click to view currently available forms
- Manufacturers Database** Click to search the kit manufacturers database
- Assessment Reports** Click to view your assessment reports Current year (untick to access all years)

Clinical Notes & Result Sheets


















 **Serology QAP** Blood-based Quality Assurance for Infectious Diseases using both Serological and Molecular Techniques

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Survey Questionnaires and Reports


Click on the button to the left of the Questionnaire or Participant Assessment Report you wish to view or print. Questionnaires are available for download on the survey open date and Participant Assessment Reports are available for download within one week of the survey due date.

Questionnaires and Reports from 2000-2003 are available upon request. Individual test survey reports (including raw data) from year 2000 to current year are available on the [Results by Disease](#) database.

Participant 21229		Legend:  Click to view  Document is not available	
2009			
<i>Antenatal Serology</i>	AN1:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	AN2:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	AN3:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	AN4:2009	 Clinical Notes & Result Sheets	
<i>Bacterial Serology</i>	B1:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	B2:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	B3:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	B4:2009	 Clinical Notes & Result Sheets	
<i>Hepatitis Serology</i>	H1:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H2:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H3:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H4:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H5:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H6:2009	 Survey opens 02-Nov-2009	
<i>IM Serology</i>	I1:2009	 Clinical Notes & Result Sheets	 You did not submit results for this survey
	I2:2009	 Clinical Notes & Result Sheets	 You did not submit results for this survey
	I3:2009	 Clinical Notes & Result Sheets	 You did not submit results for this survey
	I4:2009	 Clinical Notes & Result Sheets	 You did not submit results for this survey
	I5:2009	 Clinical Notes & Result Sheets	
	I6:2009	 Survey opens 09-Nov-2009	
<i>Lymphadenopathy Serology</i>	L1:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	L2:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	L3:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report

Clinical Notes

Survey	Open Date	Due Date	Tests Surveyed
H5:2009	17-08-09	04-09-09	Hepatitis ABC

 **RCPA Serology QAP
Clinical Notes and Test Instructions for the
Hepatitis Module 2009**

Hepatitis ABC

21, 24	Hepatitis A - H5:2009:21, 24 Clinical notes are not applicable.
22, 23	Hepatitis B - H5:2009:22, 23 Clinical notes are not applicable.
24, 25	Hepatitis C - H5:2009:24, 25 Clinical notes are not applicable.
Request	Please test specimens and treat in the same manner as routine diagnostic specimens.

To find:

- specimen numbers to test
- names (if applicable)
- clinical notes (if applicable)
- other testing instructions

Result Sheets

To find:

- generic result sheets
- if via mail complete
 - Participant No.
 - Survey No.
 - Specimen No.
 - Results

Participant No: _ _ _ _ _
Survey No: H __ :200 __

HEPATITIS SEROLOGY

Result submission

'via internet' participants: please print the document labelled "Clinical Notes & Test Instructions" at the top of this module list for details of specimens to test. Enter your results at the Serology QAP website <http://www.rcpaqap.com.au/serology> > "Member Services" > "Direct Data Entry"

'via mail' participants: refer to the attached Clinical Notes & Test Instructions and record your testing results on this result sheet. Mail results to the Serology QAP or enter results at the Serology QAP website.

Kit Information

- Please supply kit lot number and expiry date
- If you have changed kits since the last Serology QAP survey, OR have not previously supplied your kit details to the Serology QAP, please provide us with your new kit details

Test Results

- **Units** – for example, S/CO
- **Cut-off value** is the absolute value that designates the cut-off point below which is negative or equivocal, and above or equal to is low positive or positive. Do not use >, ≥, < for cut-off.
- Enter N/A (not applicable) if any of the above do not relate to your test – for example, a latex agglutination test





































HBsAg (Screening Assay)		
Kit Lot No:		
Kit Expiry Date:		
Specimen No.	Value	Circle test result
		N E P
		N E P
Cut-off:	(do not use <,>,≥)	Units:

HBsAg (Supplementary Test)		
Kit Lot No:		
Kit Expiry Date:		
Specimen No.	Value	Circle test result
		N E P
		N E P
Cut-off:	(do not use <,>,≥)	Units:

HBsAg (Confirmatory Test)		
Kit Lot No:		
Kit Expiry Date:		
Specimen No.	Value	Circle test result
		N E P

Anti-HBs		
Kit Lot No:		
Kit Expiry Date:		
Specimen No.	Value	Circle test result
		Immune Non-Imm.

Reports

<i>Hepatitis Serology</i>	H1:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H2:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H3:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	H4:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
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	I 5:2009	 Clinical Notes & Result Sheets	
	I 6:2009	 Survey opens 09-Nov-2009	
<i>Lymphadenopathy Serology</i>	L1:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	L2:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	L3:2009	 Clinical Notes & Result Sheets	 Participant Assessment Report
	L4:2009	 Survey opens 21-Sep-2009	
<i>Molecular Alphavirus/Flavivirus</i>	MAF1:2009	 Clinical Notes & Result Sheets	 Generic Report
	MAF2:2009	 Clinical Notes & Result Sheets	 Generic Report
	MAF3:2009	 Clinical Notes & Result Sheets	
<i>Molecular Avian influenza</i>	MAV1:2009	 Clinical Notes & Result Sheets	 Generic Report
	MAV2:2009	 Clinical Notes & Result Sheets	 Generic Report
	MAV3:2009	 Survey opens 12-Oct-2009	



Participant Assessment Report

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RCPA Quality Assurance Programs Pty Ltd keeps all participant details confidential. Such details will not be disclosed to a third party, unless required by legislation, without the prior written consent of the participant.

