

Message

From: Daniel Edlin [/O=Theranos Organization/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/CN=Daniel Edlin]
Sent: 10/14/2012 7:37:30 PM
To: Surekha Gangakhedkar [surekhag@theranos.com]
CC: Daniel Young [dyoung@theranos.com]; Christian Holmes [cholmes@theranos.com]; Max Fosque [mfosque@theranos.com]; Sunny Balwani [sbalwani@theranos.com]; Elizabeth Holmes [eholmes@theranos.com]
Subject: RE:

Surekha,

Following on Elizabeth's email below, I have attached the relevant section from the presentation that pertain to the immunochemistry clinical correlations. In addition to reviewing these slides, please also review the external/sanitized reports in the same context. If any changes do need to be made, please highlight them here.

Let us know if you have any questions.

Thanks,
Dan

-----Original Message-----

From: Elizabeth Holmes
Sent: Sunday, October 14, 2012 11:46 AM
To: Chinmay Pangarkar; Surekha Gangakhedkar; Paul Patel; Pranav Patel
Cc: Daniel Edlin; Daniel Young; Christian Holmes; Max Fosque; Sunny Balwani
Subject:

All:

As most of you know, we have an extremely important meeting tomorrow. Dan will be sending you the relevant sections from the presentation that detail clinical correlations for each of your respective teams.

Please review the slides and make any edits or share any comments to ensure consistency of the slides in formatting and content as well as optimal presentation. If you see any issues or think there are certain things that should be highlighted, let us know. We need follow up on this today so please get the relevant people from your teams involved to get feedback back ASAP.

Please also review the final versions of the reports - the product management team did clean up to correct language/template errors in some of them - and make any other changes to ensure they are perfect for presentation. Let us know any changes you make as we are coordinating document production in parallel for tomorrow.

Elizabeth

File Produced in Native Format

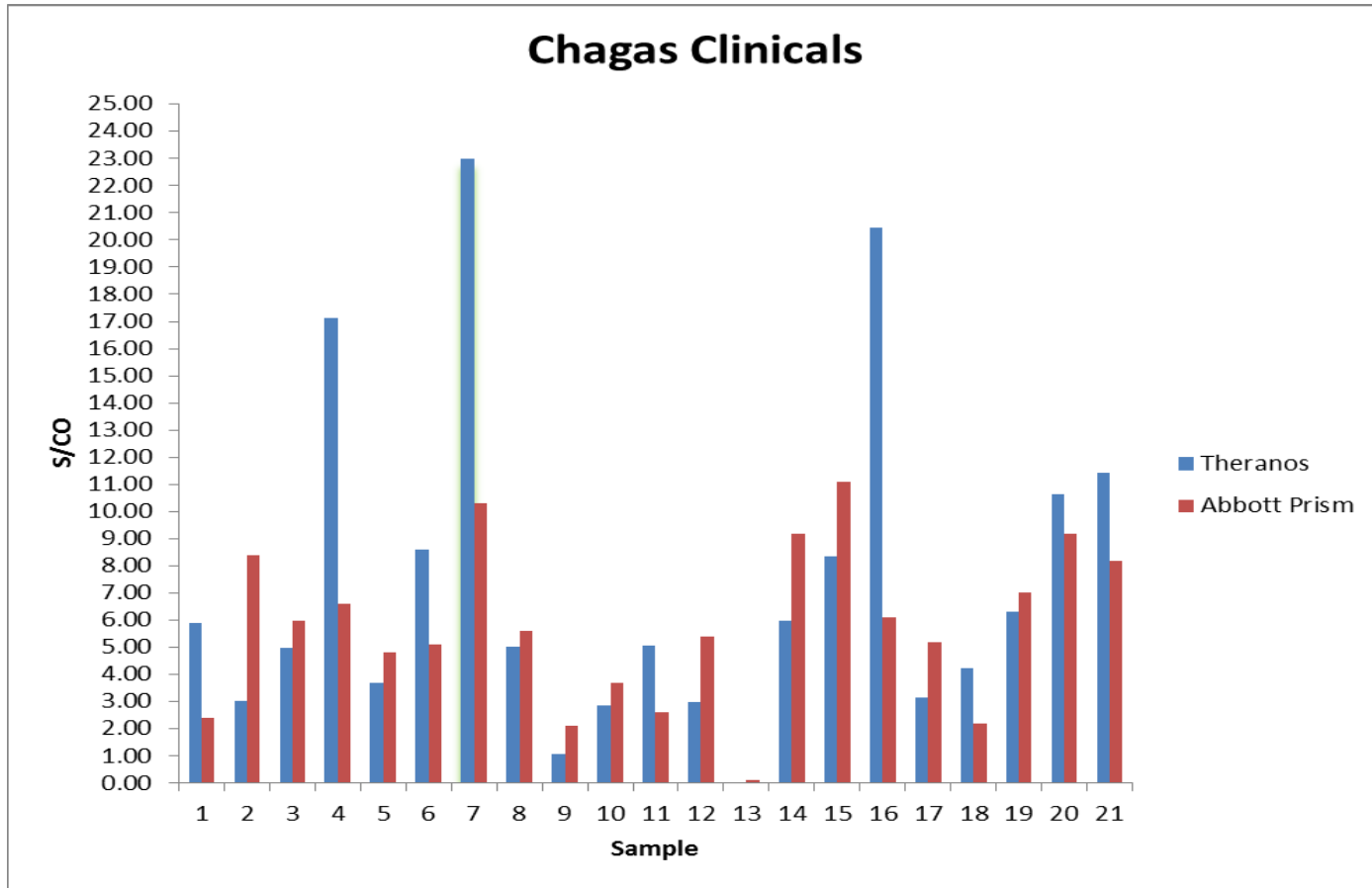
ANA antibody

The following criteria was applied to categorize the result as positive (red), negative (green) or borderline (yellow) Immco kit is FDA approved ELISA

Ab Index > 1.1
Ab Index > 0.9, < 1.1
Ab Index < 0.9

Sample ID	Theranos Ab Index	Immco Diagnostics ANA value	USBIOL Ab index	Innova Ab index	IBL Ab Index	ProMeddx Nephelometry ratio
A1	0.77	39.1	0.53	12.2	0.82	1:160
A2	0.73	23.6	0.73	10.4	0.49	1:320
A3	1.78	36.6	0.90	31.2	0.76	1:320
A4	2.36	34.3	1.07	21.5	0.72	1:160
A5	0.62	12.8	0.52	13.3	0.27	1:160
A6	1.14	39.9	1.26	13.3	0.83	1:160
A7	1.64	27.0	0.58	8.4	0.56	1:320
A8	1.89	22.5	0.69	8.4	0.47	1:320
A9	2.18	143.8	2.41	39.1	3.00	1:1280
A10	6.14	32.8	2.13	21.2	0.69	1:1280
A11	1.68	74.1	2.50	74.5	1.55	1:1280
A12	19.53	157.3	2.78	106.2	3.29	1:1280
A13	1.51	32.8	2.75	20.5	0.69	1:160
A14	3.16	31.8	1.85	19.2	0.66	1:160
A15	1.92	24.4	1.01	13.8	0.51	1:320
A16	1.85	58.5	5.36	39.4	1.22	1:1280
A17	5.57	153.8	3.81	99.8	3.21	1:1280
A18	1.45	33.4	1.03	25.1	0.70	1:640
A19	7.98	99.6	2.83	81.5	2.08	1:640
A20	1.87	51.4	0.86	21.3	1.07	1:640
A21	1.06	50.0	0.83	11.9	1.04	1:640
A22	1.38	31.7	1.16	23.2	0.66	1:640
A23	0.95	53.8	1.00	14.0	1.12	1:320
A24	1.57	38.1	1.41	13.7	0.80	1:1280
A25	1.65	55.6	2.55	17.8	1.16	1:640
A26	0.87	43.2			0.90	1:640
A27	1.69	28.2			0.59	1:640
A28	1.85	37.9			0.79	1:640
A29	0.92	23.4			0.49	1:160
A30	3.19	87.4			1.83	1:160
A32	1.68	48.9			1.02	1:160
A33	1.23	45.3			0.95	1:1280
A34	2.10	50.0			1.04	1:1280
A35	0.85	31.0			0.65	1:320
A36	0.54	40.0			0.84	1:160

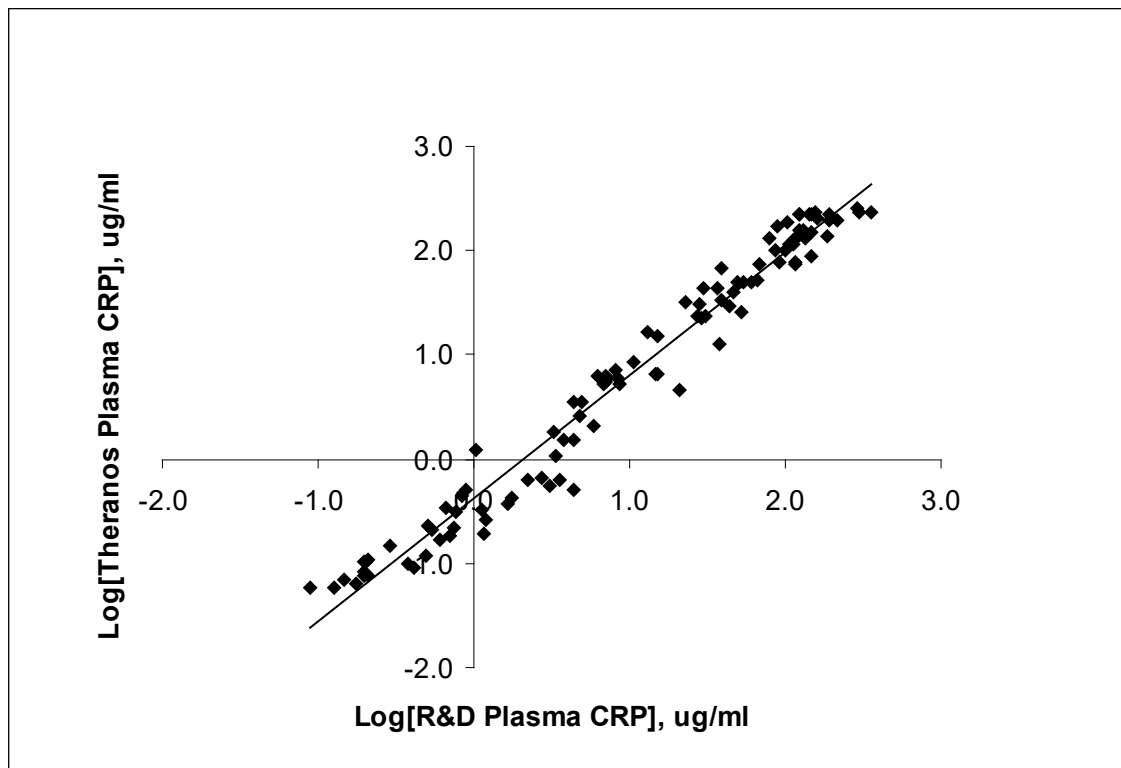
Trypanosoma cruzi (Chagas) antibody



If S/Co Positive \geq 1

CRP Test Correlation to Reference Methods Over 10,000-fold Range

$$y = 1.179x - 0.3746, r^2 = 0.99, N = 104$$



ENA – Jo-1 antibody

	Innova	Immco	IBL Int.	Theranos
Sample	Units	Result (EU/mL)	Ratio	Ab Index
1	0	6	0.1	0.6
2	1	7	0.1	0.7
3	32	126	4.4	5.7
4	127	177	6.6	18.1
5	111	169	6.6	9.6
6	5	8	0.1	0.7
7	19	4	0.1	0.0
8	3	10	0.4	0.6
9	8	13	0.3	0.7
10	1	14	0.2	0.7
11	2	12	0.3	0.0
12	1	7	0.1	0.0
13	0	5	0.1	0.0
14	1	3	0.1	0.0
15	1	20	0.2	0.3
16	0	8	0.1	0.0
17	165	175	6.2	16.6
18	1	8	0.2	0.0
19	50	138	4.4	8.1
20	9	10	0.2	0.0
21	107	175	6.3	8.9
22	8	8	0.1	0.0
23	3	10	0.4	0.0
24	5	14	0.3	0.5
25	23	2	0.1	0.4
26	107	201	7.9	2.5
27	69	158	6.5	2.3
28	110	203	8.1	2.6
29	108	208	8.2	2.7
30	109	201	8.2	3.0

