

SUMMARY OF THE SEROLOGY SCREENING INFORMATION PROGRAM - 2013

NRL is a:

- **NATA-accredited proficiency testing provider, complying with ISO 17043: 2010**
- **World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections**

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SUMMARY

NRL provides the Quality Assurance (QA) Program for blood-borne virus serology to laboratories within Australia. The QA Program consists of three post-market monitoring components: External Quality Assessment Schemes (EQAS), Quality Control (QC) Program and Serology Specificity Monitoring/Serology Screening Information Program. These components offer ongoing assessment of assay and laboratory performance.

The Serology Screening Information Program is a collection of information on the number of specimens screened to calculate the rate of positive test results in serological testing in Australia. Thus, these data have considerable epidemiological importance. These data are reported to The Kirby Institute. Using these data and the number of HIV positive individuals reported to State Health Departments assists with the estimation of HIV incidence in people that have been tested in Australia (HIV, viral hepatitis and sexually transmissible infections in Australia, Annual Surveillance Report 2013).

This report provides a summary of the HIV, HCV, HTLV and HBV screening information from blood screening, clinical diagnostic and reference testing laboratories in Australia for 2013.

Participants were asked to tally the number of specimens screened each week for each analyte and report these data, together with the name of the assay used to screen the specimens. The information presented is a summary of data reported by participants to NRL. Note: Data for some participants of the program were incomplete due to provision of incomplete data sets. Another possibility is that figures are lower in this report when compared with the previous year's report because participants have stopped testing during 2013 and have not informed NRL. Further, some participants provided no data at all.

Table 1 presents the number of participants reporting data and the number of specimens screened for each analyte in each Australian State or Territory during 2013. Table 2 presents the number of specimens screened for each analyte by assay. Table 3 presents the percentage increase or decrease in the number of participants who reported screening figures to NRL between 2012 and 2013, by analyte. Table 4 presents the overall percentage increase or decrease in the reported number of specimens screened by analyte in 2013 when compared with 2012. Figures from the 2012 report were compared with the figures presented in this report. Table 5 presents the percentage increase or decrease in the reported number of specimens screened by state and by analyte.

Discussion

- Australian Red Cross Blood Service (Blood Service) screens the most specimens using the Abbott PRISM HIV, HCV, HTLV and HBV assays (Table 2).
- The Blood Service began screening with the Abbott PRISM HIV Ag/Ab Combo CMIA in 2013 (Table 2).
- The Abbott ARCHITECT is the next most commonly used automated testing platform to screen specimens for HIV, HCV, HTLV and HBV (Table 2).
- The number of participants who reported screening figures increased for all analytes in 2013 when compared with 2012; an increase of 10.1% for HIV, 3.1% for HCV, 15.0% for HTLV and 2.7% for HBV (Table 3).
- Diagnostic and reference testing laboratories began screening with the Abbott ARCHITECT HBsAg Qualitative II CMIA in 2013 (Table 2).
- The reported number of specimens screened for HTLV (including Australian Blood Service) decreased in 2013 by 1.22% (Table 4). On the other hand, the reported number of specimens screened for HIV, HCV and HBV increased by 2.86%, 0.66% and 0.04% respectively.
- The reported number of specimens screened for HIV, HCV, HTLV and HBV in Queensland decreased for 2013 when compared with the 2012 figures; a decrease of 22.9% for HIV, 33.9% for HCV, 19.7% for HTLV and 34.2% for HBV. This decrease was mostly attributable to one laboratory. (Table 5).
- The South Australian Blood Service stopped testing for HIV, HCV, HTLV and HBV in October 2012 therefore there are no results in 2013 from the South Australian Blood Service when compared with 2012 data.

Acknowledgments

NRL would like to thank all participants of the Serology Screening Information Programme who submitted their screening figures to EDCNet.

Table 1: Number of participants reporting data and the reported number of specimens screened for each analyte in each Australian State, Territory and Australian Red Cross Blood Service, 2013. Specimens screened by the Australian Red Cross Blood Service are not included in the diagnostic and reference testing totals but are shown separately in the relevant section of the table.

Analyte	HIV		HCV		HTLV		HBV	
State	Number of Participants Reporting Data	Number of Specimens Screened	Number of Participants Reporting Data	Number of Specimens Screened	Number of Participants Reporting Data	Number of Specimens Screened	Number of Participants Reporting Data	Number of Specimens Screened
Clinical Diagnostic and Reference Testing Participants								
ACT	2	22,837	2	20,769	N/A	N/A	1	10,888
NSW	21	117,771	23	168,852	6	4,497	16	114,968
NT	2	12,083	2	8,944	1	2,115	2	10,947
QLD	8	114,565	8	107,069	3	5,568	6	95,537
SA	4	66,137	4	70,521	1	1,571	3	83,745
TAS	3	16,302	4	22,448	N/A	N/A	4	22,344
VIC	17	280,280	15	229,734	4	2,643	11	248,918
WA	5	187,650	6	171,513	1	3,022	5	112,464
Total	62	817,625	64	799,850	16	19,416	48	699,811
Australian Red Cross Blood Service Participants								
NSW	1	400,190	1	400,190	1	400,190	1	400,190
QLD	1	278,876	1	278,876	1	278,876	1	278,876
VIC	1	489,495	1	504,024	1	496,850	1	496,860
WA	1	141,647	1	131,666	1	131,662	1	132,846
Total	4	1,310,208	4	1,314,756	4	1,307,578	4	1,308,772
Grand Total	66	2,127,833	68	2,114,606	20	1,326,994	52	2,008,583

Table 2: Number of specimens screened by analyte and assay in 2013.

