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Rubella Virus Immunoglobulin G Assay Development Report

Theranos, Inc.

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1. ASSAY INFORMATION[TC "ASSAY INFORMATION" \F C \L "2"]

1.1 Assay Specifications[TC "Assay Specifications" \f C \l "3"]

This assay is designed to detect human immunoglobulin (IgG) specific for Rubella virus in human whole blood, plasma and serum. The assay has a reportable range of 2.7 to 170.0 IU/mL, and is calibrated to the WHO First International Standard (NIBSC RUBI-1-94).

1.1.1 Reference Assays [TC "Reference Assays and Standards" \f C \l "3"]

The following commercial ELISA kits have been used in house as predicate methods:

- BioQuant Rubella IgG ELISA (Cat# BQ025G)
- Alpco Rubella IgG ELISA (Cat# 27-GD82)

1.1.2 Materials and Methods[TC "Materials and Methods" \f C \l "1"]

An antigen-coated surface serves as the capture surface for the Rubella-specific IgG. The sample (whole blood, plasma or serum) is diluted and then incubated on the capture surface for 10 minutes, the surface is washed, and then an alkaline phosphatase-labeled anti-human IgG antibody is incubated on the surface for 10 minutes. After the detection antibody incubation, another washing cycle is performed and the alkaline phosphatase substrate is incubated on the surface for 10 minutes, and the resulting chemiluminescence is read in Relative Light Units (RLU).

Table [SEQ Table * ARABIC]: Materials

Name	Supplier	Catalog #
Rubella (HPV-77) Antigen	Genway	11-511-248285
Mouse Anti-Human IgG1 Antibody	Novus Biologicals	NB100-2046
Alkaline Phosphatase Labeling Kit	Dojindo	LK13-10
Phospho Glo Substrate	KPL	
Blocking Buffer (3% BSA in TBS, 0.05% Sodium Azide)	Sigma (BSA, Fraction V, 99% Pure)	A3059-500G
Carbonate-bicarbonate buffer	Sigma	C3041

2. ASSAY DEVELOPMENT[TC "ASSAY OPTIMIZATION" \F C \L "2"]

1.1 Detection Antibody Conjugate Verification[TC "Detection Antibody Conjugate Verification" \f C \l "1"]

The anti-human IgG detection antibody conjugate was verified to detect human IgG at a concentration of 100 ng/mL in blocking buffer on a microtitre plate with known concentrations of human IgG (Biomeda) coated on the surface.

Table [SEQ Table * ARABIC]: Anti-IgG Detection Antibody Verification (MTP)

[IgG] ug/mL In Well	Mean RLU	Std.Dev.	CV%
100	1851459	15850	0.9
20	1379592	40358	2.9
4	892932	11248	1.3
0.8	143789	5453	3.8
0.16	25525	396	1.6
0	1290	60	4.7

1.2 Plasma Screening on a Microtitre Plate[TC "Plasma Screening" \f C \l "1"]

An archive of human plasma was screened to select relative high and low controls. Plasma from high-level samples was pooled to form a high control plasma material and plasma from low samples was pooled to create a low control. After an initial exploration of coating methods and titration of the antigen surface, a microtitre plate was coated with 10 ug/mL of the antigen and used to screen randomly-chosen samples from the plasma archive at a sample dilution of 1:10 and a detection antibody concentration of 100 ng/mL in blocking buffer.

Table [SEQ Table * ARABIC]: Plasma Screening (MTP)

Sample#	Mean RLU	CV%	Vaccine Status
1	90045	2.6	Unknown
2	42797	0.0	Unknown
3	27145	7.9	Unknown
4	42671	1.3	Unknown
5	29230	5.9	Unknown
6	34978	1.2	Unknown
7	2507	3.1	Unknown
8	67902	1.9	Unknown
9	4632	8.9	Unknown
10	90391	5.5	Unknown
11	41886	5.5	Unknown
12	36686	1.9	Unknown
13	58641	0.9	Unknown
14	68500	2.7	Unknown
15	92192	4.0	Unknown
16	35699	3.5	Vaccinated
Buffer Blank	1137	0.8	

1.3 Calibration[TC "Calibration" \f C \l "1"]

To create a set of calibration standards for the Rubella IgG assay, plasma samples containing the highest levels of Rubella IgG were pooled and serially diluted into assay buffer.