Ab index >1.1	Positive
Ab index >0.9<1.1	Equivocal
Ab index < 0.9	Negative

Estradiol – Precision

QC Levels for 3 Day Precision and Accuracy

Nominal [Estradiol] pg/mL	Cartridge	Recovered [Estradiol] pg/mL					
		Day 1	Day 2	Day 3	Mean Conc.	CV %	% Recovery
478.50	1	522	481	448	455	8	95
	2	402	426	485			
	3	440	444	444			
92.63	1	114	104	72	92	14	99
	2	104	91	85			
	3	90	81	87			
45.38	1	36	37	37	41	11	90
	2	40	38	44			
	3	44	48	44			

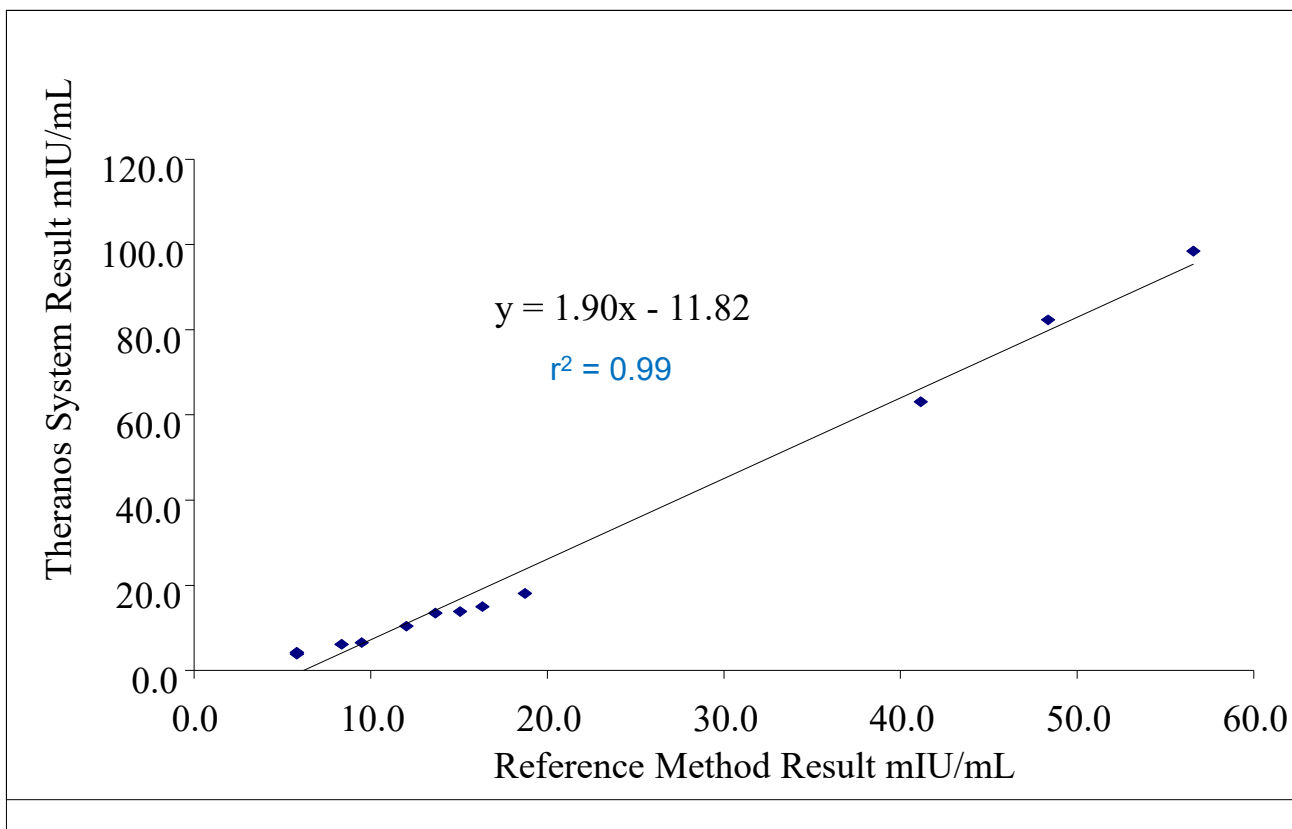
Estradiol - Precision

Analyzer	Signal (RLU)		Conc. pg/mL
	Mean RLU	Difference from Mean	
1	9287	-5	74
2	9523	-2	71
3	9991	2	66
4	10160	4	64
5	9397	-4	72
6	10383	7	62
7	10275	5	63
8	10351	6	62
9	8432	-14	84
10	8334	-15	86
11	9041	-7	77
12	9457	-3	72
13	10687	10	59
14	10984	13	57
15	10704	10	59
16	10823	11	58
17	10125	4	65
18	10222	5	64
19	10168	4	64
20	10452	7	61
21	8832	-9	79
22	8365	-14	85
23	8425	-14	84
24	9562	-2	71

Inter-Analyzer Concentration CVs			
Mean Conc. pg/mL	StD ev	CV%	% Recovery
69	9	13	92

Inter-Analyzer Signal CVs		
Mean RLU	StDev	CV%
9749	835	9

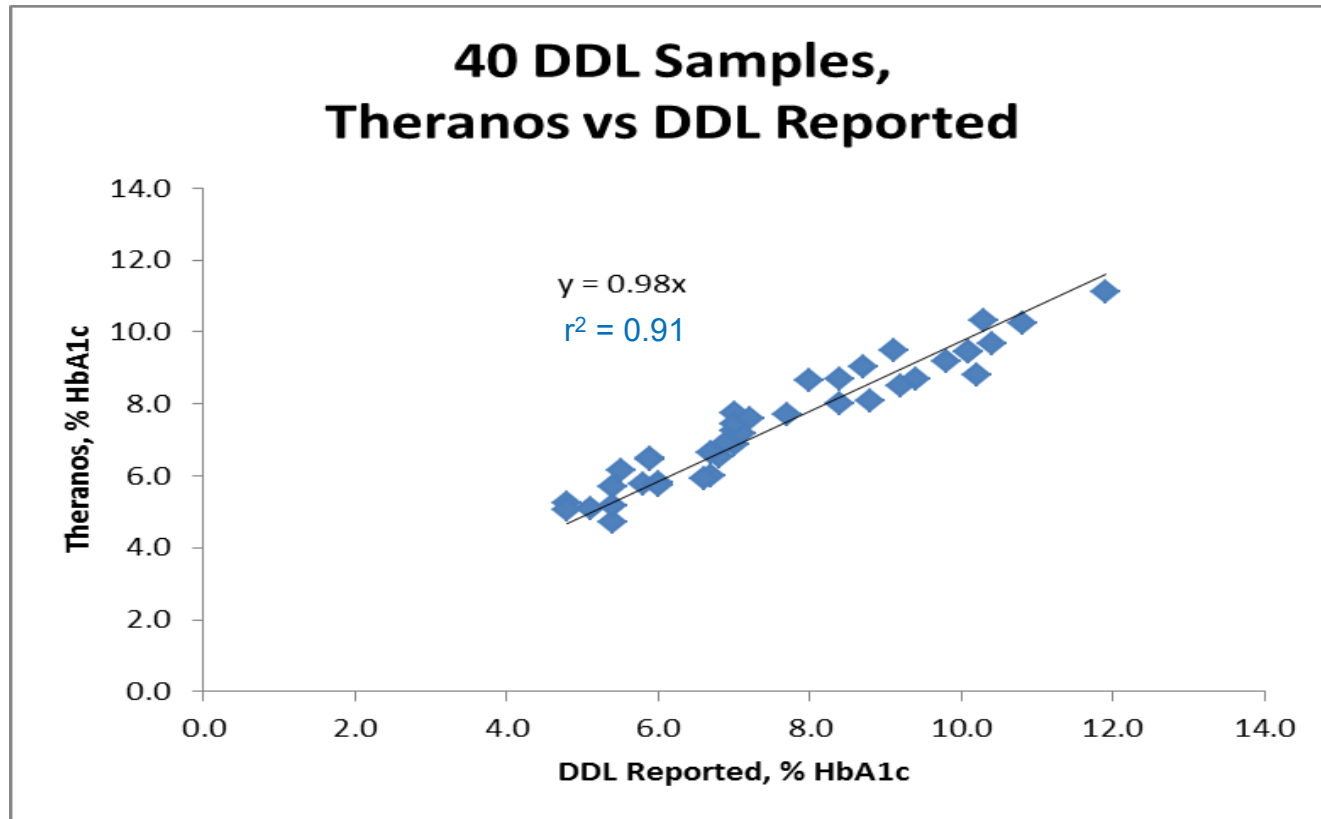
Follicle stimulating Hormone (FSH)



Anti-HAV IgM

Sample	Theranos		Siemens Advia Centaur		Abbott Architect		DiaSorin-ETI-HA-IGMK Plus	
	S/CO	Result	S/CO	Result	S/CO	Result	S/CO	Result
1	0.4	Negative	0.3	Negative	0.8	Negative	0.1	Negative
2	0.3	Negative	0.2	Negative	0.4	Negative	0.1	Negative
3	0.3	Negative	0.2	Negative	0.5	Negative	0.0	Negative
4	0.2	Negative	0.2	Negative	0.3	Negative	0.1	Negative
5	6.7	Positive	> 7.0	Positive	2.8	Positive	6.1	Positive
6	4.5	Positive	4.1	Positive	1.1	Positive	3.8	Positive
7	4.4	Positive	4.0	Positive	1	Positive	3.5	Positive
8	0.4	Negative	0.3	Negative	0.7	Negative	0.1	Negative
9	0.2	Negative	0.2	Negative	0.4	Negative	0.1	Negative
10	0.3	Negative	0.4	Negative	0.4	Negative	0.1	Negative
11	8.0	Positive	> 7.0	Positive	3.6	Positive	6.5	Positive
12	0.2	Negative	0.2	Negative	0.4	Negative	0.0	Negative
13	0.8	Negative	0.3	Negative	0.7	Negative	0.1	Negative
14	2.6	Positive	2.5	Positive	0.6	Negative	1.3	Positive
15	5.8	Positive	5.9	Positive	1.5	Positive	5.2	Positive
16	0.5	Negative	0.4	Negative	0.4	Negative	0.1	Negative
17	9.6	Positive	6.5	Positive	2.1	Positive	5.3	Positive
18	0.2	Negative	0.2	Negative	0.5	Negative	0.0	Negative
19	6.8	Positive	3.4	Positive	1.7	Positive	3.0	Positive
20	1.8	Positive	0.2	Negative	0.6	Negative	0.1	Negative
21	0.5	Negative	0.3	Negative	0.4	Negative	0.1	Negative

