Evaluation of Abbott Architect CMV IgG Assay Product code 6C15

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Introduction

The Microbiological Diagnostics Assessment Service (HPA-MiDAS) in conjunction with the National Transfusion Microbiology Reference Laboratory (NTMRL), North London Blood Centre carried out evaluations of six assays for the Abbott Architect *i*2000SR analyser. The analyser was installed at the NTMRL where all testing took place.

The object of the evaluations was to assess the ability of the Architect HBsAg, HIV Ag/Ab combo, Anti-HCV, Rubella IgG, anti-CMV and Syphilis TP assays to detect serological evidence of each respective marker in human serum and plasma specimens.

The results of the evaluation of the Architect CMV IgG assay are presented in this report. The kits were tested against a panel of serum/plasma specimens found to be either reactive or unreactive by relevant screening assays used in Europe. In addition, two sequential blood collections from individuals undergoing seroconversion for the relevant marker (chosen to compare directly with a range of other assays), two commercial performance panels and six national quality control samples were incorporated in this evaluation.

Abbott Diagnostics provided all equipment, reagents and consumables required for this evaluation. They were responsible for the training of the operators in the use of the analyser and for the installation and ongoing maintenance and repair of any faulty equipment.

Description of the assay

The Abbott Architect CMV IgG assay is a two-step sandwich chemiluminescent microparticle immunoassay (CMIA) for the quantitative and semi-qualitative determination of CMV IgG in human serum or plasma. CMV IgG present in the sample binds to CMV antigen coated paramagnetic particles. After a wash step a murine anti-human IgG acridinium-labelled conjugate is added. Following a further wash step, pre-trigger solution (hydrogen peroxide) and trigger solution (sodium hydroxide) are added. The resulting chemiluminescent reaction is measured in relative light units (RLUs) which are directly proportional to the amount of CMV IgG present in the sample.

Table 1: Assay information

General	
Assay name	Architect CMV IgG
Manufacturer/UK agent	Abbott Diagnostics
Product number	6C15
Number of tests per pack	100 / 400
Sample volume (including 'dead volume')	150µL

Presentation	
Assay type	Two-step chemiluminescent sandwich immunoassay
Solid phase	Paramagnetic microparticles coated with CMV antigen (virus lysate, AD169)
Conjugate	Acridinium-labelled anti-human IgG (murine)
Substrate	Pre-trigger - hydrogen peroxide solution Trigger - sodium hydroxide solution
Negative control	1
Positive control	2
Reading wavelength	n/a - chemiluminescent
Cut-off computation	n/a - curve fit. 6.0 AU/mL cut-off value
Equivocal zone	None

Stages	
Preparation/sample well loading	5 minutes
Specimen volume (excluding 'dead volume')	25µL
Incubation status	37°C
Sampling time - 1 sample	1 minute
Total time to completion (from initial loading of first sample)*	
- 1 sample	37 minutes
- 10 samples	43 minutes
- 100 samples	93 minutes

Additional equipment requirement
Centrifuge
Latex/nitrile gloves & personal protective equipment

Note: * These data were observed timings by the evaluator.
Information provided by Abbott Diagnostics: Throughput approximately 50 tests in the first hour and 100 tests per hour after the first result is generated.

Evaluation panel and method

A total of 593 samples were included in the evaluation panel, Table 2. Two hundred and eighty-nine specimens were CMV IgG negative samples and 202 were CMV IgG positive specimens. To determine their status, all the samples had been previously screened by six other assays and, for confirmation where required, a number were further tested by a Western blot assay and a CMV IgM detection assay (NBSR06004[1]).

Two seroconversion panels and two performance panels from commercial sources were also included. Six quality control samples, from the HPA and commercial sources, were included in the panel.

In addition, 23 samples were tested which are still undergoing characterisation.