Survey Number

Participant Number

Specimen Number

Hepatitis Module Report for Survey H5:2009 Due Date: 4 Sep 2009

Participant Number: 21229

Report comprises: Hepatitis ABC

Participants: 214

Report Issued: 10 Sep 2009

Report issue date

Test

No. of Participants

Test	Spec	Consensus	Result	Graphs	Your Result	Your Score	Kit in date	Total Score	Possible
HBsAg-Screening Assay	22	pos	99%		pos	2	1	3	3
HBsAg-Supplementary Test	22	pos	100%		NA	-	-	-	-
HBsAg-Confirmatory Test	22	pos	100%		pos			3	3
Anti-HBs	22	non-imm.	98%		non-imm.			3	3
Anti-HBc	22	pos	99%		pos			3	3
Anti-HBc IgM	22	neg	100%		neg			3	3
HBeAg	22	pos	99%		pos			3	3
Anti-HBe	22	neg	98%		neg	2	1	3	3
Anti-HAV Total	21	neg	98%		neg	2	1	3	3
Anti-HAV IgG	21	neg	100%		NA	-	-	-	-
Anti-HAV IgM	21	neg	100%		neg	2	1	3	3
HCV Ag-Ab Assay	24	No Consensus	-		neg	-	1	1	1
Anti-HCV-Screening Assay	24	neg	99%		NA	-	-	-	-
Anti-HCV-Supplementary Test	24	neg	100%		neg	2	1	3	3
Anti-HCV-Confirmatory Test	24	neg	100%		NA	-	-	-	-
Total Score: 100%								31	31

Access to graphical analysis of results

Your test score out of 2

Your total score as %

Other Comments

Comment: Anti-HCV-ST - Did not provide units.
Comment: HBsAg-ST - Did not provide units.

Specimen Number: 22
If consensus result is not achieved the specimen is not scored.

Your Result: pos
result

Kit expiry: 1/1 (100%) for
No score for kit past expiry date

Your total score and possible score for analyte: 31/31



Participant Survey Report

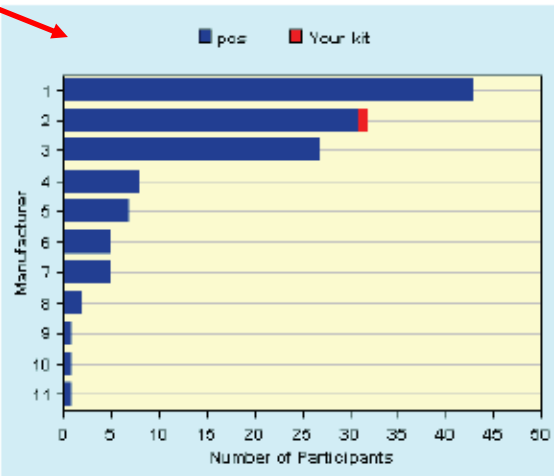
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RCPA Serology QAP
ABN 32 003 520 072

Participant 21229 Survey H4:2009 Anti-HBc Specimen 17 Participants=131

Your results where applicable are highlighted in red
Note: If the graphs appear to be zoomed, press your refresh button to fix

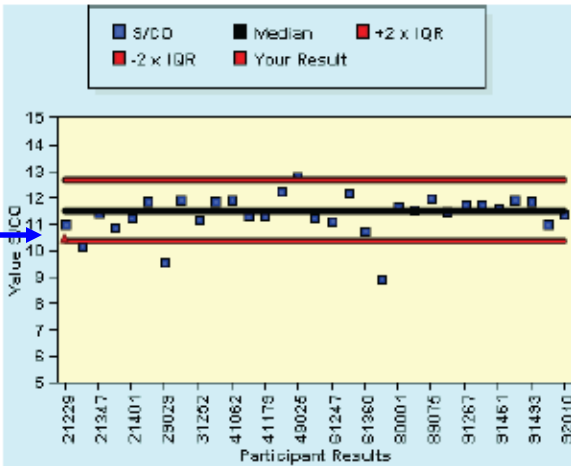
Graphical representation of your kit performance compared to other users and other kits



Your kit details and usage information compared to all other kits in use

No	Kit Details	Total	Percent
1	Abbott Diagnostics / CORE / AxSYM	43	32.8
2	Abbott Diagnostics / CORE II / Architect	31	23.7
3	Abbott Diagnostics / CORE / Architect	27	20.8
4	Siemens Healthcare Diagnostics / aHBcT / Advia Centaur	8	6.1
5	Ortho-Clinical Diagnostics / Anti-HBc / Vitros	7	5.3
6	Roche Diagnostics / Anti-HBc / Modular Analytics E170	5	3.8
7	bioMerieux / Anti-HBc / Vidas-Mini Vidas	5	3.8
8	Siemens Healthcare Diagnostics / Anti-HBc / Immulite	2	1.5
9	Siemens Healthcare Diagnostics / Enzygnost Anti-HBc Monoclonal / BEP III	1	0.8
10	Beckman Coulter / Anti-HBc / Access	1	0.8
11	Abbott Murex / Anti-HBc Total / -	1	0.8