HbA1c



DDL: Diabetes Diagnostic Lab – NGSP standardization program

Anti-HBs antibody

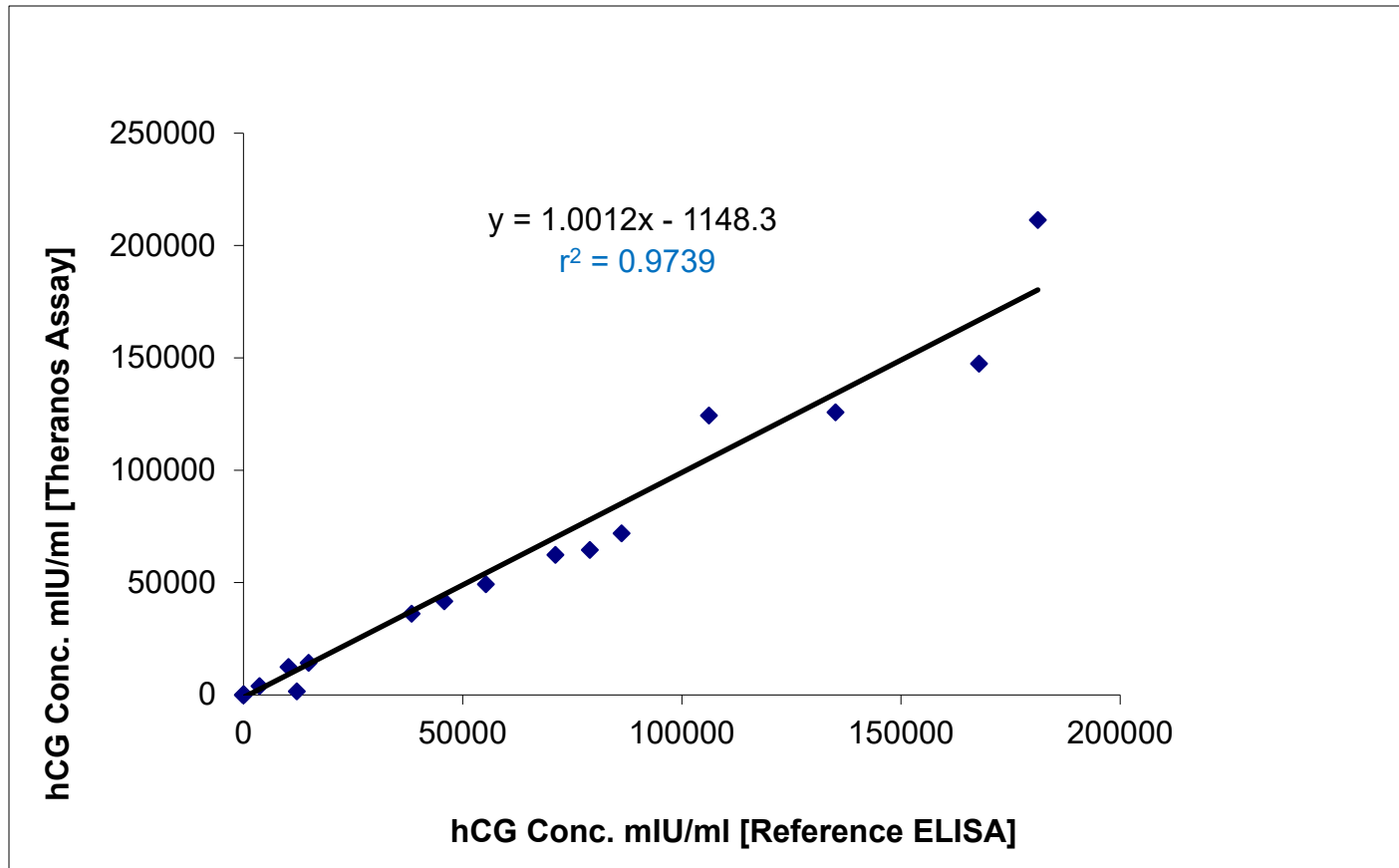
Anti-HBc/HBs Mixed Titer Performance Panel (Modified)

Member ID#	Theranos mIU/mL	Abbott Anti-HBs Architect mIU/mL
PHG203-01	1.00	13.0
PHG203-04	1138	>1000.0
PHG203-05	592.36	>1000.0
PHG203-06	1.25	2.8
PHG203-07	1025.47	687.5
PHG203-08	4.65	20.0
PHG203-09	2.48	51.0
PHG203-10	121.53	175.0
PHG203-11	1.66	0.4
PHG203-12	0.20	0.2
PHG203-13	2.16	0.6
PHG203-14	0.42	0.7

Anti-HBc IgM

Seracare anti-HBc IgM Mixed Titer Performance Panel	Theranos Anti-HBc IgM (R > 2)	DPC Immulite Anti-HBc IgM (R >10 u/mL)	Abbott Architect anti-HBc IgM (R >1)	Diasorin ETI-CORE_IgMK (R>1)
	S/Co	PEI U/mL	S/Co	S/Co
Seracare 1	0.2	<2.0	0.0	0.1
Seracare 2	9.8	>100	12.9	10.9
Seracare 3	12.3	>100	22.6	11.9
Seracare 4	4.0	15.2	0.9	2.0
Seracare 5	11.1	>100	6.0	9.2
Seracare 6	7.9	88.2	1.8	3.6
Seracare 7	12.3	>100	20.3	12.5
Seracare 8	8.3	98.7	2.1	3.9
Seracare 9	12.2	>100	19.0	11.8
Seracare 10	8.8	>100	3.2	5.9
Seracare 11	10.1	>100	6.6	11.3
Seracare 12	1.8	8.8	0.1	0.6
Seracare 13	6.7	>100	2.8	6.2
Seracare 14	11.8	>100	18.2	11.8
Seracare 15	13.0	>100	6.7	10.9
Seracare 16	9.1	>100	4.6	6.1
Seracare 17	1.4	7.7	0.3	0.9
Seracare 18	4.8	37.9	1.5	2.6
Seracare 19	12.1	>100	24.6	12.7
Seracare 20	6.5	57.7	1.4	0.7
Seracare 21	6.7	59.6	1.7	3.3
Seracare 22	5.6	32.0	1.2	2.0
Seracare 23	6.8	22.4	1.7	2.1
Seracare 24	13.8	>100	17.2	12.9
Seracare 25	11.8	>100	8.0	7.0

Human chorionic gonadotropin (hCG)