Table 2: Evaluation panel

Sample category		Number
1. Anti-CMV negative		
Blood donors' sera		289
2. Anti-CMV positive		
Blood donors' sera		202
3. Anti-CMV Indeterminate		
Blood donors' sera		23
3. Anti-CMV seroconversion panels		
BBI: RP-003		15
BBI: PTC901		8
4. Anti-CMV performance panels		
BBI - PTC201		25
BBI - PTC202		25
5. Quality control samples		
HPA QC1	3x	1
Accurun 25	3x	1
Accurun 145	3x	1
Accurun 800	3x	1
Virotrol ToRCH Positive	3x	1
Liquicheck ToRCH Negative	3x	1
TOTAL (number of tests)		**593**

Notes:
BBI = Boston Biomedica Inc (now part of SeraCare Life Sciences, Inc)
HPA = Health Protection Agency

The method described in the kit insert was followed strictly. Abbott Architect *i*2000SR is a fully automated analyser; all processing steps are performed on the instrument. The Architect assay parameters are factory set and defined in the system software.

A daily maintenance program is followed each day, the steps for which are prompted on the display screen. Principally, Probe Conditioning Solution and sodium hypochlorite solution are loaded onto the analyser by the operator and the analyser completes the program automatically. This process takes approximately 20 minutes. In addition, a weekly maintenance program is also required in which the sample, reagent and wash probes are cleaned with cotton-wool swabs soaked in distilled water and the air filters are cleaned.

Prior to running the analyser, test reagents, pre-trigger solution, trigger solution, wash buffer and reaction vessels are loaded onto the analyser and automatically primed and loaded as appropriate. The latter two may also be added whilst the analyser is in ‘Running’ mode.

Prior to running a new batch of an assay, a calibration must first be performed. The calibrators are provided in dropper bottles and an appropriate volume is placed into sample cups and

loaded onto the analyser. The calibration is valid for all subsequent tests using that particular lot number; it is not time limited. For the CMV IgG assay, the calibrator pack consists of a series of six calibrators with CMV IgG concentrations of 0.0 to 250.0 Arbitrary Units/mL (AU/mL). A calibration curve is produced by the analyser against which the RLU reading from each sample is compared to give the number of arbitrary units per mL.

Three CMV IgG kit controls are provided by Abbott Diagnostics. It is recommended that these are run at least once within every 24 hours that the test is in use. The CMV IgG controls consist of a Negative Control (≤3.1AU/mL), Positive Control 1 (30.0AU/mL, range 15.0-45.0AU/mL) and Positive Control 2 (150.0AU/mL, range 75.0-225.0AU/mL).

Specimens may be loaded in their primary tubes, if suitable for the analyser, or aliquots made into Architect sample cups. Sample processing is initiated by the loading of the samples onto the analyser. The reactions occur in the following processing sequence: -

- A reaction mixture is formed combining sample, sample diluent and microparticles in the reaction vessel.
- After the first incubation is complete, the reaction mixture undergoes a wash step. A magnetic field is applied to retain the paramagnetic microparticles within the reaction vessel during the wash procedure.
- The anti-human IgG/acridinium conjugate is then added and a further incubation takes place.
- Following a second wash step, pre-trigger (hydrogen peroxide) and trigger (sodium hydroxide) solutions are added to the reaction vessel
- The resultant chemiluminescent signal is measured and expressed as Relative Light Units.

The observed time from loading a sample to obtaining a result was 37 minutes for the CMV IgG assay. Subsequent results are obtained every 36 seconds, assuming continuous loading of samples. (18 seconds is a set cycle time per reaction vessel, for which two are required for the CMV IgG assay, and does not vary).

The criteria for interpretation are as follows: positive ≥6.0AU/mL and negative <6AU/mL. The kit insert gives a recommendation to confirm results between 6.0 and 15.0AU/mL using a CMV IgM test or by the retesting of a second sample.

Specificity

Two hundred and eighty-nine blood donors' samples were tested by the Architect CMV IgG assay, lot number 51486LU00.

Two hundred and eighty-five samples were nonreactive by the Architect CMV IgG assay to give a specificity of 98.62% (95% confidence interval 96.5 – 99.6%).