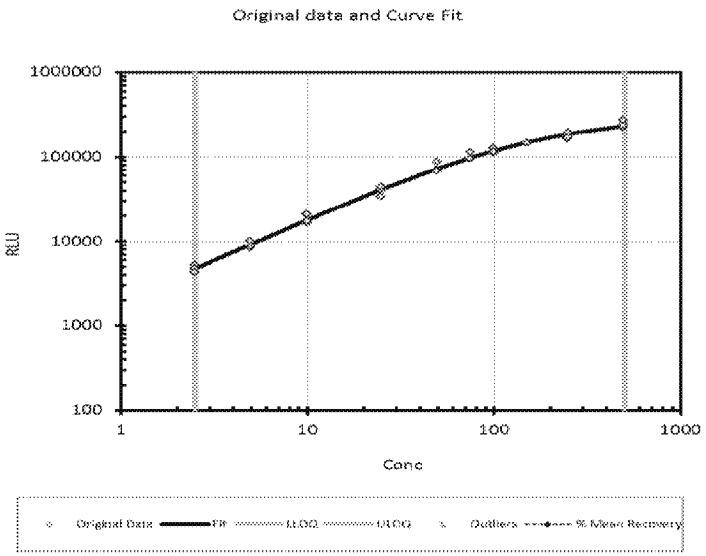
To assign these standards a quantitative value, a standard curve was created using the WHO 1st International Standard for Rubella IgG (NIBSC RUBI-1-94) in assay buffer and this standard curve was used to calculate the concentrations of the plasma-based standards. The top standard was assigned to 170 IU/mL and the remaining calibrators were assigned concentrations based on their dilution from the top standard. The point-by-point concentrations calculated for each level were within 15% of the assigned concentration. (Note: This experiment was performed with the final optimized conditions of 50 ng/mL DAb in stabilizer.

Table [SEQ Table * ARABIC]: Standard Curve: WHO (NIBSC RUBI-1-94) in Assay Buffer

[Anti-Rubella IgG] IU/mL	Mean RLU	CV %	Back-Calculated Conc., IU/mL		
			Mean Conc	CV %	% Recovery
600*	247363	6.8	OORH		
500	243256	9.3	471.4	14.5	94
250	175827	8.3	216.2	22.2	86
150	150199	19.5	162.5	15.7	108
100	118580	9.0	100.8	12.5	101
75	102065	14.9	80.3	14.6	107
50	76104	15.5	53.0	18.9	106
25	39946	16.8	24.0	15.7	96
10	18571	12.7	10.3	13.3	103
5	9152	10.8	4.9	10.5	98
2.5	4818	7.9	2.5	8.9	101
0	1735	12.3	OORL		

* anchor point

Figure [SEQ Figure * ARABIC]: WHO Standard Curve



Calibration Equation: weighted 4 Parameter logistic:

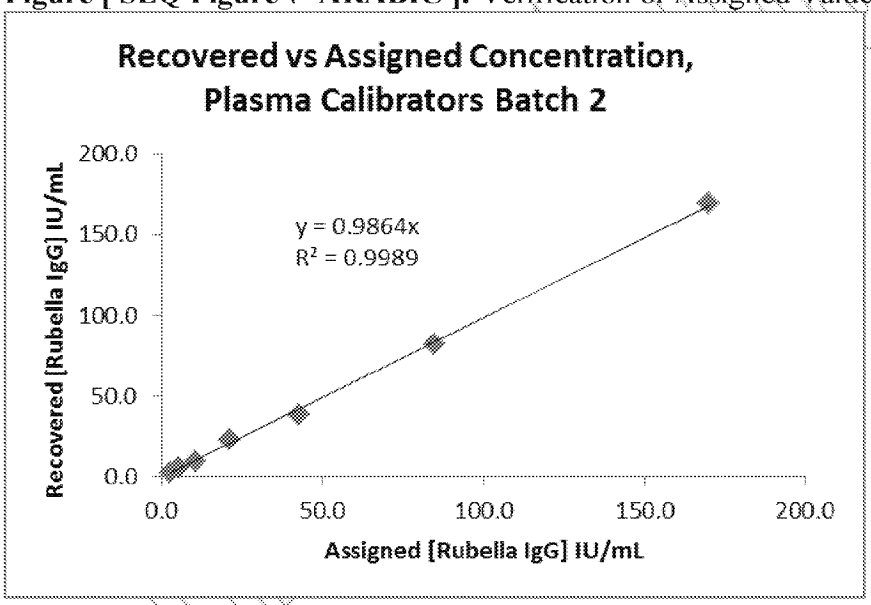
Conc = 159.367 * (((307641.696 - 119.567) / (RLU - 119.567)) - 1) ^ (1 / -1.004)