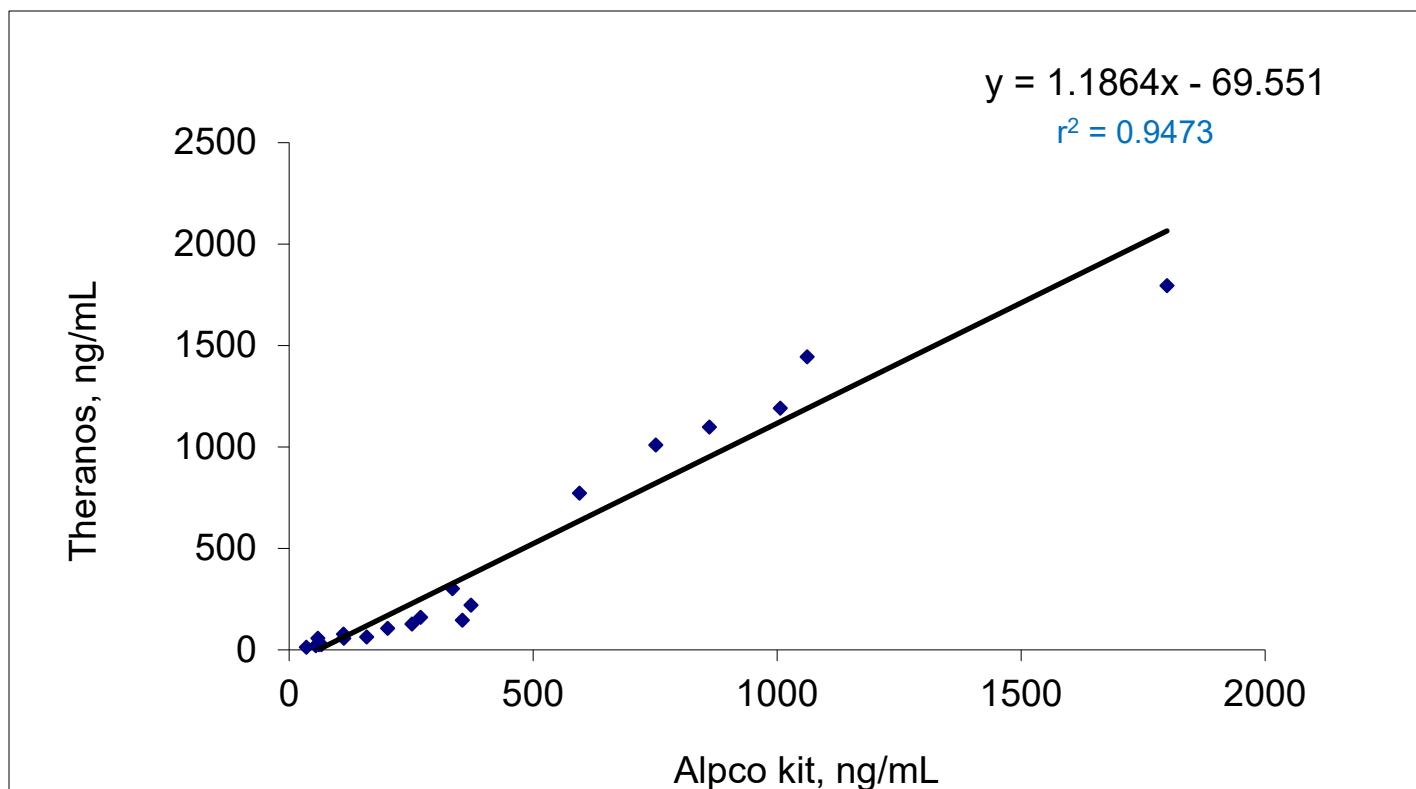


Heterophile antibody

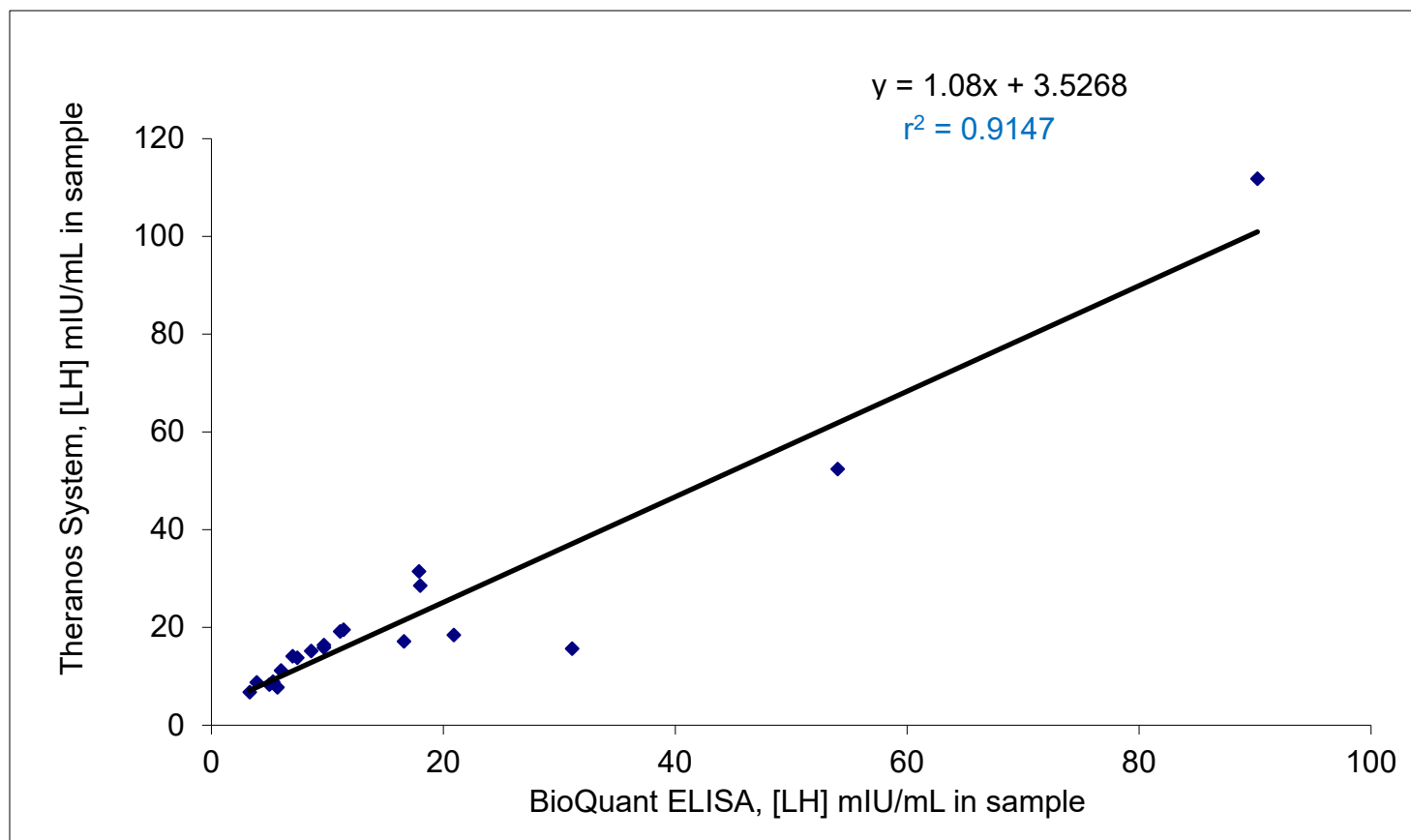
Sample ID	Theranos Ab	Osom Mono	Status Mono
1	NEG	NEG	NEG
2	NEG	NEG	NEG
3	NEG	NEG	NEG
4	NEG	NEG	NEG
5	NEG	NEG	NEG
6	NEG	NEG	NEG
7	NEG	NEG	NEG
8	NEG	NEG	NEG
9	NEG	NEG	NEG
10	NEG	NEG	NEG
11	NEG	NEG	NEG
12	NEG	NEG	NEG
13	NEG	NEG	NEG
14	NEG	NEG	NEG
15	NEG	NEG	NEG
16	NEG	NEG	NEG
17	NEG	NEG	NEG
18	NEG	NEG	NEG
19	NEG	NEG	NEG
20	NEG	NEG	NEG
21	NEG	NEG	NEG
22	NEG	NEG	NEG
23	NEG	NEG	NEG
24	NEG	NEG	NEG
25	NEG	NEG	NEG
26	NEG	NEG	NEG
27	NEG	NEG	NEG
28	NEG	NEG	NEG
29	NEG	NEG	NEG
30	NEG	NEG	NEG
31	NEG	NEG	NEG
32	NEG	NEG	NEG
33	NEG	NEG	NEG
34	NEG	NEG	NEG
35	NEG	NEG	NEG
36	NEG	NEG	NEG
37	NEG	NEG	NEG
38	NEG	NEG	NEG
39	BOR	NEG	NEG
40	NEG	POS	NEG

Sample ID	Theranos Ab	Osom Mono	Status Mono
41	POS	POS	POS
42	POS	POS	POS
43	POS	POS	POS
44	POS	POS	POS
45	POS	POS	POS
46	POS	POS	POS
47	POS	POS	POS
48	POS	POS	POS
49	POS	POS	POS
50	POS	POS	POS
51	POS	POS	POS
52	POS	POS	POS
53	POS	POS	POS
54	POS	POS	POS
55	POS	POS	POS
56	POS	POS	POS
57	POS	POS	POS
58	POS	POS	POS

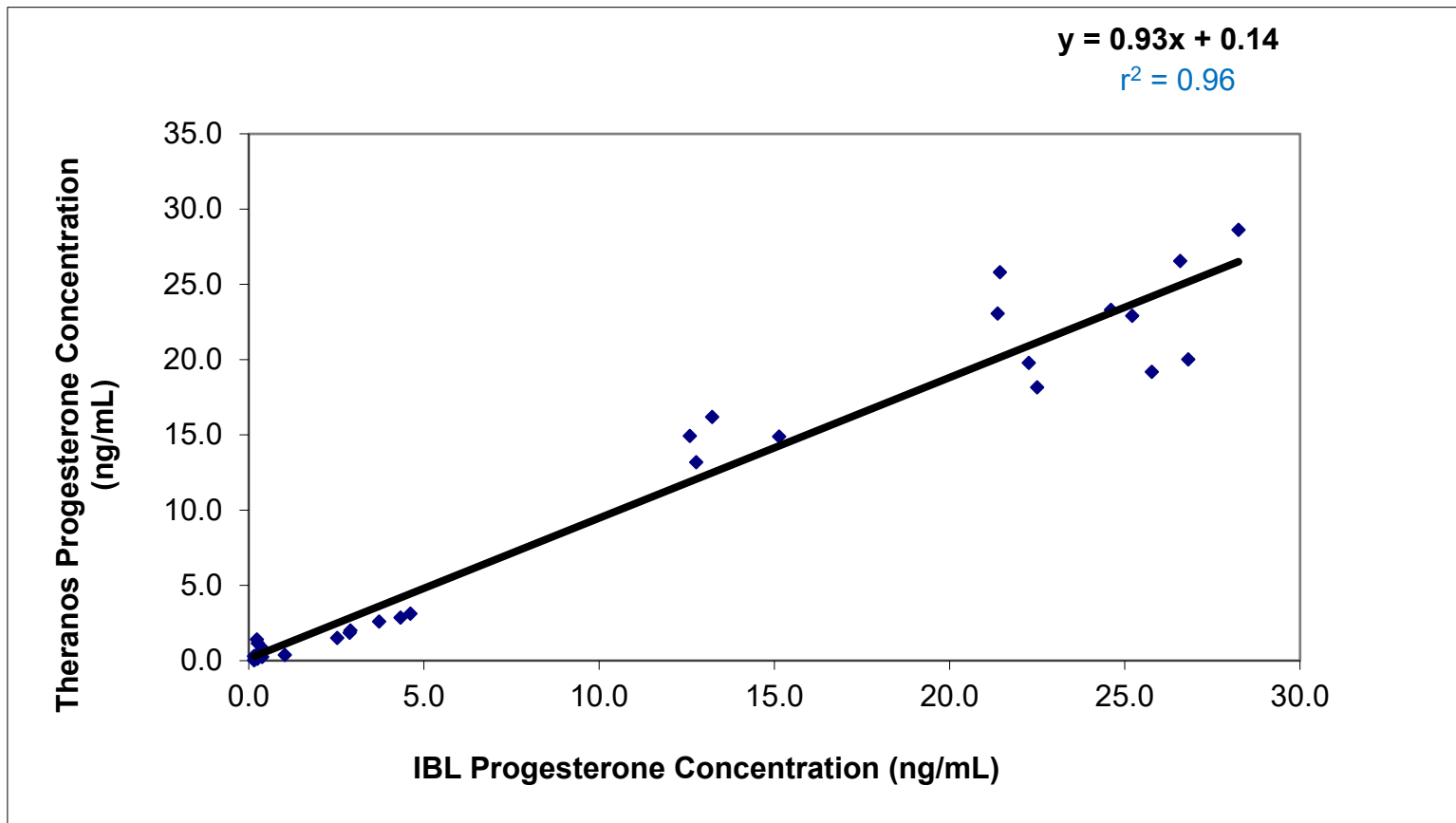
Immunoglobuline (IgE)