Four samples were initially reactive and were again reactive following retests in duplicate. This gave an initial and repeat reactive rate of 1.38% (95% confidence interval 0.37 – 3.51%), Tables 3 and 4. The results of the four samples were within the range of 6.0 – 15.0AU/mL; the kit insert states that samples which give values within this range should have further confirmatory testing. The AU/mL values for these four samples are shown in Table 5 with the results of six other assays.

Table 3: Comparative initial specificity

Assay (Manufacturer/Agent; product code)	No tested	No initial reactive	Reactive rate % (95% confidence interval)	Mean	Median	Range
Architect CMV IgG	289	4	1.38% (0.4-3.5%)	0.96	0.63	0.09-8.19
EIAgen CMV Screen* (Adaltis; 81025)	289	0	0.0% (0.0-1.3%)	0.52	0.52	0.27-0.71
Vironostika Anti-CMV III* (Biomerieux; 284124)	289	2	0.69% (0.1-2.5%)	0.63	0.62	0.33-1.10
Mastazyme-CMV* (Mast; EIA802)	289	4	1.38% (0.4-3.5%)	0.64	0.62	0.33-1.17
Bioelisa CMV colour (Biokit/Launch; 3000-1245)	289	9	3.11% (1.4-5.8%)	0.24	0.17	0.04-1.76
Mercia CMV TA* (Microgen; M503)	289	33**	11.42% (7.8-15.1%)	0.74	0.69	0.52-2.94
CMV-IgG-ELA (Medac/Cosmos; 115-Q-PKS)	289	15	5.19% (2.9-8.4%)	0.30	0.39	0.11-3.89

Note. *The results of competitive assays are presented as CO/OD to allow for direct comparison with non-competitive assays
** New cut-off formulation used for repeat results - please see report NBSR06004 for details.

Table 4: Comparative repeat specificity

Assay (Manufacturer/Agent; product code)	No tested	No repeat reactive	Reactive rate % (95% confidence interval)	Mean	Median	Range
Architect CMV IgG	289	4	1.38% (0.4-3.5%)	0.96	0.63	0.09-9.21
EIAgen CMV Screen* (Adaltis; 81025)	289	0	0.0% (0.0-1.3%)	0.52	0.52	0.27-0.71
Vironostika Anti-CMV III* (Biomerieux; 284124)	289	0	0.0% (0.0-1.3%)	0.63	0.62	0.33-0.91
Mastazyme-CMV* (Mast; EIA802)	289	4	1.38% (0.4-3.5%)	0.70	0.62	0.33-10.24
Bioelisa CMV colour (Biokit/Launch; 3000-1245)	289	6	2.08% (0.8-4.5%)	0.23	0.17	0.04-1.76
Mercia CMV TA* (Microgen; M503)	289	2**	0.69% (0.1-2.5%)**	0.57	0.55	0.34-1.14
CMV-IgG-ELA (Medac/Cosmos; 115-Q-PKS)	289	6	2.08% (0.8-4.5%)	0.42	0.30	0.11-9.90

Notes. *The results of competitive assays are presented as CO/OD to allow for direct comparison with non-competitive assays
** New cut-off formulation used for repeat results - please see report NBSR06004 for details.

Table 5: AU/ml values of reactive samples

Sample number	Architect CMV IgG AU/mL			EIAgen CMV Screen	Vironostika Anti-CMV III	Mastazyme CMV	Bioelisa CMV colour	Mercia CMV TA	CMV-IgG-ELA
				CO/OD	CO/OD	CO/OD	OD/CO	CO/OD	OD/CO
	Initial	Repeat		Initial result*					
0080	8.078	8.747	8.701	0.520	0.610	0.658	0.093	0.760	0.866
0112	7.375	7.213	7.125	0.517	0.578	0.583	0.119	0.700	0.189
0177	7.801	9.205	9.171	0.470	0.566	0.564	0.178	0.778	1.270**
0330	8.19	7.88	7.907	0.492	0.628	0.603	0.088	0.574	1.145**

Notes. *The results of competitive assays are given as CO/OD to allow for direct comparison with non-competitive assays.
Samples 0177 and 0330 were unreactive when retested in duplicate in Assay 6

Sensitivity

Two hundred and two anti-CMV IgG positive specimens were tested by the Architect CMV IgG assay, lot number 151486LU00. On initial testing, all 202 specimens were reactive by the assay to give a sensitivity of 100% (95% confidence interval 98.2-100%), Table 6. The results ranged from 17.2 - >250AU/mL with mean and median values of 156.4 and 158.1 AU/mL, respectively.