Values Graph for Specimen 17
Kit: Abbott Diagnostics / CORE II / Architect - Units: S/CO



Graph with median and +/- 2 IQR ranges. Your result indicated above a red triangle

Statistical Assessment of Values - Specimen 17

No. of Results:	31
Median:	11.51
Normalised 2 x IQR:	1.14
Lower Quartile Limit:	10.37
Upper Quartile Limit:	12.65
Robust CV:	4.96%
Minimum:	8.95
Maximum:	12.77
Range:	3.82

Statistical assessment of results for this specimen

Distribution of Results - Specimen 17

Result	No.	Percent
pos	131	100.0

Summary of the qualitative results for this specimen

Cumulative Year to Date Scores for Participant 21229				
Survey	Your Score	Possible Score	Your Percent	All Participants
AN1:2007	31	31	100%	96%
AN2:2007	32	32	100%	97%
AN3:2007	28	28	100%	98%
AN4:2007	29	29	100%	97%
B1:2007	22	22	100%	93%
B2:2007	25	26	96%	94%
B3:2007	25	26	96%	95%
B4:2007	47	52	90%	94%
H1:2007	64	64	100%	99%
H2:2007	64	64	100%	99%
H3:2007	64	64	100%	99%
H4:2007	60	60	100%	98%
H5:2007	59	59	100%	98%
H6:2007	90	90	100%	99%
L1:2007	39	40	98%	95%
L2:2007	46	46	100%	95%

Cumulative score for all participants

Overall Year to Date:	1189	1214	98%	
-----------------------	------	------	-----	--

For four Antenatal surveys for 2007 this participant scored full marks - 100%

For the fourth Bacterial survey for 2007 this participant did not score full marks – result is 90%

Overall score for 2007 can be easily identified as 98%

Results by Disease



The screenshot shows the Serology QAP website interface. At the top, there is a navigation bar with links for Home, About Serology QAP, Programs/Enrolment, Login/Member Services, News/Resources, Committees, and Contact Us. Below this is a 'Member Services' section with a list of links: Direct Data Entry, Results by Disease, Questionnaires & Reports, Dynamic Graphs of Results, Serology QAP Forms, Manufacturers Database, and Assessment Reports. The 'Results by Disease' link is highlighted with a green circle. Below the screenshot, a large red oval contains the text: 'To find: complete report with all raw data' and 'Antenatal Serology - Rubella, HBsAg, Syphilis reports'.

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Member Services

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- Serology QAP Forms** Click to view currently available forms
- Manufacturers Database** Click to search the kit manufacturers database
- Assessment Reports** Click to view your assessment reports Current year (untick to access all years)

To find: complete report with all raw data
Antenatal Serology - Rubella, HBsAg, Syphilis reports

PART 2

Case Studies

- Assay Cases
- Protocol Cases
- Feedback

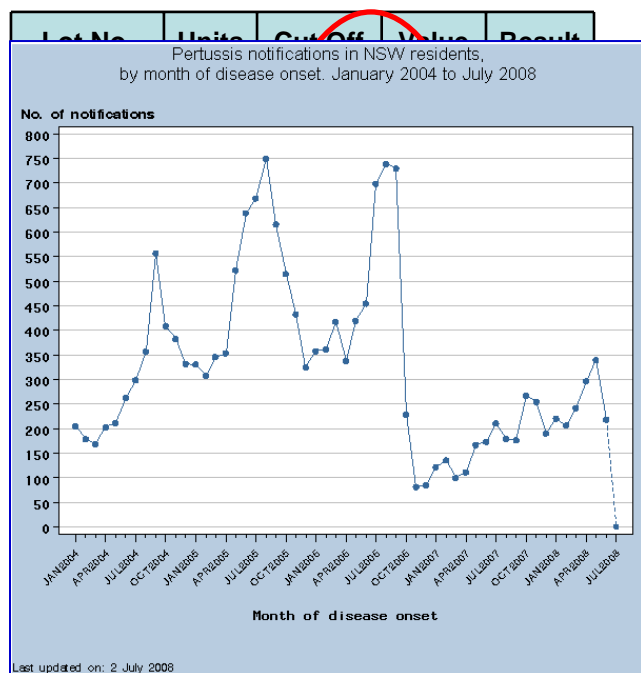
Assay Cases

- *Bordetella pertussis*
- Dengue
- Salmonella
- Hepatitis B
- Hydatid
- Rubella
- VZ IgG

Bordetella pertussis

Pre-issue Results	P2-2006-6A	
PanBio B.pertussis IgA	Negative	Equivocal

- 20/ 21 participants returned raised IgA result using the same kit
- ~ 40% values were close to cut-off value
- Triggered participant concerns



5269	S/CO	1.1	1.3	raised
5269	OD	1	1.55	raised

Investigation

- product recall - cut-off determination point too low
- increase in false positive results
- increase in infectious disease notifications

Outcome

- adjustments to the assay
- participants have evaluated other IgA assays
- consider disease interpretation
 - vaccination status, patient symptoms, date of onset, exp history
 - paired acute & convalescent sera
 - use of molecular testing to assist diagnosis of acute pertussis