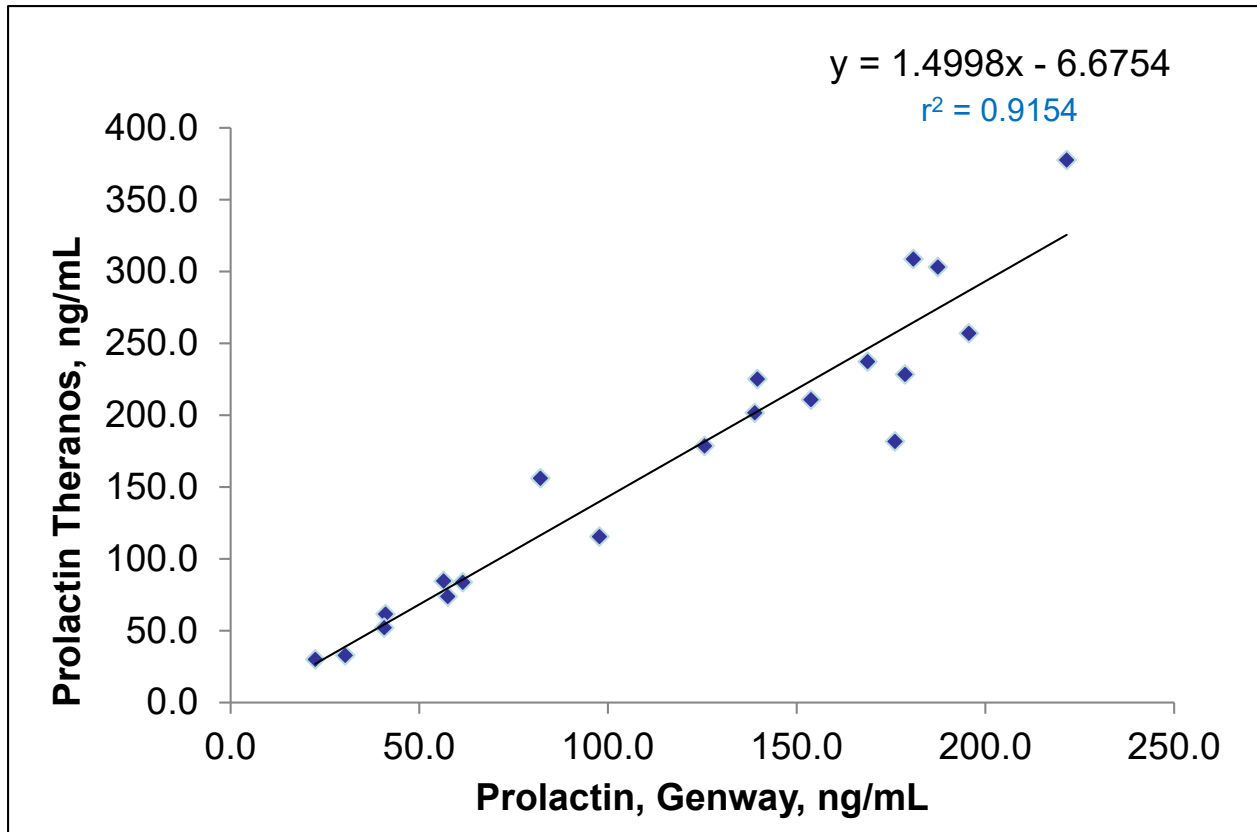
Luteinizing Hormone (LH)



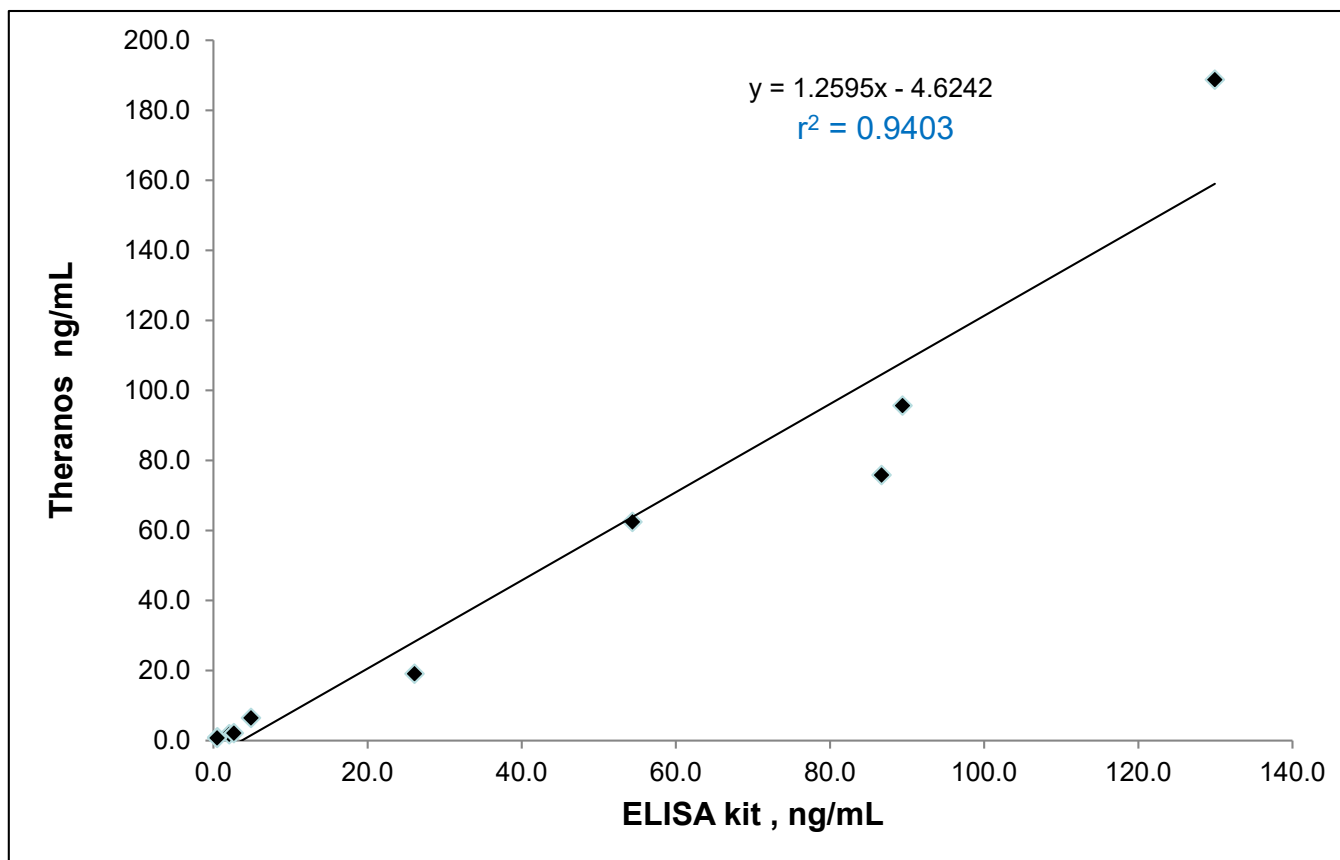
Progesterone



Prolactin



Total PSA



RF IgM antibody

Set Type	Sample ID	ALPCO	INOVA	DRG	Theranos
		Mean Conc(IU/mL)	Mean Conc(IU/mL)	Mean Conc(IU/mL)	Mean Conc (IU/mL)
Positive	19	166	573	347	190
	27	741	2191	815	1397
	38	159	291	25	1885
	40	22	20	25	OORL
	41	602	766	1187	1063
	42	858	1210	839	1577
	43	232	381	778	354
	44	78	187	19	891
	45	597	993	5603	1941
	46	484	988	1217	987
	47	273	914	2110	708
	48	316	914	722	744
	49	1048	2982	942	1652
	50	580	1071	97	1266
	51	258	632	221	545
	52	277	314	1728	645
	53	912	1423	980	1304
	54	179	128	OORL	835
	55	171	277	135	365
	56	93	116	100	125
57	101	1805	956	NES	
58	552	948	348	1448	
59	413	783	863	900	
60	508	1561	328	1159	

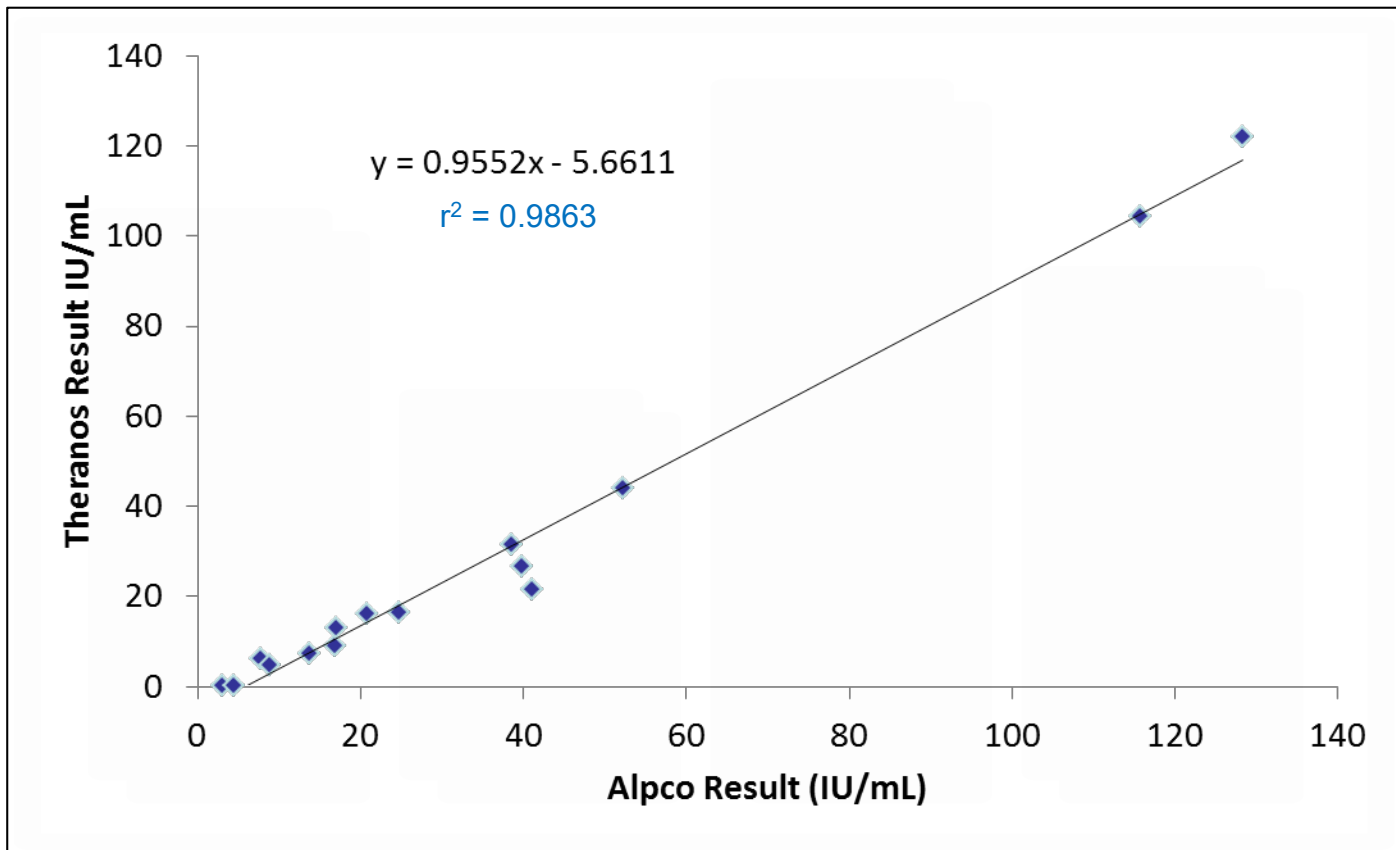
Set Type	Sample ID	ALPCO	INOVA	DRG	Theranos
		Mean Conc(IU/mL)	Mean Conc(IU/mL)	Mean Conc(IU/mL)	Mean Conc (IU/mL)
Negative	B1	0.9	0.6	4.0	OORL
	B2	0.9	0.2	OORL	OORL
	B3	1.5	1.9	OORL	OORL
	B4	2.0	1.1	7.0	OORL
	B5	1.2	1.0	3.2	OORL
	B6	1.0	0.6	OORL	OORL
	B7	0.7	0.2	OORL	OORL
	B8	0.7	0.3	OORL	OORL
	B9	8.0	9.3	13.3	OORL
	B10	1.6	0.9	7.2	OORL
	B11	1.4	1.1	OORL	OORL
	B12	3.4	2.9	0.6	OORL