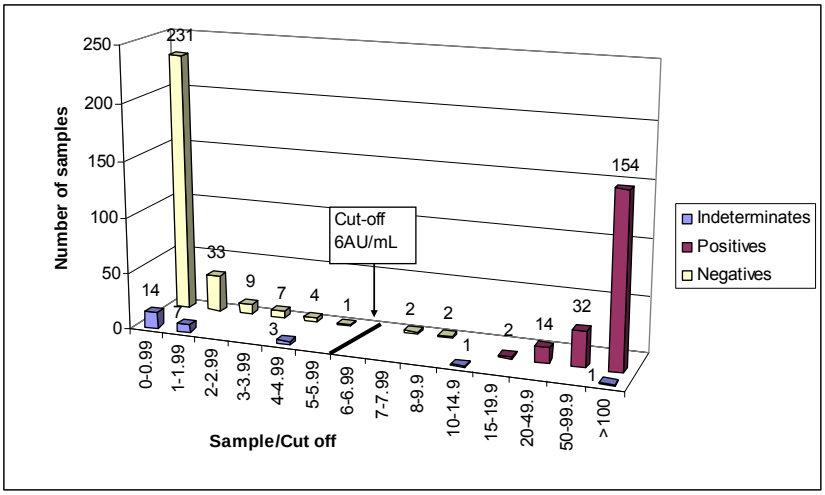
Table 6: Comparative initial sensitivity

Assay	No positive/no tested	Sensitivity % (95% confidence interval %)	Mean	Median	Range
Architect CMV IgG	202/202	100 (98.2-100)	156.4	158.1	17.2->250
EIAgen CMV Screen* (Adaltis; 81025)	201/202	99.5 (97.3-100)	4.25	4.40	0.39-8.61
Vironostika Anti-CMV III* (Biomerieux; 284124)	200/202	99.0 (96.5-99.9)	5.56	5.64	0.56-10.23
Mastazyme-CMV* (Mast; EIA802)	201/202	99.5 (97.3-100)	4.67	4.81	0.43-7.46
Bioelisa CMV colour (Biokit/Launch; 3000-1245)	199/202	98.5 (95.7-99.7)	2.55	2.59	0.43-4.20
Mercia CMV TA* (Microgen; M503)	201/202	99.5 (97.3-100)	34.45	22.44	0.87-184.88
CMV-IgG-ELA (Medac/Cosmos; 115-Q-PKS)	202/202	100 (98.2-100)	10.29	10.63	1.71-15.55
Note. *The results of competitive assays are presented as CO/OD to allow for direct comparison with non-competitive assays					

Distribution of initial reactivities

The distribution of reactivities for the 289 CMV IgG negative, 202 CMV IgG positive and 26 indeterminate (ie samples not assigned a negative/positive status) specimens is shown in Figure 1. Assays with good discrimination have few or no samples wrongly classified and few reactions close to the cut-off. Four of the 289 anti-CMV IgG negatives were repeatedly reactive by the Architect CMV IgG assay. All 202 anti-CMV IgG positive specimens gave high reactivities.

Figure 1: Distribution of initial reactivities



Seroconversion and performance panel sensitivity

Two commercial seroconversion panels were tested. Of the 23 specimens represented in the two panels, 19 were detected by the Architect CMV IgG assay, Tables 7 and *Appendix* Table 12.

Two commercial performance panels were also tested, comprising 23 anti-CMV IgG positive and two anti-CMV IgG negative samples in each panel. The Architect CMV IgG assay detected all 23 positive samples in both panels PTC201 and PTC202, Tables 8 and *Appendix* Table 12.