Dengue

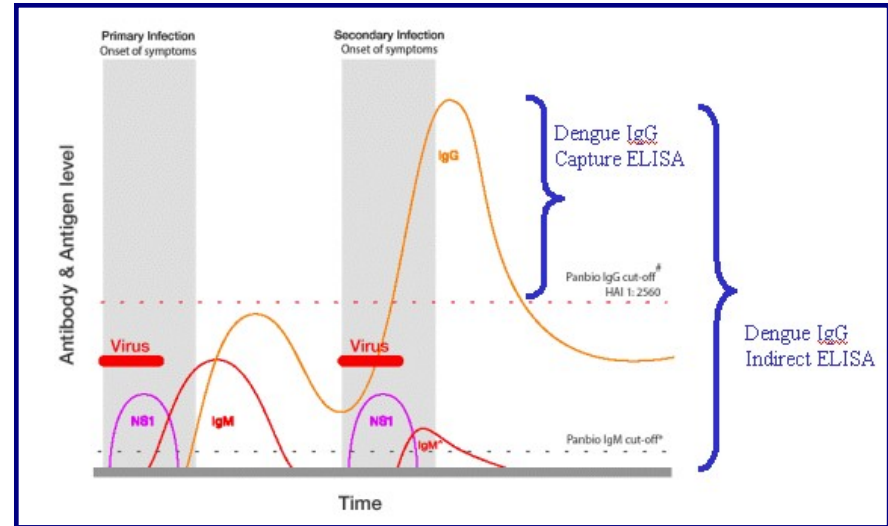
- Result discrepancies?

Investigation

- past exposure/ 2^o/ 1^o infection

Outcome - distribution of educational material by assay manufacturer & SQAP (V1-2007 Flavivirus)

- design of SQAP DDE reviewed & revised



V1-2007 Specimen 1A	Method	Units	Cut Off	Value	Result
Dengue IgG Capture	ELISA	OD	0.513	0.184	neg
Dengue IgG Capture	ELISA	S/CO	11	8	neg
Dengue IgG Capture	ELISA	PBU	10	6.184	neg
Dengue IgG Capture	ELISA	PBU	23	7.69	neg
Dengue IgG Indirect	ELISA	OD	0.958	1.706	pos
Dengue IgG Indirect	ELISA	OD	0.861	1.66	pos
Dengue IgG Indirect	ELISA	PBU	10	19.24	pos
Dengue IgG Indirect	ELISA	PBU	12	21.32	pos
Dengue Virus Duo IgM & IgG	ICT	N/A	N/A	N/A	pos
Dengue Virus Duo IgM & IgG	ICT	N/A	N/A	N/A	pos
Dengue Virus Duo IgM & IgG	ICT	N/A	N/A	N/A	pos

Panbio Dengue ELISA kits: most appropriate application

	Early detection	Primary dengue (most prevalent)	Seroconversion, seroepidemiology & surveillance	Both primary and secondary dengue	Secondary dengue
pan-E Dengue Early Dengue NS1 Antigen Capture ELISA	✓				
Dengue IgM Capture ELISA		✓			
Dengue IgG Capture ELISA					✓
Dengue Duo IgM Capture & IgG Capture ELISA				✓	
Dengue IgG Indirect ELISA		✓	✓		

Salmonella

- 11/28 elevated S.typhi 'O' antigen
- 6/26 elevated S.typhi 'H' antigen

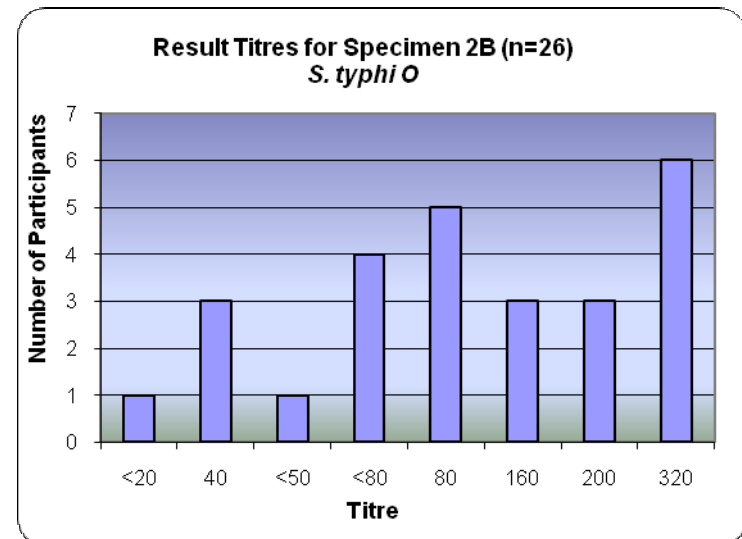
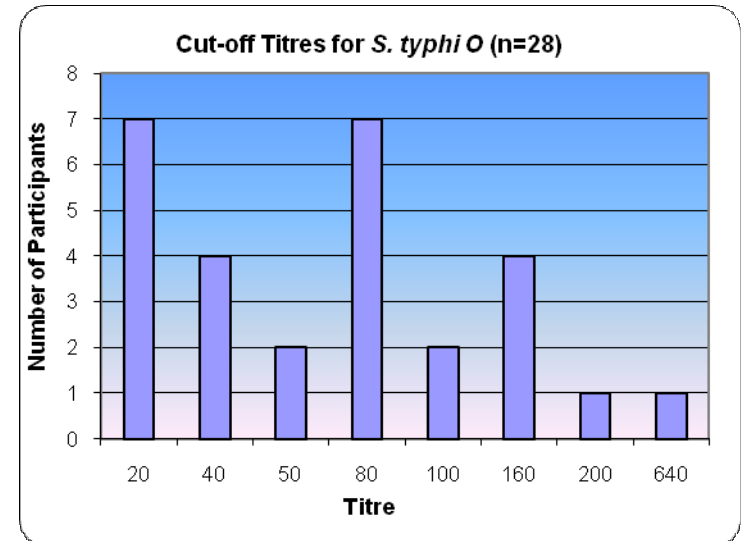
Investigation