Signal Min = 3861
Signal Max = 241194

Table [SEQ Table * ARABIC]: Plasma Standards

Level	Dilution Factor	Mean RLU	CV %	Calculated Conc., IU/mL		WHO-Assigned Conc. IU/mL	% Recovery
				Mean Conc.	CV %		
1	1.000	159616	6.7	169.3	11.9	170.0	100
2	0.500	103634	14.1	82.1	19.4	85.0	97
3	0.250	59160	9.4	38.2	5.2	42.5	90
4	0.125	38368	24.1	23.0	26.3	21.3	108
5	0.063	17160	7.9	9.5	3.8	10.6	89
6	0.031	11026	12.8	5.9	13.1	5.3	112
7	0.016	4767	10.9	2.5	12.6	2.7	94
8	0.008	1627	18.8	OORL	-	0.0	100

Figure [SEQ Figure * ARABIC]: Verification of Assigned Values for Plasma Standards



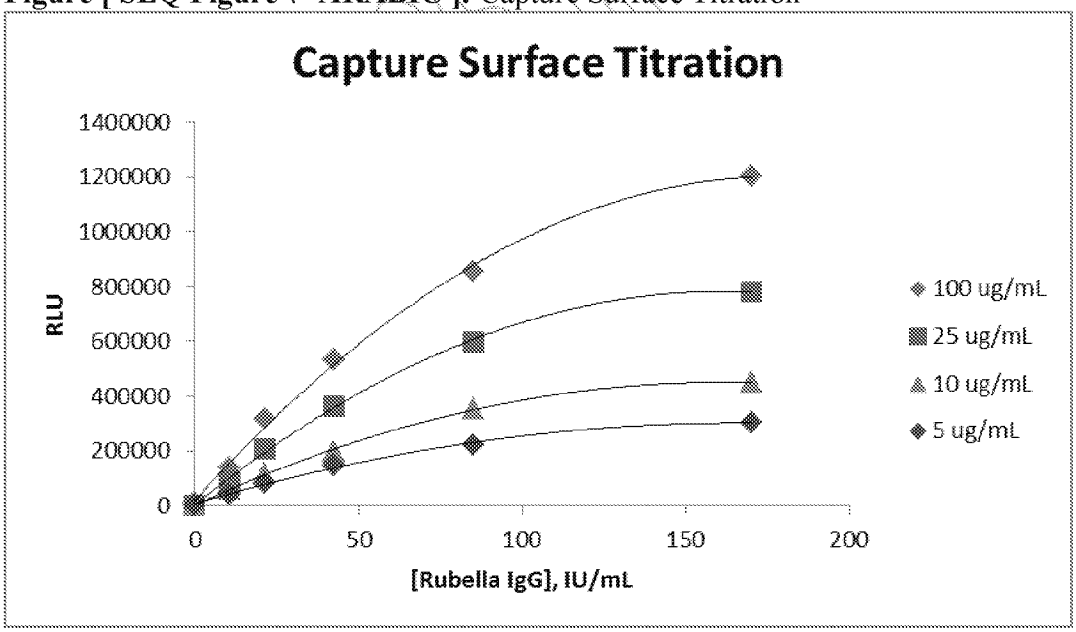
1.4 Capture Surface Titration [TC "Capture Surface Titration on the Theranos System" \f C \l "1"]

Capture surfaces were titrated with 100, 25, 10, and 5 ug/mL of Rubella antigen to optimize the capture surface, with the detection antibody at 100 ng/mL in blocking buffer. Based on signal to background, 10ug /mL was optimal.

Table [SEQ Table * ARABIC]: Titration of Rubella Antigen on the Capture Surface

	100 ug/mL		25 ug/mL		10 ug/mL		5 ug/mL	
Conc, IU/mL	**Mean RLU**	**CV %**	**Mean RLU**	**CV %**	**Mean RLU**	**CV %**	**Mean RLU**	**CV %**
170.0	1203476	1.7	781996	7.9	449017	13.1	303623	2.5
85.0	855931	17.7	599665	10.3	352488	5.9	220733	11.8
42.5	531707	8.1	364749	11.1	199928	13.0	148987	7.3
21.3	315522	1.5	206727	3.6	117350	3.6	82353	8.7
10.6	137296	14.6	87054	5.8	58305	9.9	41387	8.1
0.0	8110	9.4	2254	5.9	1044	6.2	861	20.4
S/B	*148*		*347*		*430*		*353*	

