s22

s22

s22

Australian Government
Department of Health
Therapeutic Goods Administration

Laboratories Branch

Biochemistry – Cell Culture Manual	
Procedure	CC – 28 – Anti-D Activity – WORKSHEET
Written	s22 [redacted]
Authorised	s22 [redacted]
Date issued	Friday, 11 March 2016
Revision #	3

Anti-D Activity – WORKSHEET

Analyst: s22 [redacted] Date: 17JAN2017

Sample Information

All standards, controls and samples should be measured in **TRIPLICATE**.

Standard: Name: 2nd IS Anti-D

Ref#: 01/572

Conc: 285 IU/vial

Sample 1: Rhophylac LIMS# 160800319O B# 4367600001 conc 1500 IU/2mL

Sample 2: Rh(D) IgG LIMS# " ... 3191 B# 3690850044 conc 250 IU/vial

Sample 3: " " LIMS# " ... 3192 B# 3680010064 conc 625 IU/vial

Sample 4: 2nd IS Anti-D LIMS# FZ 01JUN2016 B# 01/572 conc 285 IU/mL

Reagents

PBS-BSA Prepared on 11JAN2017 Expiry 18JAN2017

Secondary Antibody - Goat Anti-Human IgG – Alexa Fluor 488

Batch # 1786428A Expiry 21-08-2018

- Dilute 1:100 in PBS-BSA

Total Volume Secondary Ab required	*Volume Ab*	*Volume PBS-BSA*
3.6mL	36µl	3564µl

Red Blood cells Batch # 02421232 Expiry 14FEB2017

Abtectcell III, 3%

- Dilute 1:10, in PBS-BSA

	Total required	*Red Blood Cells*	*PBS-BSA*
R1R1	4mL	400µl	3.6mL
rr	400µl	40µl	360µl

Dilutions

For samples over 50 IU/ml, perform a pre dilution

Predilution *Dilute standard/sample to a concentration of **7.5 IU/ml** in **PBS-BSA***

Standard: 10 µL of 285 IU/mL + 370 µL of PBS-BSA = **7.5 IU/mL**

Sample 1: 10 µL of 600 IU/mL + 790 µL of PBS-BSA = **7.5 IU/mL**

Sample 2: 12 µL of 200 IU/mL + 308 µL of PBS-BSA = **7.5 IU/mL**

Sample 3: 10 µL of 525 IU/mL + 690 µL of PBS-BSA = **7.5 IU/mL**

Sample 4: 10 µL of 285 IU/mL + 370 µL of PBS-BSA = **7.5 IU/mL**

*Dilute standard/sample to a final concentration of **0.5 IU/mL** in **PBS-BSA***

Standard: 16 µL of 4.5 IU/mL + 224 µL of PBS-BSA = **0.5 IU/mL**

Sample 1: 16 µL of 7.5 IU/mL + 224 µL of PBS-BSA = **0.5 IU/mL**

Sample 2: 16 µL of 7.5 IU/mL + 224 µL of PBS-BSA = **0.5 IU/mL**

Sample 3: 16 µL of 7.5 IU/mL + 224 µL of PBS-BSA = **0.5 IU/mL**

Sample 4: 16 µL of 7.5 IU/mL + 224 µL of PBS-BSA = **0.5 IU/mL**

Incubations

	Start time	*End Time*	*Number Washes*
Incubation 1 (RBC and samples)	10:27	11:07	2
Incubation 2 (Secondary Antibody)	11.40	12.10	2

Pipettes Used

LIMS# 5653 Expiry 6MAR2017

LIMS# 5646 Expiry 6 MAR2017

LIMS# 30026 Expiry 6 MAR2017

LIMS# 32024 Expiry 23 APR2017

LIMS# Expiry

Worksheet entered by: s22 Signed s22

Checked s22 24 Jan 17

Results:

- Export the FCS files into a new date-labelled folder on the desktop
- Perform batch analysis on each carousel and export the CMV file to the new folder
- Export the date labelled folder (via USB) to the i Drive for analysis
- Open the CMV file in Anti-D Excel template, and sort the data into dose tables for statistical analysis
- Analyse via parallel line analysis in CombiStats using the Anti-D.epm template
- Once analysis is complete, save the data in the relevant TRIM testing file

System Suitability: **Pass** / ~~Fail~~

- 6 peak particles to be run prior to the assay and at the conclusion of the assay.
- Median FITC-A is recorded for each of the 6 populations

System Suitability Criteria: % difference between populations 4, 5, 6, 7 & 8 is ≤ 1%
% difference between population 3 is < 10%