- only 39% would identify recent infection
- wide range of cut-off values & results
- technically simple procedure
- difficulty in reading agglutination
- variability between operators & runs

Outcome

- low sens of Salmonella agglut described
- parallel testing acute & convalescent

ST2-2008-2B



Hepatitis B

- consensus result positive for HBcAb
- Siemens/Bayer Advia Centaur
(6/12 neg/eqv result, 6/12 pos result)

Investigation

- cut-off values provided - 0.3 (1), 0.5 (2), 1.0 (3)
- all values > 0.5 = POS
- all should be considered Positive

Outcome - use of correct cut-off values are essential for correct interpretation
- distribution of educational material by assay manufacturer

Samples with a calculated value of less than 0.50 Index Value are considered nonreactive for total antibodies to hepatitis B core antigen.

Samples with a calculated value greater than or equal to 0.50 Index Value are considered reactive for total antibodies to hepatitis B core antigen.

ADVIA Centaur Assay Manual

H1-2008

Cut Off Value	Specimen 3	
	Value	Result
0.5	0.69	neg
1	0.91	equ
1	0.8	equ
0.5	0.91	pos
0.5	0.89	pos
0.3	0.78	equ
0.5	0.93	neg
1	0.9	neg
0.5	0.93	pos
0.5	0.79	pos
0.5	1.13	pos
0.49	0.66	pos

Hydatid

- Lack of inter-laboratory standardisation of results

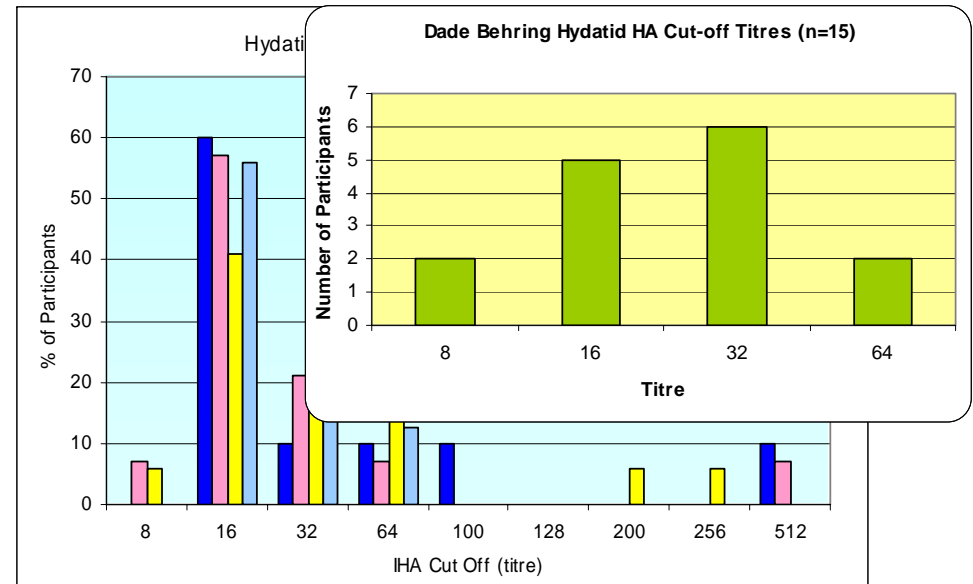
Investigation

- review of assay cut-off values
- causes of large result ranges; operator variability, reconstitution of reagents, reagents not being fresh, thawed samples not being thoroughly homogenised

Outcome

- no clear guidance from the manufacturer on interpretation of a titre of 1:16
- no validation information or references for are supplied in the kit insert
- lack of reference laboratory in Aust

Assay Case



(Natalie Roberts et al, Five Year Analysis of Hydatid Serology Results in the RCPA Serology Quality Assurance Program, ASM 2005)

The kit insert in the Dade Behring assay states:

“Serum dilutions of 1:32 to 1:64 and higher provide diagnostically useful titres. Mid-range serum titers lie between 1:512 and 1:2048.

Low positive serum titers (1:32 to 1:128) should only be accepted as positive when evaluated in conjunction with a second serological method (eg CFT, IFT, ELISA).”