Table 7: Seroconversion sensitivity for 2 panels

Assay	Number of positive samples (number of days from initial bleed to first reactive sample)		Total (RP003 + PTC901)
	RP003	PTC901	
	n=15	n=8	n=23
Architect CMV IgG	15	4	19
EIAgen CMV Screen* (Adaltis; 81025)	13	4	17
Vironostika Anti-CMV III* (Biomerieux; 284124)	14	4	18
Mastazyme-CMV* (Mast; EIA802)	13	4	17
Bioelisa CMV colour (Biokit/Launch; 3000-1245)	13	4	17
Mercia CMV TA* (Microgen; M503)	14	5	19
CMV-IgG-ELA (Medac/Cosmos; 115-Q-PKS)	12	5	17

Notes: The total for each assay was the number of reactive samples for the panel

For the purposes of scoring, a cut-off value of 1 was used to determine reactivity/non-reactivity.

Table 8: Sensitivity for two performance panels

Assay	Number of positive samples		Total (PTC201 + PTC202)
	PTC201	PTC202	
	n=25	n=25	n=50
Architect CMV IgG	23	23	46
EIAgen CMV Screen* (Adaltis; 81025)	23	22	45
Vironostika Anti-CMV III* (Biomerieux; 284124)	23	23	46
Mastazyme-CMV* (Mast; EIA802)	23	23	46
Bioelisa CMV colour (Biokit/Launch; 3000-1245)	22	21	43
Mercia CMV TA* (Microgen; M503)	21	22	43
CMV-IgG-ELA (Medac/Cosmos; 115-Q-PKS)	23	23	46

For the purposes of scoring, a cut-off value of 1 was used to determine reactivity/non-reactivity.

Lot comparison

A subset of the main evaluation panel was tested in a second lot of the assay (Lot number 49370LU01). Forty CMV IgG positive specimens, 10 negative specimens, two seroconversion panels, one performance panel and six quality control samples were compared, Tables 9, 10 and *Appendix* Table 12. Both lots of the assay identified the same number of positive specimens with a total of 72. The AU/mL values obtained from both lots were similar for all the samples compared.

Table 9: Comparison of two lots of Architect CMV IgG

Specimen category	Number of specimens	Number of initial reactive specimens (>6AU)	
		51486LU00	49370LU01
CMV IgG negative	10	0	0
CMV IgG positive	40	40	40
RP003	15	15	15
PTC901	8	4	4
PTC202	25	23	23
Total	98	72	72

Table 10: Comparison of six quality control samples

Quality control sample	Architect CMV IgG							
	Lot 51486LU00				Lot 49370LU01			
	Test 1	Test 2	Test 3	Mean	Test 1	Test 2	Test 3	Mean
HPA anti-CMV QC1	53.72	49.44	46.96	50.04	49.25	47.85	49.49	48.87
Accurun 145	38.49	40.00	39.31	39.27	37.05	39.95	37.69	38.23
Accurun 25 multi-marker positive control	43.59	43.44	42.26	43.10	43.66	42.32	NT	42.99
Virotrol ToRCH positive control	43.28	45.12	44.88	44.43	43.30	42.48	42.18	42.65
Accurun 800 Accurun ToRCH negative control	2.37	1.74	NT	2.06	2.02	1.87	1.61	1.83
Bio-Rad Liquicheck ToRCH Plus negative control	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

A quality control sample/statistical assay control should be chosen to have a reactivity within the linear dynamic range of the assay. Our findings suggest that all controls tested would be suitable for use in the Architect CMV IgG assay.

Indeterminate samples

The panel of anti-CMV IgG negative and positive blood donors' samples initially totalled 511 specimens. Of these, 289 were confirmed as negative and 202 confirmed as positive when the samples were characterised. The remaining 26 samples have not yet been assigned a status and therefore have not been included in the sensitivity and specificity calculations for the Architect CMV IgG assay. The samples were tested in the assay, however, and the results are shown, along with the results of other assays, in Figure 1 and *Appendix* Table 11.