Assay Name	Number of Reported Specimens Screened
HIV Assays	
Abbott PRISM HIV O Plus ChLIA	675,644
Abbott PRISM HIV Ag/Ab Combo ChLIA	634,564
Abbott ARCHITECT HIV Ag/Ab Combo CMIA	516,802
Roche Elecsys HIV combi PT ECLIA	131,262
Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV) ChLIA	126,632
DiaSorin Murex HIV-1.2.O EIA	23,269
Siemens ADVIA Centaur HIV1/O/2 Enhanced (EHIV) ChLIA	11,752
Ortho VITROS Anti-HIV 1+2 Assay	3,593
Abbott AxSYM HIV Ag/Ab Combo MEIA	2,056
Alere Determine HIV-1/2 Rapid Test	1,496
Bio-Rad Genscreen HIV-1/2 Version 2 EIA	763
Total	2,127,833
HCV Assays	
Abbott PRISM HCV ChLIA	1,314,756
Abbott ARCHITECT Anti-HCV CMIA	470,194
Siemens ADVIA Centaur HCV ChLIA	140,556
Roche Elecsys Anti-HCV ECLIA	140,101
Bio-Rad MONOLISA HCV Ag-Ab ULTRA EIA	16,610
DiaSorin Murex anti-HCV (version 4.0) EIA	16,504
Roche Elecsys Anti-HCV II ECLIA	6,751
Ortho VITROS Anti-HCV Assay	4,256
Innogenetics INNOTEST HCV Ab IV EIA	2,046
Abbott AxSYM HCV Version 3.0 MEIA	1,880
Bio-Rad MONOLISA anti-HCV Plus Version 2 EIA	680
MP Diagnostics HCV-SPOT	272
Total	2,114,606
HTLV Assays	
Abbott PRISM HTLV-I/HTLV-II ChLIA	1,307,578
Abbott ARCHITECT rHTLV-I/II CMIA	14,399
DiaSorin Murex HTLV I+II EIA	5,017
Total	1,326,994
HBV Assays	
Abbott PRISM HBsAg ChLIA	1,308,772
Abbott ARCHITECT HBsAg Qualitative CMIA	234,533
Abbott ARCHITECT HBsAg Qualitative II CMIA	163,458
Siemens ADVIA Centaur HBsAgII ChLIA	159,011
Abbott ARCHITECT HBsAg CMIA	52,565
Roche Elecsys HBsAg II ECLIA	33,131
Siemens ADVIA Centaur HBsAg ChLIA	26,476
Roche Elecsys HBsAg ECLIA	23,074
DiaSorin Murex HBsAg Version 3 EIA	3,124
Ortho VITROS HBsAg Assay	2,003
Abbott AxSYM HBsAg Version 2 MEIA	1,589
Bio-Rad MONOLISA HBsAg ULTRA EIA	847
Total	2,008,583

Table 3: The percentage increase or decrease in the number of participants who reported screening figures (diagnostic and reference testing laboratories) to NRL between 2012 and 2013, by analyte.

Analyte	Number of Participants Reporting Data in 2012	Percentage Increase/ Decrease from 2012 to 2013
HIV	62	10.1
HCV	64	3.1
HTLV	16	15.0
HBV	48	2.7

Table 4: The percentage increase or decrease in the total number of reported screening figures (including Australian Blood Service) to NRL between 2012 and 2013, by analyte.

Analyte	Number of specimens screened (including Blood Service) for 2012	Percentage Increase/ Decrease from 2012 to 2013
HIV	2,127,833	2.86
HCV	2,114,606	0.66
HTLV	1,326,994	-1.22
HBV	2,008,583	0.04

Table 5: The percentage increase or **decrease** in the number of specimens screened (excluding Australian Blood Service) and reported to NRL between 2012 and 2013, by state and by analyte.

Analyte	HIV (2013)			HCV (2013)			HTLV (2013)			HBV (2013)		
	No. of Participants Reporting Data	No. of Specimens Screened	Percentage increase or decrease in reported specimens screened between 2012 and 2013	No. of Participants Reporting Data	No. of Specimens Screened	Percentage increase or decrease in reported specimens screened between 2012 and 2013	No. of Participants Reporting Data	No. of Specimens Screened	Percentage increase or decrease in reported specimens screened between 2012 and 2013	No. of Participants Reporting Data	No. of Specimens Screened	Percentage increase or decrease in reported specimens screened between 2012 and 2013
ACT	2	22,837	1.8	2	20,769	0.5	N/A	N/A	N/A	1	10,888	3.1
NSW	21	117,771	-8.3	23	168,852	-8.0	6	4,497	3.9	16	114,968	-13.1
NT	2	12,083	20.0	2	8,944	14.7	1	2,115	19.2	2	10,947	12.1
QLD	8	114,565	-22.9	8	107,069	-33.9	3	5,568	-19.7	6	95,537	-34.2
SA	4	66,137	55.6	4	70,521	60.2	1	1,571	63.6	3	83,745	158.0
TAS	3	16,302	1.6	4	22,448	1.8	N/A	N/A	N/A	4	22,344	4.8
VIC	17	280,280	39.9	15	229,734	24.5	4	2,643	188.2	11	248,918	10.6
WA	5	187,650	7.9	6	171,513	13.7	1	3,022	53.2	5	112,464	7.6