6 Peak Particles: Batch # AH01 Exp date 11 JAN 2018

	6 Peak Particles: Before Assay Median FITC-A	6 Peak Particles: After Assay Median FITC-A	% difference: 100 – [(Before/After)*100]	Acceptance Criteria	Pass / Fail
Population 3	60	60	0	< 10%	PASS
Population 4	1600	1598	-0.13	≤ 1.0%	PASS
Population 5	5023	5027	0.08	≤ 1.0%	PASS
Population 6	15630	15616	-0.09	≤ 1.0%	PASS
Population 7	44144	44187	0.1	≤ 1.0%	PASS
Population 8	92460	92514	0.06	≤ 1.0%	PASS

Parallel Line Analysis:

Combistats: *Use the Anti-D.epm template*
Model: *Parallel Lines*
Design: *Completely randomised*
Transformation: *y' = log(y)*
Variance: *Observed residuals*

- Analyse the Standard against one Sample at a time
- Choose at least 3 doses for the analysis (must be the same doses in both the standard and sample)
- Discuss any deviations with test/sample manager

For the predicted potency to be valid, the ANOVA must meet the following criteria:

- Regression is significant (at least 1 *, preferably 3 ***)
- Non-parallelism is not significant (no stars present)
- Non-linearity is not significant (no stars present)

s22

16T
15A

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017

Remarks: Anti-D IgG Survey 2017

Standard			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/vial		
Doses	(1)	(2)	(3)
0.5 IU	3275	2932	3027
0.25 IU	1882	1595	1538
0.125 IU	941	763	767
0.0625 IU	510	430	430

Sample 1			
Id.	Rhophylac		
Lims #	1608003190		
Batch#	4367600001		
Ass. pot.	600 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	4619	4621	3448
0.25 IU	2525	2617	1778
0.125 IU	1274	1346	949
0.0625 IU	736	747	540

Sample 2			
Id.	Rh(D) IgG		
Lims #	1608003191		
Batch#	3690850044		
Ass. pot.	200 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	3631	3455	3324
0.25 IU	1830	1617	1526
0.125 IU	987	853	768
0.0625 IU	544	477	446

Sample 3			
Id.	Rh(D) IgG		
Lims #	1608003192		
Batch#	3680010064		
Ass. pot.	525 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	4358	3527	3499
0.25 IU	2017	1638	1647
0.125 IU	1032	846	843
0.0625 IU	552	442	466

Sample 4			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	3249	3185	3111
0.25 IU	1684	1626	1519
0.125 IU	896	882	836
0.0625 IU	507	513	444

Model: Parallel lines
Design: Completely randomised
Transformation: y' = log(y)
Variance: Observed residuals

Common slope(factor) = 0.403703 (0.389136 to 0.418269)
Correlation | r |: 0.989728

Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	4	0.168045	0.0420113	15.579	0.000 (***)
Regression	1	5.87266	5.87266	>1000	0.000 (***)
Non-parallelism	4	0.00759236	0.00189809	0.704	0.594
Non-linearity	10	0.0105829	0.00105829	0.392	0.942
Standard	2	0.00140860	0.000704300	0.261	0.771
Sample 1	2	0.000827767	0.000413884	0.153	0.858
Sample 2	2	0.00397916	0.00198958	0.738	0.485
Sample 3	2	0.00289292	0.00144646	0.536	0.589
Sample 4	2	0.00147448	0.000737239	0.273	0.762
Treatments	19	6.05888	0.318889	118.252	0.000 (***)
Residual error	40	0.107868	0.00269669		
Total	59	6.16675	0.104521		

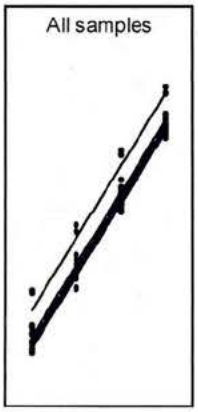
Sample 1			
Id.	Rhophylac		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	778.346	866.016	964.891
Rel. to Ass.	129.7%	144.3%	160.8%
Rel. to Est.	89.9%	100.0%	111.4%

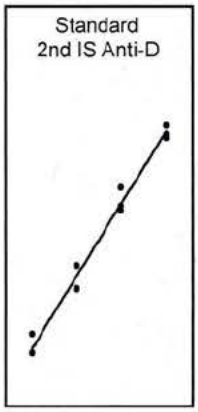
Sample 2			
Id.	Rh(D) IgG		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	191.577	213.031	236.945
Rel. to Ass.	95.8%	106.5%	118.5%
Rel. to Est.	89.9%	100.0%	111.2%

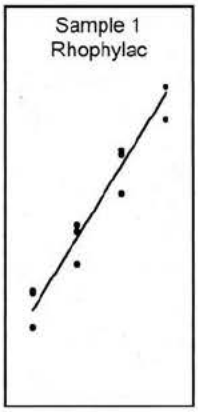
Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017