Conclusion

The Architect CMV IgG assay gave an initial and repeat reactive rate of 1.39%, whereby four of the 289 CMV IgG negative specimens were repeatedly reactive with readings of 7.38 – 8.19AU/mL. (Without the existence of a gold standard, it was necessary to characterise the panel specimens according to the results observed in six other CMV antibody assays. Under these circumstances, we cannot exclude the possibility that a more sensitive test would give rise to a perceived lower specificity.)

All 202 CMV IgG positive samples tested were reactive in the assay to give a sensitivity of 100%. All the specimens were strongly positive with values greater than 17AU/mL.

Two seroconversion panels were tested for which the Architect CMV IgG assay detected 19 of the total of 23 specimens. One other assay with which it was compared also detected 19 specimens. Two performance panels were also tested for which the Architect CMV IgG assay detected all 46 of the CMV IgG positive specimens. Three other assays with which the Architect CMV IgG assay was compared also detected the 46 positive specimens.

A small lot comparison was undertaken in which both lots of the Architect CMV IgG assay gave similar AU/mL results for all samples tested.

Reference

1. **Mitchell N, Burgess C, Curtis J, Perry KR** (2008): Evaluation of six Cytomegalovirus IgG/total antibody kits suitable for use in the UK National Blood Service. NBSR06004.
Available from www.hpa-midas.org.uk/reports

Appendix

Table 11: Results for specimens with status undetermined

Specimen number	Architect CMV IgG		Assay 1	Assay 2	Assay 3	Assay 4	Assay 5	Assay 6	Mikrogen Western Blot	
	Initial result AU/mL	Repeat result AU/mL	Initial / Repeat result	Initial / Repeat result	Initial / Repeat result	Initial / Repeat result	Initial / Repeat result	Initial / Repeat result	Initial result	Repeat result
06M0020	1.667	NT	Neg	Neg	Neg	Neg	POS / POS	Neg	POS	Borderline
06M0026	1.717	NT	Neg	Neg	Neg	Pos / TBT	Equiv / Equiv	Neg	Neg	NT
06M0031	6.827	NT	Neg	Pos / TBT	Pos	Neg	Neg	Neg	Neg	NT
06M0040	4.415	NT	Neg	Neg	Neg	Pos / TBT	POS / POS	Neg	Neg	NT
06M0104	0.322	NT	Neg	Neg	Neg	Equiv / Equiv	POS / POS	Neg	Neg	NT
06m0142	0.909	NT	Neg	Neg	Neg	Pos / TBT	POS / POS	Neg	Neg	NT
06M0143	1.894	NT	Neg	Neg	Neg	Equiv / Equiv	POS / POS	Neg	Neg	Neg
06M0201	0.906	NT	Neg	Neg	Neg	POS / POS	Equiv / POS	POS / Neg	Neg	NT
06M0202	0.754	NT	Neg	Neg	Neg	Equiv / TBT	POS / POS	Neg	Neg	NT
06M0257	0.721	NT	Neg	Neg	Neg	Equiv / POS	POS / POS	Neg	Neg	NT
06m0270	0.727	NT	Neg	Neg	Neg	Neg	Neg	Neg	POS	Borderline
06M0300	0.969	NT	Neg	Neg	Neg	Neg	POS / Equiv	Neg	POS	Neg
06m0305	1.901	NT	Neg	Neg	Neg	Pos / TBT	Equiv / TBT	Pos / TBT	Borderline	NT
06M0307	17.237	7.88 / 7.91	POS	POS	POS	Neg	Neg / TBT	POS	NT	Neg
06M0342	0.652	NT	Neg	Neg	Neg	Neg	Neg	POS / POS	POS	Borderline
06M0363	0.649	NT	Neg	Equiv / POS	Equiv / POS	Neg	Neg	Neg	Neg	Neg
06M0394	0.712	NT	Neg	Equiv / neg	Equiv / Equiv	Neg	Neg	Neg	Neg	Neg
06M0417	1.444	NT	Neg	Equiv / Equiv	Neg	Neg	Neg	POS / Equiv	Neg	Neg
06M0425	11.201	9.64 / 9.96	Neg	Neg	Neg	Equiv / neg	POS / POS	Neg	Borderline	Borderline
06M0479	1.881	NT	Equiv / neg	POS / POS	POS	Neg	Neg	Neg	Neg	NT
06M0484	0.882	NT	Neg	Equiv / neg	Equiv / Equiv	Neg	Neg	Neg	Neg	Borderline
06M0487	0.623	NT	Equiv / POS	POS / POS	POS / POS	Neg	Neg	Neg	Neg	NT
06M0510	0.783	NT	Neg	POS / POS	POS	Neg	Neg	Neg	Neg	NT