Figure [SEQ Figure * ARABIC]: Capture Surface Titration



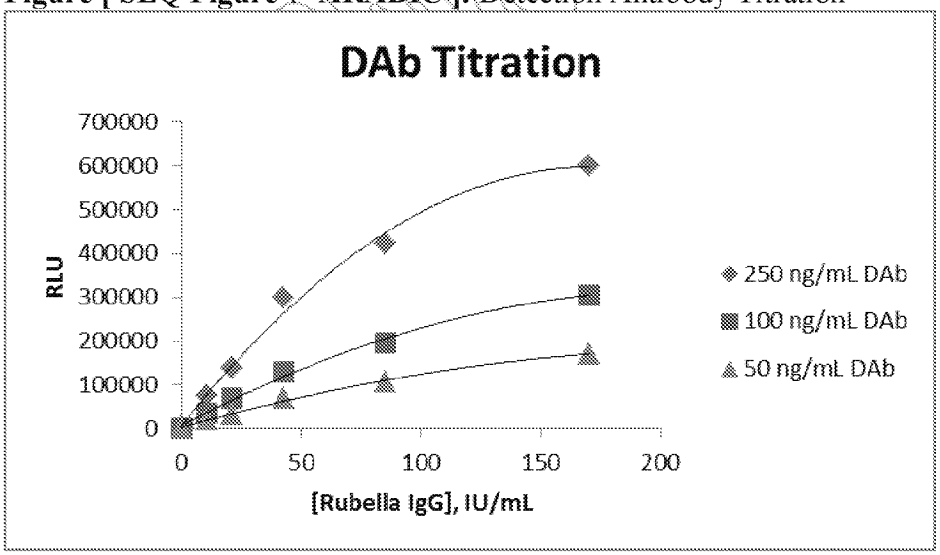
1.5 Detection Antibody Titration [TC "Detection Conjugate Titration on the Theranos System" \f C \l "1"]

The alkaline phosphatase labeled anti-human IgG detection antibody was titrated in a commercial stabilizer, with the capture surface coated at 10 ug/mL and a post sample wash. Initial optimization had used a DAb concentration of 250 ng/mL, however after finalizing the reader protocol, the DAb was re-titrated as shown below and a lower concentration was chosen. A concentration of 50 ng/mL was chosen based on low background, sufficient modulation and the most linear assay response across the range.

Table [SEQ Table * ARABIC]: Titration of the Detection Antibody

	250 ng/mL		100 ng/mL		50 ng/mL	
Conc, IU/mL	**Mean RLU**	**CV %**	**Mean RLU**	**CV %**	**Mean RLU**	**CV %**
170.0	601519	9.1	305738	5.8	171094	21.2
85.0	423153	15.6	196235	10.2	105784	22.8
42.5	300383	6.0	128678	14.7	69296	8.7
21.3	137056	2.3	69152	12.5	32707	17.8
10.6	74218	8.5	36310	15.1	19447	6.9
0.0	2548	14.7	1717	13.8	1205	17.1

Figure [SEQ Figure * ARABIC]: Detection Antibody Titration



1.6 Protocol Optimization

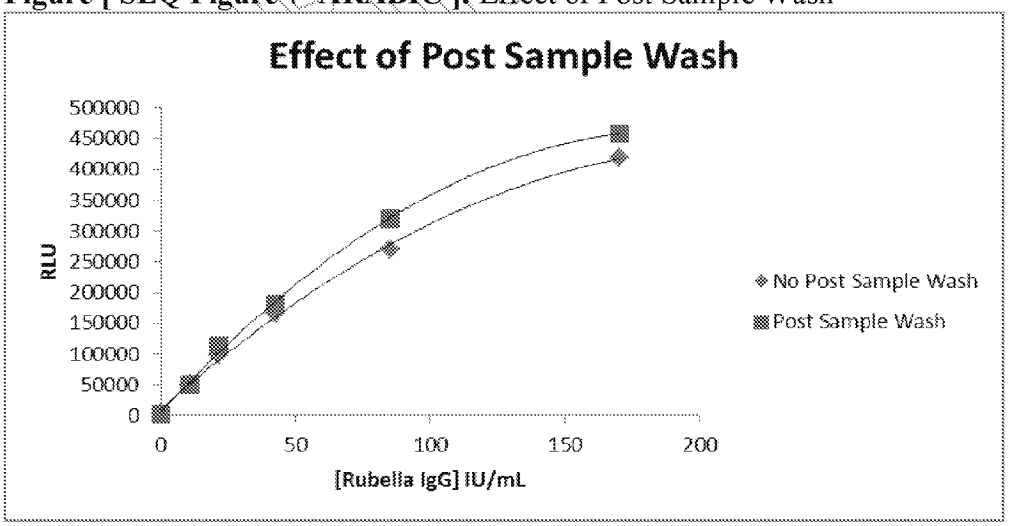
1.6.1 Post Sample Wash

The effect of a post sample wash was tested with the capture surface coated at 10 ug/mL Rubella antigen, a 1:25 sample dilution, and the detection antibody at 250 ng/mL in Stabilizer. The post sample wash had very little effect on the dose response, the assay would respond well with a post sample wash or without, but due to the possibility of improved accuracy and slight increase in signal to background, the assay was optimized with a post sample wash.