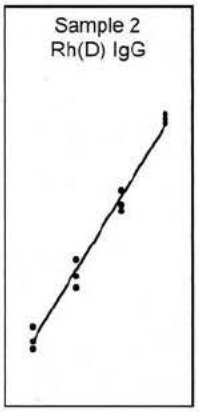
Sample 3			
Id.	Rh(D) IgG		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	528.443	587.614	653.688
Rel. to Ass.	100.7%	111.9%	124.5%
Rel. to Est.	89.9%	100.0%	111.2%

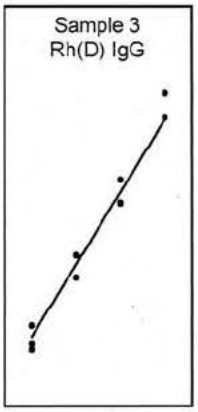
Sample 4			
Id.	2nd IS Anti-D		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	265.231	294.943	328.026
Rel. to Ass.	93.1%	103.5%	115.1%
Rel. to Est.	89.9%	100.0%	111.2%

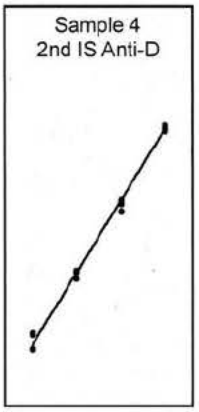












Executed by: s22 17JAN2017

Calculated by:

Approved by:

ID: TGAL/AUS

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22 [redacted]
Date of assay	17Jan2017

Remarks: Anti-D IgG Survey 2017

Standard			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/vial		
Doses	(1)	(2)	(3)
0.5 IU	3275	2932	3027
0.25 IU	1882	1595	1538
0.125 IU	941	763	767
0.0625 IU	510	430	430

Sample 1			
Id.	Rhophylac		
Lims #	1608003190		
Batch#	4367600001		
Ass. pot.	600 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	4619	4621	3448
0.25 IU	2525	2617	1778
0.125 IU	1274	1346	949
0.0625 IU	736	747	540

Sample 2			
Id.	Rh(D) IgG		
Lims #	1608003191		
Batch#	3690850044		
Ass. pot.	200 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~3631~~	~~3455~~	~~3324~~
0.25 IU	~~1830~~	~~1617~~	~~1526~~
0.125 IU	~~987~~	~~853~~	~~768~~
0.0625 IU	~~544~~	~~477~~	~~446~~

Sample 3			
Id.	Rh(D) IgG		
Lims #	1608003192		
Batch#	3680010064		
Ass. pot.	525 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~4358~~	~~3527~~	~~3499~~
0.25 IU	~~2017~~	~~1638~~	~~1647~~
0.125 IU	~~1032~~	~~846~~	~~843~~
0.0625 IU	~~552~~	~~442~~	~~466~~

Sample 4			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~3249~~	~~3185~~	~~3111~~
0.25 IU	~~1684~~	~~1626~~	~~1519~~
0.125 IU	~~896~~	~~882~~	~~836~~
0.0625 IU	~~507~~	~~513~~	444

Model: Parallel lines
Design: Completely randomised
Transformation: y' = log(y)
Variance: Observed residuals

Common slope(factor) = 0.395091 (0.364979 to 0.425203)
Correlation | r |: 0.985248

Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	1	0.131688	0.131688	30.713	0.000 (***)
Regression	1	2.24991	2.24991	524.737	0.000 (***)
Non-parallelism	1	0.00101370	0.00101370	0.236	0.633
Non-linearity	4	0.00223637	0.000559092	0.130	0.969
Standard	2	0.00140860	0.000704300	0.164	0.850
Sample 1	2	0.000827767	0.000413884	0.097	0.909
Treatments	7	2.38485	0.340693	79.458	0.000 (***)
Residual error	16	0.0686032	0.00428770		
Total	23	2.45345	0.106672		

Sample 1			
Id.	Rhophylac		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	755.135	872.971	1015.75
Rel. to Ass.	125.9%	145.5%	169.3%
Rel. to Est.	86.5%	100.0%	116.4%