Note. TBT = Repeat tests outstanding

Key

- Negative
- Equivocal
- Disparate initial & repeat result
- Positive

Table 12: Architect CMV IgG results for two commercial seroconversion panels, RP003 and PTC901, and two performance panels, PTC201 and PTC202.

Panel	AU/mL	
	51486LU00	49370LU01
RP003-01	**8.049**	**7.601**
RP003-02	**22.641**	**19.989**
RP003-03	**51.849**	**48.738**
RP003-04	**87.591**	**86.759**
RP003-05	**91.891**	**85.43**
RP003-06	**89.634**	**86.575**
RP003-07	**84.974**	**82.655**
RP003-08	**82.711**	**79.359**
RP003-09	**74.543**	**74.397**
RP003-10	**79.256**	**79.348**
RP003-11	**79.124**	**78.179**
RP003-12	**80.947**	**85.683**
RP003-13	**92.301**	**86.272**
RP003-14	**85.301**	**82.198**
RP003-15	**82.313**	**85.201**

Panel	AU/mL	
	51486LU00	49370LU01
PTC901-01	2.429	1.89
PTC901-02	1.404	1.299
PTC901-03	1.51	1.27
PTC901-04	1.423	1.25
PTC901-05	3.435	2.778
PTC901-06	**44.516**	**41.65**
PTC901-07	**75.828**	**69.387**
PTC901-08	**94.863**	**90.373**
PTC901-09	**127.379**	**116.375**

Panel	AU/mL
	51486LU00
PTC201-01	**99.353**
PTC201-02	**207.976**
PTC201-03	**12.257**
PTC201-04	**199.31**
PTC201-05	**>205**
PTC201-06	2.435
PTC201-07	**82.557**
PTC201-08	**122.265**
PTC201-09	**155.542**
PTC201-10	**18.694**
PTC201-11	**36.61**
PTC201-12	**222.691**
PTC201-13	**101.635**
PTC201-14	**170.735**
PTC201-15	**176.156**
PTC201-16	**70.131**
PTC201-17	**27.083**
PTC201-18	5.931
PTC201-19	**>205**
PTC201-20	**24.689**
PTC201-21	**232.352**
PTC201-22	**76.731**
PTC201-23	**167.694**
PTC201-24	**26.928**
PTC201-25	**162.701**

Panel	AU/mL	
	51486LU00	49370LU01
PTC202-01	**69.487**	**71.085**
PTC202-02	**66.264**	**63.887**
PTC202-03	**165.983**	**159.417**
PTC202-04	**65.649**	**61.034**
PTC202-05	**78.035**	**76.945**
PTC202-06	3.428	3.595
PTC202-07	**37.404**	**37.803**
PTC202-08	**185.932**	**165.694**
PTC202-09	**156.764**	**155.231**
PTC202-10	**84.769**	**83.074**
PTC202-11	**30.844**	**31.497**
PTC202-12	**107.727**	**99.524**
PTC202-13	**101.661**	**97.083**
PTC202-14	**72.55**	**70.422**
PTC202-15	**80.368**	**79.672**
PTC202-16	**217.23**	**211.405**
PTC202-17	**>205**	**>205**
PTC202-18	**145.934**	**135.912**
PTC202-19	**232.684**	**226.046**
PTC202-20	**200.857**	**201.463**
PTC202-21	**199.476**	**194.313**
PTC202-22	**114.692**	**104.79**
PTC202-23	**211.678**	**197.934**
PTC202-24	1.475	0.987
PTC202-25	**69.648**	**69.246**