Rubella

- wide distribution of Rubella IgG results in IU/mL

Investigation

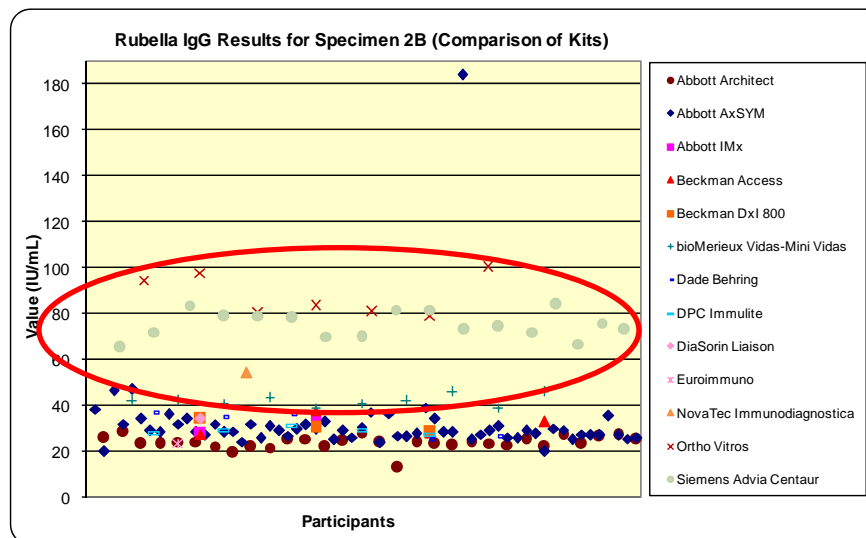
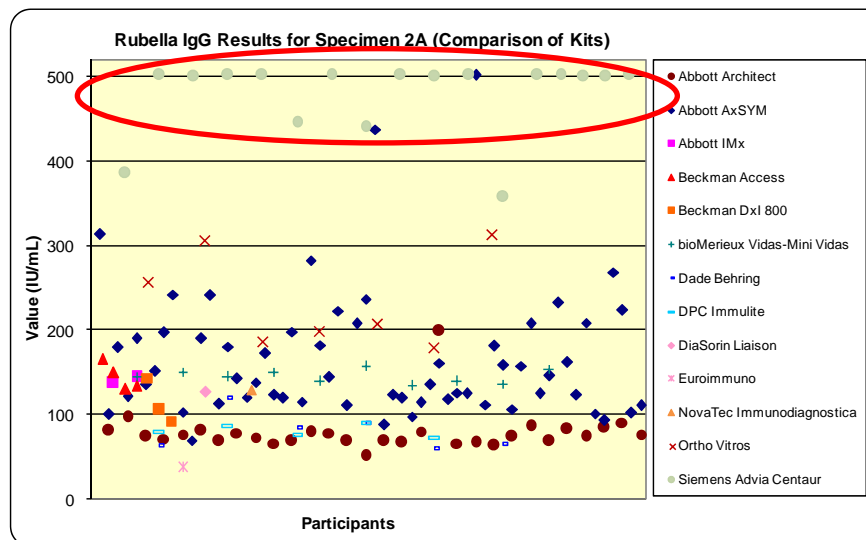
- review in each report
- Siemens Advia Centaur & OrthoClin Vitros - higher values

- Abbott AxSYM results more widespread in Specimen 2A

Outcome

- different international standards
- continue to monitor

Pre-issue results	AN2-2008-2A	AN2-2008-2B
Rubella IgG	Positive (80 IU/mL)	Positive (38 IU/mL)



VZ IgG

- consensus result negative for VZ IgG
- Trinity Biotech Captia – mixed results
(3/9 neg, 3/9 eqv, 3/9 pos result)

Investigation

- serum specimen
- values close to cut-off value
- 2 labs in 2008 survey positive for negative specimen

Outcome

- pending testing

Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4A	Result 4A
Trinity Biotech	Captia VZV IgG	ELISA	Triturus	547	Jun-10	S/CO	1.1	0.51	neg
Trinity Biotech	Captia VZV IgG	ELISA	-	545	Feb-10	S/CO	1.0	0.827	neg
Trinity Biotech	Captia VZV IgG	ELISA	-	546	Jun-10	S/CO	1.0	1.0	equ
Trinity Biotech	Captia VZV IgG	ELISA	Triturus	545	Sep-09	S/CO	1.1	1.25	pos
Trinity Biotech	Captia VZV IgG	ELISA	Triturus	545	Oct-09	S/CO	1.10	1.24	pos
Trinity Biotech	Captia VZV IgG	ELISA	-	2325600-542	Oct-09	S/CO	1.1	0.903	equ
Trinity Biotech	Captia VZV IgG	ELISA	-	2325600-547	Jun-10	S/CO	1.1	0.934	equ
Trinity Biotech	Captia VZV IgG	ELISA	-	547	Jun-10	S/CO	1	0.648	neg
Trinity Biotech	Captia VZV IgG	ELISA	Triturus	545	Feb-10	S/CO	1.10	1.41	pos



Protocol Cases

- HIV RNA
- Mycoplasma
- Avian Influenza
- Hepatitis C genotype
- Hepatitis B DNA
- Hepatitis A