OORL: Out of range low
NES: Not enough sample

RF IgG antibody

Set Type	Sample#	Theranos S/Co	DRG Mean Conc (U/ml)	Alpco Mean Conc (U/ml)
ProMedDx	1	13.5	993	2143
	2	12.1	464	169
	3	20.2	298	121
	6	18.7	624	81
	9	10.8	366	70
	10	48.3	27	73
	11	22.1	357	987
	12	8.2	234	160
	13	12.3	35	94
	14	8.9	407	72
	15	3.9	505	217
	16	6.0	550	115
	17	2.3	61	221
	18	11.7	902	90
	23	1.7	113	129
	26	1.2	311	102
	31	16.7	540	120
	33	7.9	121	145
	37	4.6	128	97
39	1.7	125	312	
Bioreclamation (Normal Sera)	M11	0.1	19	69
	M12	0.1	12	29
	M13	0.1	15	57
	M14	0.1	16	31
	M15	0.1	8	30
	F11	0.1	15	52
	F12	0.1	10	24
	F13	0.1	16	51
	F14	0.1	17	54
	F15	0.1	10	24
	Set 2	1	0.1	6
2		0.1	5	28
3		0.1	5	26
5		0.1	6	36
6		0.1	8	36
20		0.1	5	24
21		0.1	3	23
22		0.8	5	45
29		0.1	5	35

Rubella Antibody



Anti-Scl 70 antibody

Sample ID	Human Test Samples			ANTIBODY INDEX			
	Matrix	Species	Strain	Theranos	INOVA	IMMCO	IBL
CLN1	Serum	Normal	N/A	0.04	4	5	0.15
CLN2	Serum	Normal	N/A	0.04	4	2	0.07
CLN3	Serum	Normal	N/A	0.06	4	6	0.16
CLN4	Serum	Normal	N/A	0.09	4	2	0.13
CLN5	Serum	Normal	N/A	0.07	5	3	0.10
CLN6	Serum	Normal	N/A	0.06	3	4	0.16
CLN7	Serum	Normal	N/A	0.05	4	7	0.3
CLN8	Serum	Normal	N/A	0.11	5	5	0.15
CLN9	Serum	Normal	N/A	0.06	3	14	0.08
CLN10	Serum	Normal	N/A	0.05	3	6	0.12
CLN11	Serum	Normal	N/A	0.59	9	33	0.29
CLN12	Serum	Normal	N/A	0.04	5	5	0.22
CLN13	Serum	Normal	N/A	0.05	4	2	0.18
CLN14	Serum	Normal	N/A	0.04	11	174	3.06
CLS1	Serum	Autoimmune	Scleroderma	7.35	9	186	0.33
CLS2	Serum	Autoimmune	Scleroderma	0.72	19	70	0.73
CLS9	Serum	Autoimmune	Scleroderma	1.60	100	213	3.76
SS10	Serum	Autoimmune	Sjogren	1.02	5	91	0.19
SCL06	Serum	Autoimmune	Scleroderma	0.95	23	83	1.78
SCL16	Serum	Autoimmune	Scleroderma	6.35	3	194	3.07
SCL25	Serum	Autoimmune	Scleroderma	3.59	141	267	5.25
SCL29	Serum	Autoimmune	Scleroderma	3.04	124	257	2.66
SCL38	Serum	Autoimmune	Scleroderma	0.24	1	69	0.10
SCL39	Serum	Autoimmune	Scleroderma	3.33	146	293	5.58
SCL40	Serum	Autoimmune	Scleroderma	4.50	139	280	5.78

Samples are considered to be positive, borderline, or negative for Scl-70 antibodies if their Ab Indices are found to be greater than 1.1, between 0.9 and 1.1, or less than 0.9, respectively.

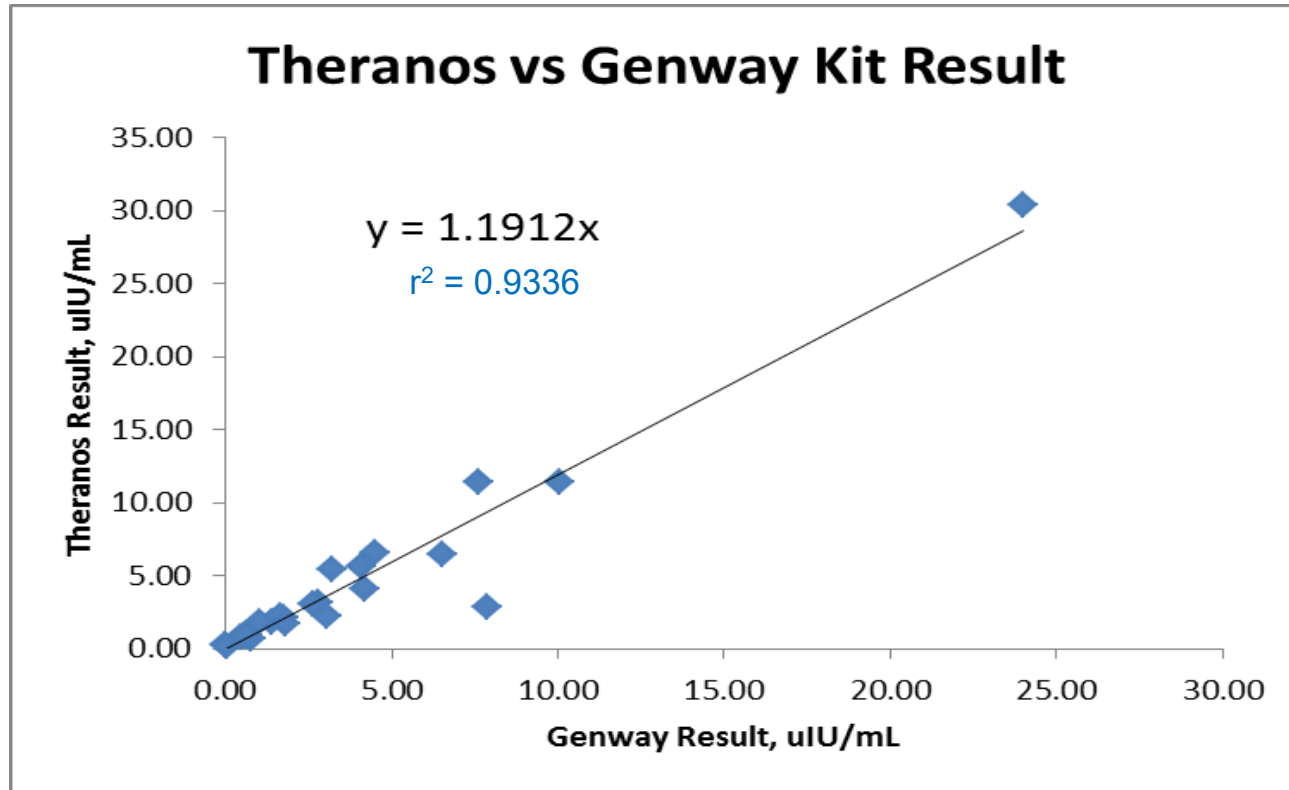
Anti-SSA antibody

	Innova	Immco	IBL Int.	Theranos
Sample	Units	Result (EU/mL)	Ratio	Ab Index
ScL01	42.1	53	0.28	5.0
SCL02	3.9	4	0.38	0.6
ScL03	8.5	9	0.16	0.6
ScL04	17.8	10	0.42	0.4
ScL05	3.8	3	0.44	0.3
ScL06	3.7	2	0.24	0.5
ScL07	4.5	2	0.23	0.3
ScL08	3.7	2	0.22	0.4
ScL09	5.1	5	0.33	0.3
ScL10	17.4	8	0.29	1.1
SL01	102.9	78	5.51	212.8
SL02	4.7	5	0.30	0.5
SL03	3.8	3	0.23	0.4
SL04	70.8	66	5.50	2.5
SL05	3.6	2	0.58	0.3
SL06	59.5	49	5.29	0.9
SL07	4.5	7	0.24	0.6
SL08	86.1	69	5.32	1.7
SL09	3.6	11	0.67	0.6
SL10	3.7	3	0.19	0.4
Sjo01	108.6	57	5.87	33.2
Sjo02	3.5	3	0.23	0.3
Sjo03	125.6	74	6.22	373.3
Sjo04	24.2	57	2.45	14.7
Sjo05	96.9	78	5.61	203.2

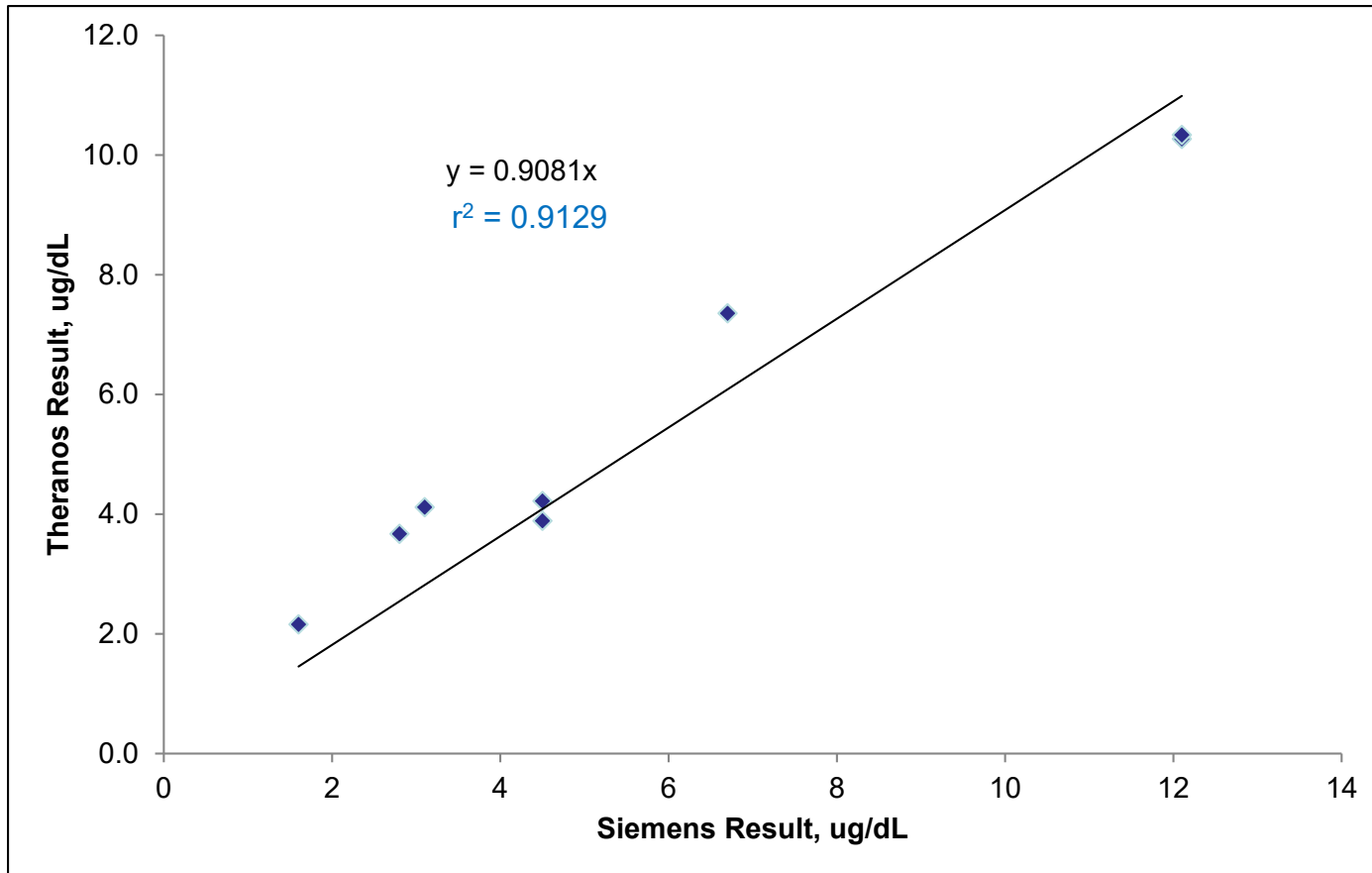
The following criteria was applied to categorize the result as positive (red), negative (green) or borderline (yellow).