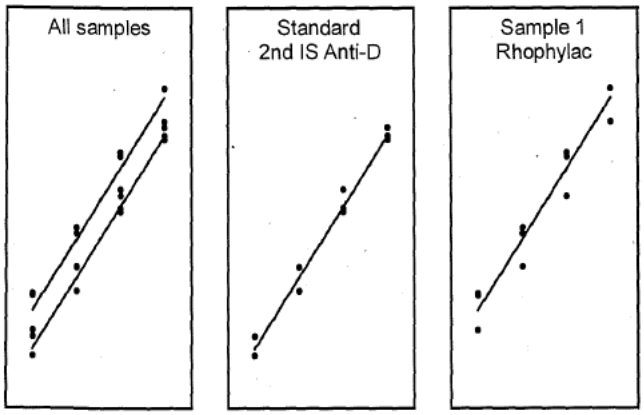
50 x 2 = 1745.9 IU/2 mL (÷5 = 349.2 µg/5yr)

s22 [redacted] 17/1/2017

Validated s22 [redacted] 24/01/17

ID: TGAL/AUS

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22 [redacted]
Date of assay	17Jan2017



Executed by: Calculated by: Approved by:

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017

Remarks: Anti-D IgG Survey 2017

Standard			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/vial		
Doses	(1)	(2)	(3)
0.5 IU	3275	2932	3027
0.25 IU	1882	1595	1538
0.125 IU	941	763	767
0.0625 IU	510	430	430

Sample 1			
Id.	Rhophylac		
Lims #	1608003190		
Batch#	4367600001		
Ass. pot.	600 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~4619~~	~~4621~~	~~3448~~
0.25 IU	~~2525~~	~~2617~~	~~1778~~
0.125 IU	~~1274~~	~~1346~~	~~949~~
0.0625 IU	~~736~~	~~747~~	~~540~~

Sample 2			
Id.	Rh(D) IgG		
Lims #	1608003191		
Batch#	3690850044		
Ass. pot.	200 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	3631	3455	3324
0.25 IU	1830	1617	1526
0.125 IU	987	853	768
0.0625 IU	544	477	446

Sample 3			
Id.	Rh(D) IgG		
Lims #	1608003192		
Batch#	3680010064		
Ass. pot.	525 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~4358~~	~~3527~~	~~3499~~
0.25 IU	~~2017~~	~~1638~~	~~1647~~
0.125 IU	~~1032~~	~~846~~	~~843~~
0.0625 IU	~~552~~	~~442~~	~~466~~

Sample 4			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~3249~~	~~3185~~	~~3111~~
0.25 IU	~~1684~~	~~1626~~	~~1519~~
0.125 IU	~~896~~	~~882~~	~~836~~
0.0625 IU	~~507~~	~~513~~	~~444~~

Model: Parallel lines
Design: Completely randomised
Transformation: y' = log(y)
Variance: Observed residuals

Common slope(factor) = 0.406460 (0.387062 to 0.425859)
Correlation | r |: 0.992950

Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	1	0.00389614	0.00389614	2.190	0.158
Regression	1	2.38127	2.38127	>1000	0.000 (***)
Non-parallelism	1	0.000128276	0.000128276	0.072	0.792
Non-linearity	4	0.00538776	0.00134694	0.757	0.568
Standard	2	0.00140860	0.000704300	0.396	0.680
Sample 2	2	0.00397916	0.00198958	1.118	0.351
Treatments	7	2.39068	0.341526	191.926	0.000 (***)
Residual error	16	0.0284714	0.00177946		
Total	23	2.41915	0.105181		

Sample 2			
Id.	Rh(D) IgG		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	194.645	212.940	233.053
Rel. to Ass.	97.3%	106.5%	116.5%
Rel. to Est.	91.4%	100.0%	109.4%

50 x 1.62 mL = 344.96 IU/vial

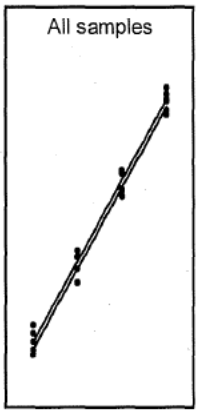
s22

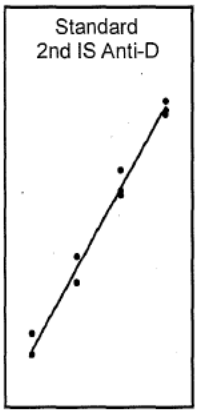
17JAN2017

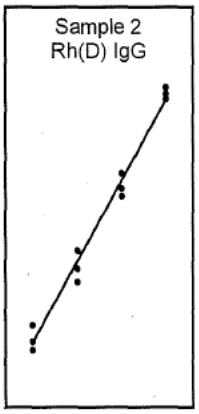
Validated s22 24/01/17.