HIV RNA

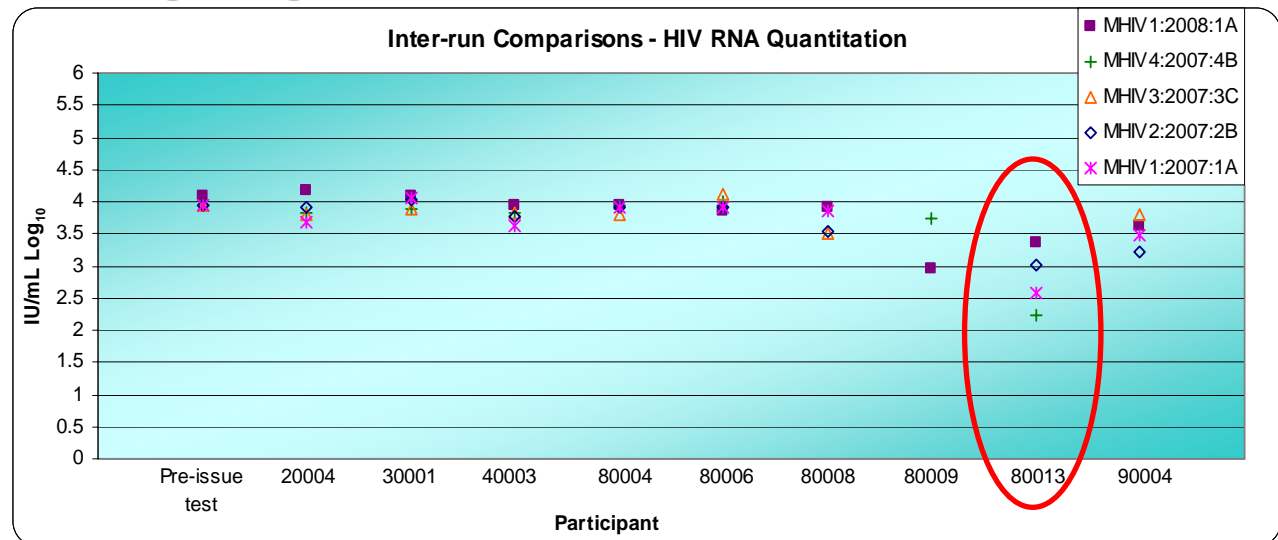
- inter-run comparison showed results lower than other participants

Investigation

- manual assay in use
- one specimen reported as <50 IU/mL
- 2008 result highest achieved (dispatched in 2008)
- answered 'yes' to storing reagents in defrost freezer

Outcome

- specimen storage could be a problem
- monitor future surveys



Pre-issue Results	B2-2007-5A	B4-2007-12A
Mycoplasma IgM	Positive	Positive

Mycoplasma

- most participants returning positive results

Investigation

- involved manufacturer
- additional specimens run on different instrumentation
- SQAP - mix gently and microfuge for 10mins
- Part - centrifuge specimens 10,000rpm

Outcome - participant concluded centrifugation was problematic

- manufacturer concluded instrumentation protocol

- results to be monitored

Kit Name	Automation	Units	Cut Off	Value 5A	Result 5A
Original Result	BEP III	S/CO	1.15	0.92	equ
Kit Name	Automation	Units	Cut Off	Value 12A	Result 12A
Original Result	BEP III	S/CO	1.15	0.55	neg

Avian Influenza

- negative results for all H5 specimens in 2008 - survey 1

Investigation

- specimen storage problem (stored at 4°C for 2 days) – investigated & rejected
SQAP stability study indicated specimens stable 10 days at 37°C (AV1:2006)
- specimens inactivated by laboratory specimen reception on receipt
SQAP instructions regarding pre-issue inactivation are clearly documented

Outcome

- part. specimen reception inactivating specimens; hence diluting RNA
- participant reviewing laboratory specimen handling procedures

Hepatitis C genotype

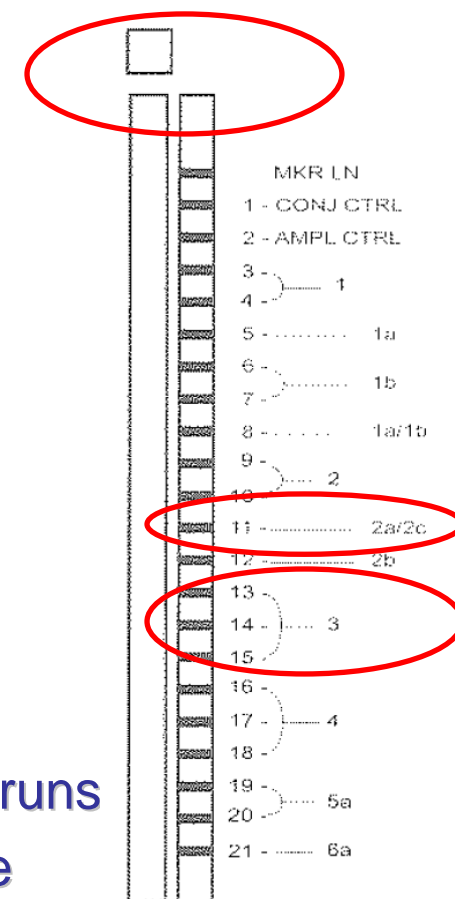
- misgenotyping of duplicate specimens

Investigation

- large run, strips dropped prior to reading
- penciled strip numbers 10 and 16 mis-read
- one was a patient sample the other QAP
- genotypes mis-assigned

Outcome

- frequent smaller rather than fewer large runs
- check strip reading prior to result release
- part. correctly genotyped same specimen in subsequent surveys



MDM:2006				MHCG1:2007:1A		MHCG2:2007:2B		MHCG3:2007:3C		MHCG4:2007:4C	
2F		2I		Genotype	Subtype	Genotype	Subtype	Genotype	Subtype	Genotype	Subtype
2	a/c	3	a	3	a	3	a	3	a	3	a