Ab Index > 1.1
Ab Index > 0.9, < 1.1
Ab Index < 0.9

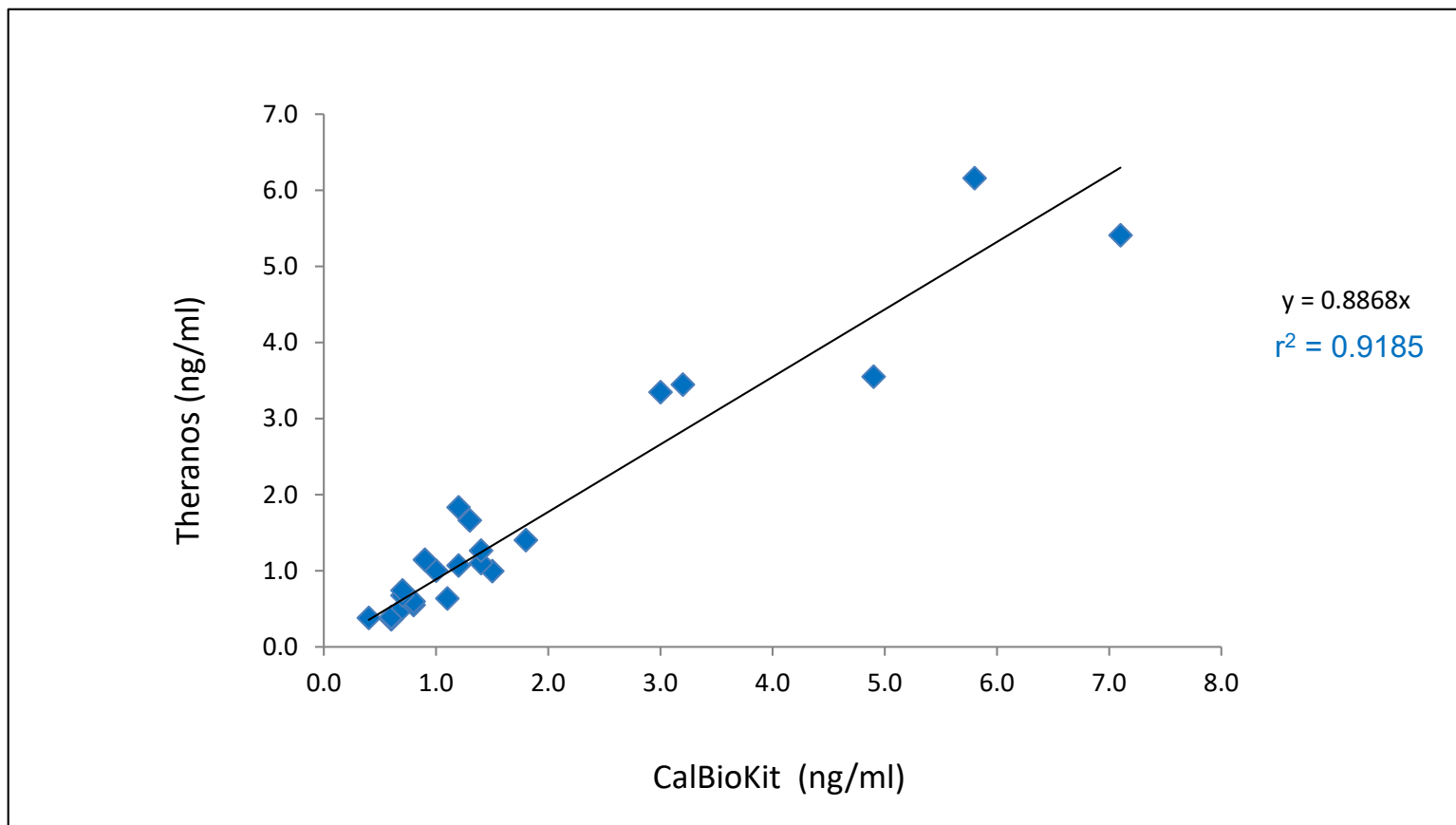
Thyroid stimulating hormone



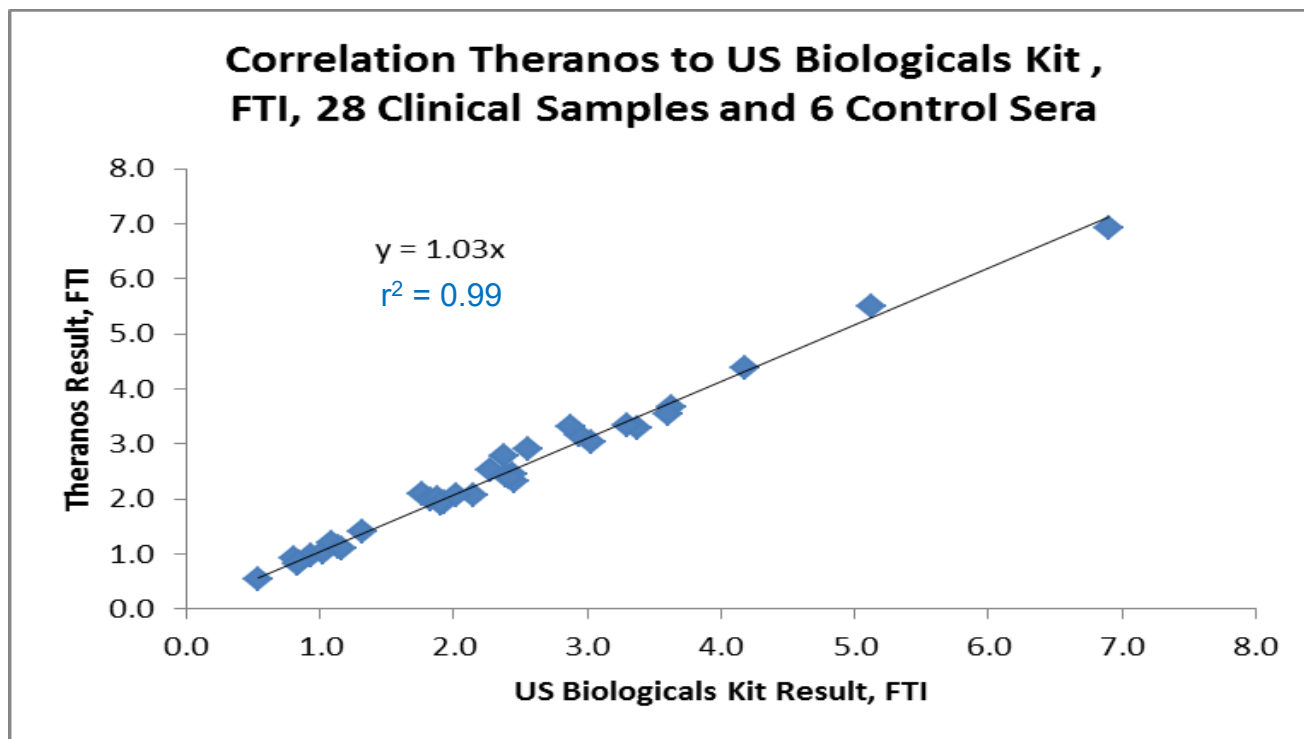
Total Thyroxine (TT4)