ID: TGAL/AUS

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017







Executed by: Calculated by: Approved by:

ID: TGAL/AUS

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017

Remarks: Anti-D IgG Survey 2017

Standard			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/vial		
Doses	(1)	(2)	(3)
0.5 IU	3275	2932	3027
0.25 IU	1882	1595	1538
0.125 IU	941	763	767
0.0625 IU	510	430	430

Sample 1			
Id.	Rhophylac		
Lims #	1608003190		
Batch#	4367600001		
Ass. pot.	600 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~4619~~	~~4621~~	~~3448~~
0.25 IU	~~2525~~	~~2617~~	~~1778~~
0.125 IU	~~1274~~	~~1346~~	~~949~~
0.0625 IU	~~736~~	~~747~~	~~540~~

Sample 2			
Id.	Rh(D) IgG		
Lims #	1608003191		
Batch#	3690850044		
Ass. pot.	200 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~3631~~	~~3455~~	~~3324~~
0.25 IU	~~1830~~	~~1617~~	~~1526~~
0.125 IU	~~987~~	~~853~~	~~768~~
0.0625 IU	~~544~~	~~477~~	~~446~~

Sample 3			
Id.	Rh(D) IgG		
Lims #	1608003192		
Batch#	3680010064		
Ass. pot.	525 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	4358	3527	3499
0.25 IU	2017	1638	1647
0.125 IU	1032	846	843
0.0625 IU	552	442	466

Sample 4			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~3249~~	~~3185~~	~~3111~~
0.25 IU	~~1684~~	~~1626~~	~~1519~~
0.125 IU	~~896~~	~~882~~	~~836~~
0.0625 IU	~~507~~	~~513~~	444

Model: Parallel lines
Design: Completely randomised
Transformation: y' = log(y)
Variance: Observed residuals

Common slope(factor) = 0.415582 (0.393787 to 0.437377)
Correlation | r |: 0.991641

Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	1	0.0124139	0.0124139	5.526	0.032 (*)
Regression	1	2.48935	2.48935	>1000	0.000 (***)
Non-parallelism	1	0.00211206	0.00211206	0.940	0.347
Non-linearity	4	0.00430152	0.00107538	0.479	0.751
Standard	2	0.00140860	0.000704300	0.314	0.735
Sample 3	2	0.00289292	0.00144646	0.644	0.538
Treatments	7	2.50818	0.358311	159.512	0.000 (***)
Residual error	16	0.0359408	0.00224630		
Total	23	2.54412	0.110614		

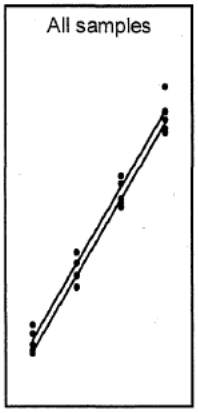
Sample 3			
Id.	Rh(D) IgG		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	530.674	585.725	647.063
Rel. to Ass.	101.1%	111.6%	123.3%
Rel. to Est.	90.6%	100.0%	110.5%

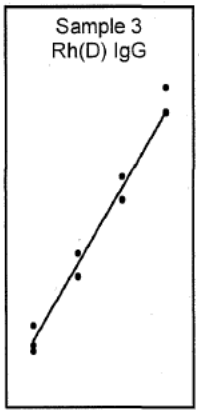
50 x 1.32 mL = 773.16 IU/vial s22 17/Jan/2017

Validated s22 24/01/17

ID: TGAL/AUS

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017





Executed by: Calculated by: Approved by:

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22 [redacted]
Date of assay	17Jan2017

Remarks: Anti-D IgG Survey 2017

Standard			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/vial		
Doses	(1)	(2)	(3)
0.5 IU	3275	2932	3027
0.25 IU	1882	1595	1538
0.125 IU	941	763	767
0.0625 IU	510	430	430

Sample 1			
Id.	Rhophylac		
Lims #	1608003190		
Batch#	4367600001		
Ass. pot.	600 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~4619~~	~~4621~~	~~3448~~
0.25 IU	~~2525~~	~~2617~~	~~1778~~
0.125 IU	~~1274~~	~~1346~~	~~949~~
0.0625 IU	~~736~~	~~747~~	~~540~~

Sample 2			
Id.	Rh(D) IgG		
Lims #	1608003191		
Batch#	3690850044		
Ass. pot.	200 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~3631~~	~~3455~~	~~3324~~
0.25 IU	~~1830~~	~~1617~~	~~1526~~
0.125 IU	~~987~~	~~853~~	~~768~~
0.0625 IU	~~544~~	~~477~~	~~446~~

Sample 3			
Id.	Rh(D) IgG		
Lims #	1608003192		
Batch#	3680010064		
Ass. pot.	525 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	~~4358~~	~~3527~~	~~3499~~
0.25 IU	~~2017~~	~~1638~~	~~1647~~
0.125 IU	~~1032~~	~~846~~	~~843~~
0.0625 IU	~~552~~	~~442~~	~~466~~