Hepatitis C genotype

- misgenotyping of specimens over two surveys

Investigation

- Survey 1 {
 - forward and reverse sequencing (different primers) - reverse was failing
 - QC at start of run - no indication of problem
- Survey 2 {
 - Final check by QC officer - insufficient data – transcription error

- Outcome
- forward & reverse primers must not fail (if so, repeat)
 - QC at beginning & end of run
 - all data checked by QC officer
 - repeat testing of QA - correct results

MHCG1-2008				MHCG2-2008			
Pre-issue Result	1a	3a	2b	Pre-issue Result	4a	1b	3a
Participant Result	1	1	1	Participant Result	3	4	3

Hepatitis B DNA

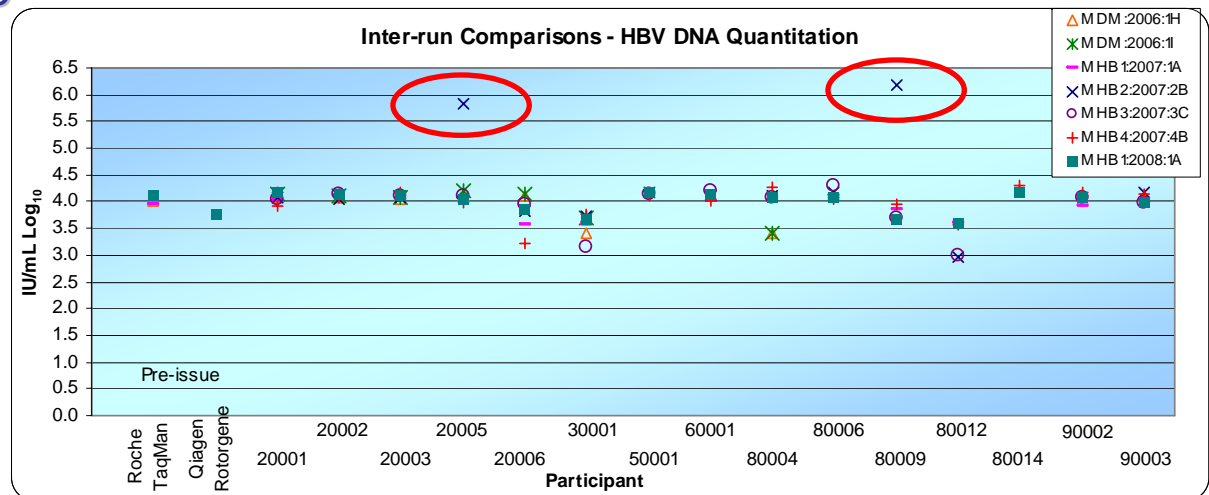
- inter-run comparison showed results higher than other participants

Investigation

- one participant had made a transcription error
- one participant had mis-calculated the result (1000 times higher)

Outcome

- transcription errors are an ongoing problem
- check calculation of quantitative results



Hepatitis A

- mis-interpretation of result values

Investigation

- review assay inserts
- assays involved were automated & often downloaded directly to LIS

Outcome

- training of instrument operators to ensure correct manual interpretation of values
- final check of results

Anti-HAV (total) Results for Survey H5:2007

Kit Name	Automation	Units	Cut Off	Value 21	Result 21	Value 24	Result 24
HAVAB-2.0	Architect	S/CO	1.2	0.065	pos	1.81	neg
HAVAB-2.0	Architect	S/CO	1.2	0.075	neg	1.803	pos
HAVAB-2.0	AxSYM	S/CO	1.2	0.167	pos	1.848	pos

Anti-HAV IgM Results for Survey H5:2007

Kit Name	Automation	Units	Cut Off	Value 21	Result 21	Value 24	Result 24
HAVAb - IgM	Architect	S/CO	1.2	5.7	pos	0.29	pos
HAVAb - IgM	Architect	S/CO	1.2	4.64	pos	0.19	neg
HAVAb - IgM	Architect	S/CO	1.2	5.31	pos	0.25	pos
HAVAb - IgM	Architect	S/CO	1.2	5.64	pos	0.53	neg
HAVAB-	AxSYM	Index	1.2	4.17	pos	0.04	neg
HAVAB-M 2.0	AxSYM	S/CO	1.2	4.55	neg	0.06	pos
HAVAB-M 2.0	AxSYM	Index	1.2	4.97	pos	0.06	neg

Conclusion

www.rcpaqap.com.au/serology

- SQAP Updates

- result sheets/ clinical notes
- participant assessment reports

- Case Studies

- assay cases
- protocols cases

GUEST LOGIN

Participant number: 99991

Password: delegate



Participant Feedback

“I would like to record our lab's appreciation for the RCPA Avian Flu QA programme as it is an important means to improve our H5 PCR assay in the absence of real patient samples.”

(Singapore participant)

“...technically proficiency testing has demonstrated to us issues with our proficiency, so we can now begin to make improvements on our specimen handling.” *(VIC participant)*

“We would welcome any involvement /participation in your HPV QA programmes – it’s great that you are establishing this service”

(New Zealand participant)

“The Serology QAP is the best website of all of the QA’s, it’s really easy to use” *(NSW participant)*