Total T3

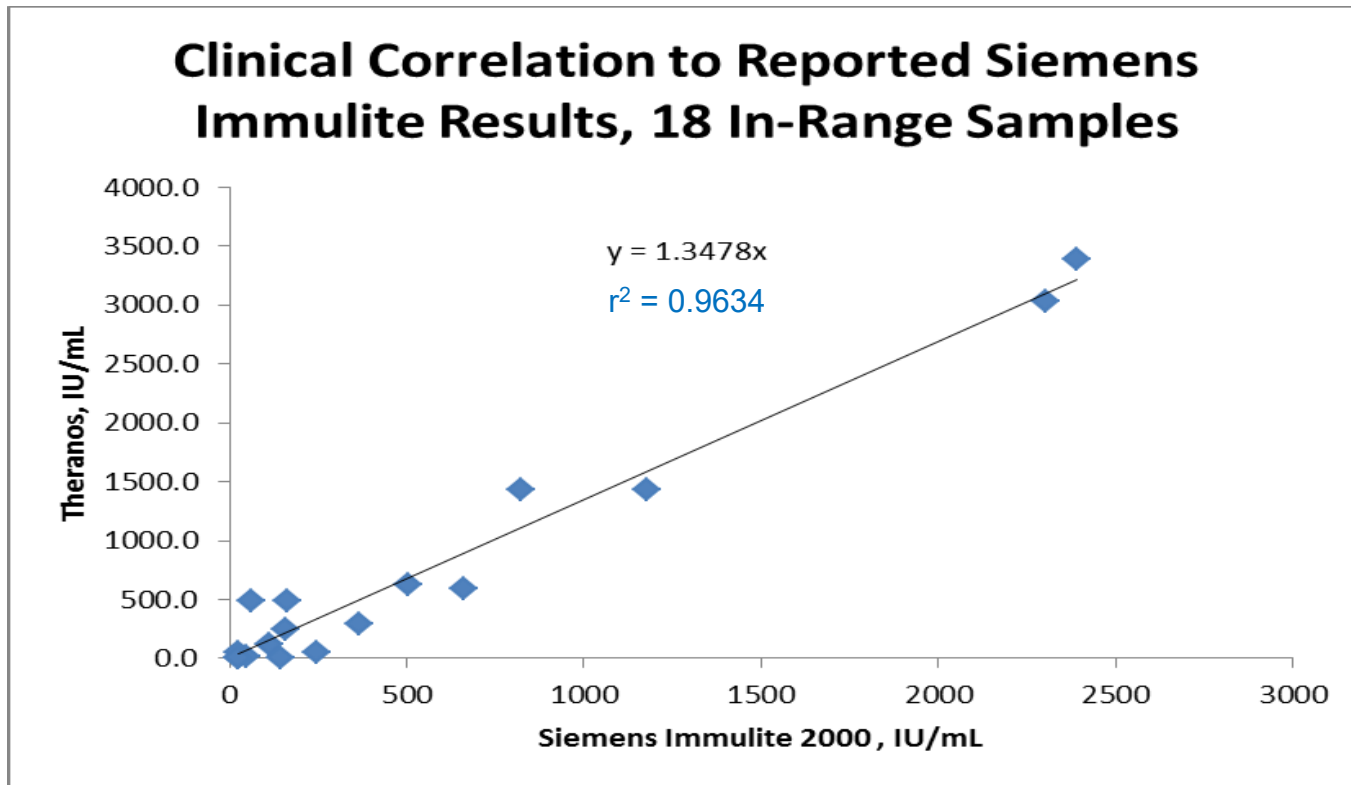


T3 Uptake assay

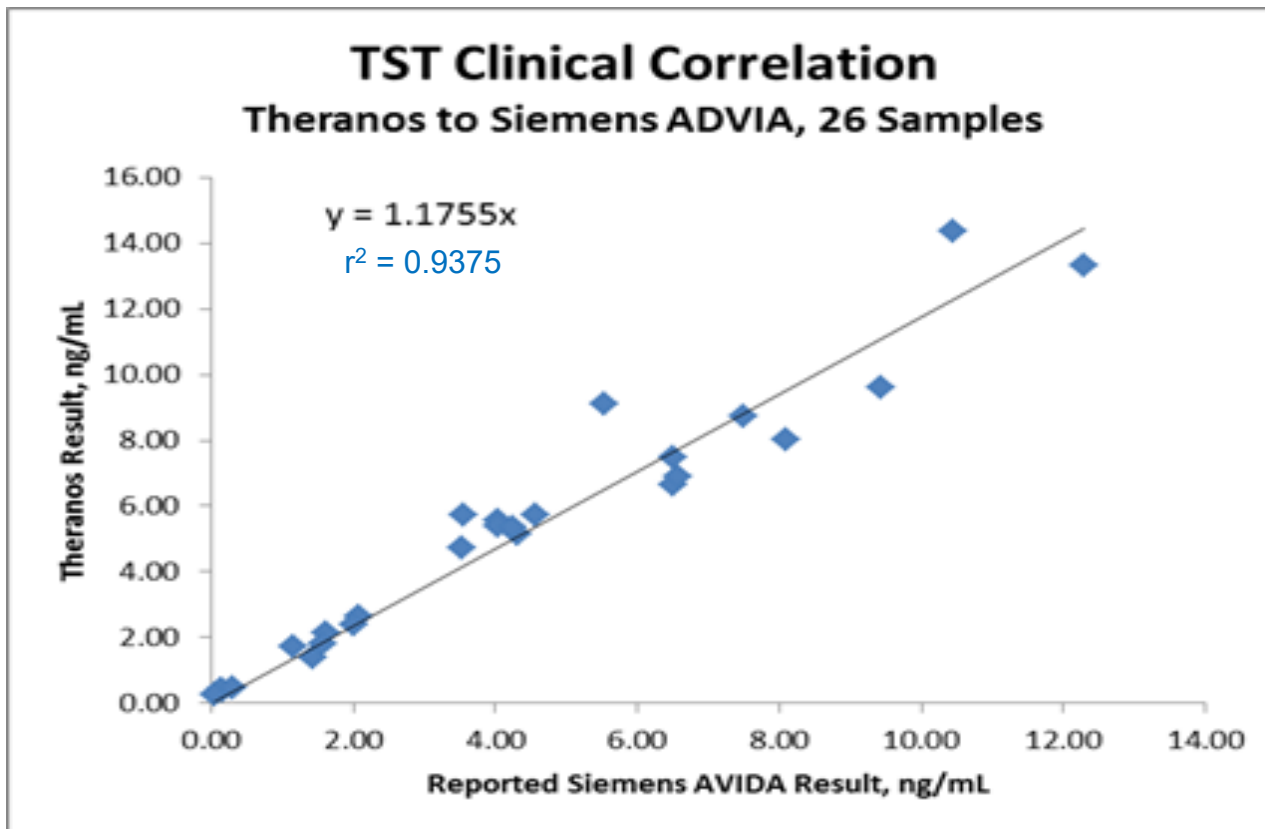


The T Uptake % is used to compute the Free Thyroxine Index (FTI) from the Total T4

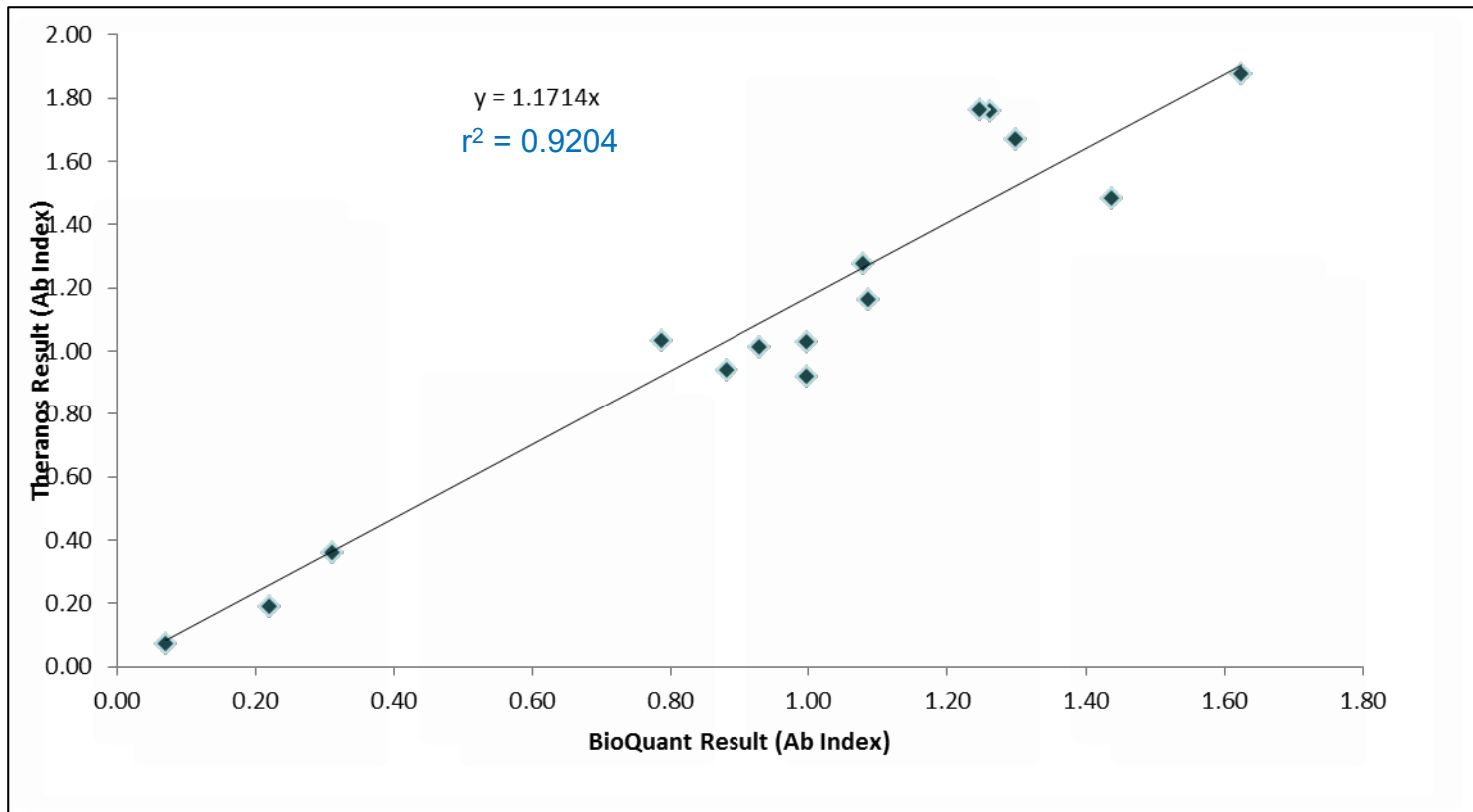
Anti-Thyroglobulin Antibody (IgG)



Total Testosterone



Varicella Zoster virus - IgG



VZV – IgG Precision

Precision and Accuracy for 3 Days/Lots, Concentration (IU/mL)

N = 3 cartridges per point

[VZV IgG] IU/mL	Day/Lot 1			Day/Lot 2			Day/Lot 3			Inter-Lot		
	Mean Conc.	CV %	% Rec.	Mean Conc.	CV %	% Rec.	Mean Conc.	CV %	% Rec.	Mean Conc.	CV %	% Rec.
11.00	9.97	22.3	91	11.40	9.5	104	9.83	33.6	89	10.47	18.9	95
5.50	4.65	2.4	85	6.65	13.6	121	6.09	15.9	111	5.94	18.5	108
2.75	2.33	15.3	85	3.07	7.3	112	2.65	8.1	96	2.68	14.9	98
1.38	1.27	13.5	92	1.46	10.6	106	1.46	12.3	107	1.40	12.6	101
0.69	0.65	11.1	94	0.75	6.7	109	0.71	6.9	104	0.70	9.6	102
0.34	0.32	7.8	93	0.34	13.7	98	0.35	4.0	103	0.34	9.2	98
0.17	0.17	9.2	99	0.18	9.7	105	0.17	1.9	98	0.17	7.5	101
0	OORL	-	-	OORL	-	-	OORL	-	-	OORL	-	-
Positive Control	4.25	8.6	-	3.70	11.7	-	4.25	9.3	-	4.05	11.0	-
Negative Control	OORL	-	-	OORL	-	-	OORL	-	-	OORL	-	-

VZV – IgG Precision

Inter-Analyzer Precision, Concentration (IU/mL)

Analyzer	Tip 1	Tip 2	Intra-Cartridge			Inter-Cartridge	
			Mean	CV %	% Recovery	Mean	CV %
1	0.26	0.27	0.26	4.1	86	0.31	7.2
2	0.34	0.35	0.35	1.1	113		
3	0.30	0.36	0.33	11.4	108		
4	0.26	0.28	0.27	4.8	89		
5	0.30	0.31	0.30	2.1	99		
6	0.28	0.27	0.28	3.6	90		
7	0.29	0.31	0.30	2.7	98		
8	0.32	0.32	0.32	0.3	104		
9	0.30	0.28	0.29	6.1	95		
10	0.32	0.33	0.32	1.0	106		
11	0.28	0.27	0.27	0.8	89		
12	0.30	0.32	0.31	4.4	100		
13	0.29	0.32	0.31	7.5	100		
14	0.35	0.32	0.34	4.8	109		
15	0.35	0.33	0.34	4.0	111		
16	0.31	0.31	0.31	1.2	101		
17	0.29	0.33	0.31	8.8	100		
18	0.31	0.25	0.28	16.8	91		
19	0.32	0.29	0.30	6.3	99		
20	0.29	0.31	0.30	5.9	98		
21	0.30	0.32	0.31	4.3	100		
22	0.33	0.31	0.32	4.7	104		
23	0.33	0.32	0.32	1.9	105		
24	0.33	0.31	0.32	5.0	103		

25-OH Vitamin D