Sample 4			
Id.	2nd IS Anti-D		
Batch#	01/572		
Ass. pot.	285 IU/ml		
Doses	(1)	(2)	(3)
0.5 IU	3249	3185	3111
0.25 IU	1684	1626	1519
0.125 IU	896	882	836
0.0625 IU	507	513	444

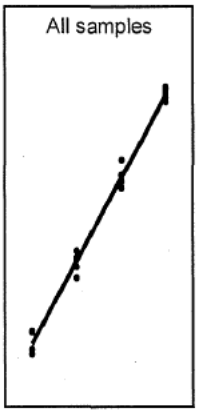
Model: Parallel lines
Design: Completely randomised
Transformation: y' = log(y)
Variance: Observed residuals

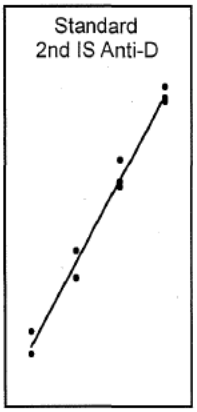
Common slope(factor) = 0.397339 (0.381582 to 0.413096)
Correlation | r |: 0.995158

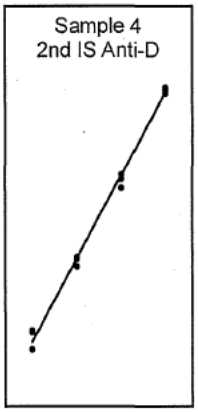
Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	1	0.00114996	0.00114996	0.979	0.337
Regression	1	2.27559	2.27559	>1000	0.000 (***)
Non-parallelism	1	0.000543061	0.000543061	0.463	0.506
Non-linearity	4	0.00288308	0.000720770	0.614	0.659
Standard	2	0.00140860	0.000704300	0.600	0.561
Sample 4	2	0.00147448	0.000737239	0.628	0.546
Treatments	7	2.28017	0.325738	277.447	0.000 (***)
Residual error	16	0.0187849	0.00117406		
Total	23	2.29895	0.0999545		

Sample 4			
Id.	2nd IS Anti-D		
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	273.876	295.105	318.031
Rel. to Ass.	96.1%	103.5%	111.6%
Rel. to Est.	92.8%	100.0%	107.8%

Substance	Anti-D IgG
Method	Anti-D Flow
Analyst	s22
Date of assay	17Jan2017







Executed by: Calculated by: Approved by:

I:\apps\OLSS Databases\Bi emistry\Combistats Working Files\Anti-D\surv 7Jan 2017 carousel 1 and 2

Tube Name	P1 FITC-A Median	P2 FITC-A Median	P3 FITC-A Median	P4 FITC-A Median	P5 FITC-A Median	P6 FITC-A Median	P7 FITC-A Median	P8 FITC-A Median
6 Peak Beads Start	6974	6935	60 ✓	1600 ✓	5023 ✓	15630 ✓	44144 ✓	92460 ✓
IS-1 0-5 IU	3275 ✓	3055	126	1789	4537			88635
IS-1 0-25 IU	1882 ✓	1830	176	1632	4629	15826		92894
IS-1 0-125 IU	941 ✓	882	91	1446	4520			100397
IS-1 0-063 IU	510 ✓	469	115	1305	5382			
T1-1 0-5 IU	4619 ✓	3859		1759	4812			
T1-1 025 IU	2525 ✓	2459		1764	4523			
T1-1 0-125 IU	1274 ✓	1235		1616	4172			
T1-1 0-063 IU	736 ✓	692	116	1440	6086			
T2-1 0-5 IU	3631 ✓	3469		1771	4592		37042	
T2-1 0-25 IU	1830 ✓	1654	125	1613	4801			
T2-1 0-125 IU	987 ✓	931	77	1397				
T2-1 0-063 IU	544 ✓	521	112					
T3-1 0-5 IU	4358 ✓	4188	84	1908	4868	13073	41389	
T3-1 0-25 IU	2017 ✓	1912	31	1740	4416			
T3-1 0-125 IU	1032 ✓	1005	58	1463				
T3-1 0-063 IU	552 ✓	518	135	1360				
T4-1 0-5 IU	3249 ✓	3054		1831	4541			
T4-1 0-25 IU	1684 ✓	1557	106	1626	5507			
T4-1 0-125 IU	896 ✓	844	145	1446				
T4-1 0-063 IU	507 ✓	494	151	1361				
IS-2 0-5 IU	2932 ✓	2684	53	1754	4298	13727		
IS-2 0-25 IU	1595 ✓	1474	96	1563	4369			
IS-2 0-125 IU	763 ✓	709	139	1363				
IS-2 0-063 IU	430 ✓	424	146					
T1-2 0-5 IU	4621 ✓	4220	91	1863	4858			
T1-2 0-25IU	2617 ✓	2459	81	1735	4518			
T1-2 0-125 IU	1346 ✓	1278		1535				
T1-2 0-063 IU	747 ✓	700		1552				
T2-2 0-5 IU	3455 ✓	2989	119	1752	4456			
T2-2 0-25 IU	1617 ✓	1562		1600	4244			
T2-2 0-125 IU	853 ✓	828		1372				
T2-2 0-063 IU	477 ✓	474	145	1397				
T3-2 0-5 IU	3527 ✓	3098	44	1740	4570			
T3-2 0-25 IU	1638 ✓	1529		1607	5366			

I:\apps\OLSS Databases\Biochemistry\Combistats Working Files\Anti-D\survey 17Jan 2017 carousel 1 and 2

T3-2 0-125 IU	846 ✓	813	109	1541				
T3-2 0-063 IU	442 ✓	422	152	1344				
T4-2 0-5 IU	3185 ✓	2888	102	1751	4465			
T4-2 0-25 IU	1626 ✓	1573		1615	4379			
T4-2 0-125 IU	882 ✓	828		1452				
T4-2 0-063 IU	513 ✓	469	163	1531				
IStd-3 0-5 IU	3027 ✓	2556		1713	4372			
IStd-3 0-25 IU	1538 ✓	1407		1500	4349			
IStd-3 0-125 IU	767 ✓	694		1416				
IStd-3 0-063 IU	430 ✓	394	142	1399				
T1-3 0-5 IU	3448 ✓	3042	168	1797	4685			
T1-3 0-25 IU	1778 ✓	1561	62	1571	3962			
T1-3 0-125 IU	949 ✓	897		1397				
T1-3 0-063 IU	540 ✓	524	163	1544				
T2-3 0-5IU	3324 ✓	2896		1746	4571			
T2-3 0-25IU	1526 ✓	1380	92	1595	4291			
T2-3 0-125IU	768 ✓	716		1444				
T2-3 0-063IU	446 ✓	444	153	1482				
T3-3 0-5IU	3499 ✓	3006		1808	4430	16195		
T3-3 0-25IU	1647 ✓	1471		1576	4014			
T3-3 0-125IU	843 ✓	812		1352	3922			
T3-3 0-063IU	466 ✓	449	165		5092			
T4-3 0-5IU	3111 ✓	2692		1799	4474			
T4-3 0-25IU	1519 ✓	1387		1538	5504			
T4-3 0-125IU	836 ✓	775	87	1430				
T4-3 0-063IU	444 ✓	420	104	1482	4489			
R1R1-1	91 ✓	91	91	1850				
R1R1-2	92 ✓	99	98	1602				
rr-1	74 ✓	84	90					
rr-2	74 ✓	81	86					
6 Peaks End	8544	7067	60 ✓	1598 ✓	5027 ✓	15616 ✓	44187 ✓	92514 ✓

Checked data.
s22
2017.

I:\apps\OLSS Databases\[redacted]hemistry\Combistats Working Files\Anti-D\QC[redacted]Jan2017 - Survey Testing

Tube Name	Record Date	P1 %Parent	P1 FITC-A Mean	P1 PE-A Mean	P1 PerCP-Cy5-5-A Mean	P1 PE-Cy7-A Mean	P1 APC-A Mean	P1 APC-Cy7-A Mean
Rep1	Jan 17, 2017	100	4880	4214	3819	3632	5299	4602

Passes QC
s22
17 JAN 2017

checked
s22
20/01/2017

Validated
s22 24/01/17.

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

Australian Government
Department of Health
Therapeutic Goods Administration

Office of Laboratories and Scientific Services

Operations	Biochemistry – Forms
Procedure	Forms – Reagent Preparation Record
Written	s22 [redacted]
Authorised	s22 [redacted]
Date issued	20/06/2014
Revision #	3

Reagent Name: PBS/BSA

Final Volume: 100mL

Prepared by:	Date:	Expiry Date:	Batch #: eg. LB01OCT09-1	Storage Temperature:
s22 [redacted]	17JAN2017	24JAN2017	s22 [redacted] 17JAN17-1	2-8°C

Component	Manufacturer	Batch #	Required Amount	Measured Amount	Balance / Pipette LIMS #	Final Conc (%, mM, etc)
Albumin, bovine serum	SIGMA-A	SLBD2256V	1g	1.002g	32126	1%
PBS	s22 [redacted]	s22 [redacted] 3JAN17-1	100mL	100mL	volumetric	

pH Adjustment	Target pH:	Initial pH:	Adjusted with: HCl / HNO_3 / H_2SO_4 / H_3PO_4 NaOH / KOH / Other:	Final pH:	pH Electrode LIMS#: (circle) 8165 / 32109
	—	—			

Filtration (circle): None 0.45µm 0.2µm Other: _____

Other Comments:

Attach Balance Printout Here

17-Jan-2017 08:02:12
001:N + 1.002 g

Record Details	R14 814225 Forms - Reagent Preparation Record		
Last Editor	s22 [redacted]	Edit Date	23/06/2014 12:08 PM
Print Date	3/01/2017 11:42 AM		Page 1 of 1

27

Australian Government
Department of Health
Therapeutic Goods Administration

Office of Laboratories and Scientific Services

Operations	Biochemistry – Forms
Procedure	Forms – Reagent Preparation Record
Written	s22 [redacted]
Authorised	s22 [redacted]
Date issued	20/06/2014
Revision #	3

Reagent Name: PBS

Final Volume: 200ml.

Prepared by:	Date:	Expiry Date:	Batch #: eg. LB01OCT09-1	Storage Temperature:
s22 [redacted]	13/01/2017	13/02/2017	s22 [redacted] 13Jan2017 - 1	2-8°C.

Component	Manufacturer	Batch #	Required Amount	Measured Amount	Balance / Pipette LIMS #	Final Conc (%, mM, etc)
Phosphate Buffer Saline	SIGMA	051M8213	1 tablet	1 tablet	N/A	
Ultra pure H_2O	—	—	200ml	200ml	vol. flask	

pH Adjustment

Target pH:	Initial pH:	Adjusted with:	Final pH:	pH Electrode LIMS#: (circle)
N/A	N/A	HCl / HNO_3 / H_2SO_4 / H_3PO_4 NaOH / KOH / Other: N/A	N/A	8165 / 32109

Filtration (circle): (None) 0.45µm 0.2µm Other: _____

Other Comments:

Attach Balance Print Outs Here

Australian Government
Department of Health
Therapeutic Goods Administration

Office of Laboratories and Scientific Services

Operations	Biochemistry – Forms
Procedure	Forms – Reagent Preparation Record
Written	s22 [redacted]
Authorised	s22 [redacted]
Date issued	20/06/2014
Revision #	3

Reagent Name: PBS/BSA for Anti-D

Final Volume: 200ml

Prepared by:	Date:	Expiry Date:	Batch #: eg. LB01OCT09-1	Storage Temperature:
s22 [redacted]	11JAN2017	18JAN2017	s22 [redacted] 4JAN2017-1	2-8°c

Component	Manufacturer	Batch #	Required Amount	Measured Amount	Balance / Pipette LIMS #	Final Conc (%, mM, etc)
Albumin, bovine serum	SIGMA-A	SLBD2256V	2g	2.001g	32126	1%
PBS	s22 [redacted]	s22 [redacted] 3JAN2017-4	200 ML	200ML	volumetric	

pH Adjustment	Target pH: ~	Initial pH:	Adjusted with: HCl / HNO_3 / H_2SO_4 / H_3PO_4 NaOH / KOH / Other:	Final pH:	pH Electrode LIMS#: (circle) 8165 / 32109

Filtration (circle): (None) 0.45µm 0.2µm Other: _____

Other Comments:

Attach B[illegible]uts Here

11-Jan-2017 08:37:57
001:N - 2.001 g

Australian Government
Department of Health
Therapeutic Goods Administration

Office of Laboratories and Scientific Services

Operations	Biochemistry – Forms
Procedure	Forms – Reagent Preparation Record
Written	s22 [redacted]
Authorised	s22 [redacted]
Date issued	20/06/2014
Revision #	3

Reagent Name: PBS for Anti-D

Final Volume: 400mL

Prepared by:	Date:	Expiry Date:	Batch #: eg. LB01OCT09-1	Storage Temperature:
s22 [redacted]	3JAN2017	3FEB2017	s22 [redacted] 3JAN2017-4	2-8°C

Component	Manufacturer	Batch #	Required Amount	Measured Amount	Balance / Pipette LIMS #	Final Conc (%, mM, etc)
Phosphate Buffered Saline	SIGMA	051M8213	2 tablets	2 tablets	—	
H_2O	Arium		400mL	400mL	volumetric	

pH Adjustment	Target pH: —	Initial pH: —	Adjusted with: HCl / HNO_3 / H_2SO_4 / H_3PO_4 NaOH / KOH / Other:	Final pH:	pH Electrode LIMS#: (circle) 8165 / 32109

Filtration (circle): (None) 0.45µm 0.2µm Other: _____

Other Comments:

Attach Balance Print Outs Here

s22

s22

S22

s22

s22

s22


s22

s22


s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22

s22