Table [SEQ Table * ARABIC]: Effect of Post Sample Wash

[Rubella IgG] IU/mL	No Post Sample Wash		Post Sample Wash	
	Mean RLU	CV %	Mean RLU	CV %
170.0	418699	3.4	458130	6.5
85.0	269712	6.9	320283	8.3
42.5	165245	8.9	180838	4.2
21.3	98840	11.2	113503	5.5
10.6	51320	16.1	51108	2.3
0	1943	8.9	1919	11.3
S/B	*216*		*239*	

Figure [SEQ Figure * ARABIC]: Effect of Post Sample Wash



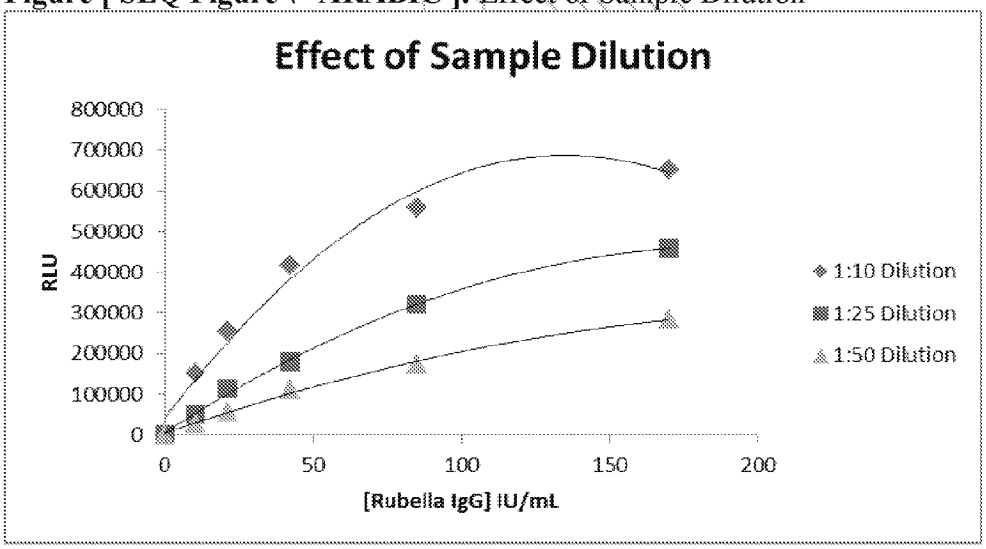
1.6.2 Sample Dilution

Sample dilutions of 1:10, 1:25 and 1:50 were tested with 250 ng/mL DAb in stabilizer. A 1:25 sample dilution showed sufficient modulation while avoiding saturation of the dose response at the high end of the range.

Table [SEQ Table * ARABIC]: Effect of Sample Dilution

[Rubella IgG] IU/mL	1:10 Dilution		1:25 Dilution		1:50 Dilution	
	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %
170.0	651063	6.0	458130	6.5	283516	
85.0	558825	5.0	320283	8.3	173956	10.6
42.5	417760	11.6	180838	4.2	112175	18.5
21.3	253269	7.7	113503	5.5	55525	19.5
10.6	151459	7.0	51108	2.3	28745	23.3
0	1918	2.2	1919	11.3	2171	19.9
S/B	*339*		*239*		*131*	

Figure [SEQ Figure * ARABIC]: Effect of Sample Dilution



1.7 Whole Blood Screen and Hematocrit Effect

Whole blood samples were screened to determine the endogenous levels of Rubella IgG. To determine the hematocrit effect for this assay, plasma was prepared from these blood samples and the recovery of Rubella IgG compared to the whole blood result was determined. In plasma, the measured amount of Rubella IgG is 1.6 times the amount measured in whole blood. This experiment was performed with a DAb concentration of 250 ng/mL in stabilizer.

Table [SEQ Table * ARABIC]: Standard Curve: Plasma Standards

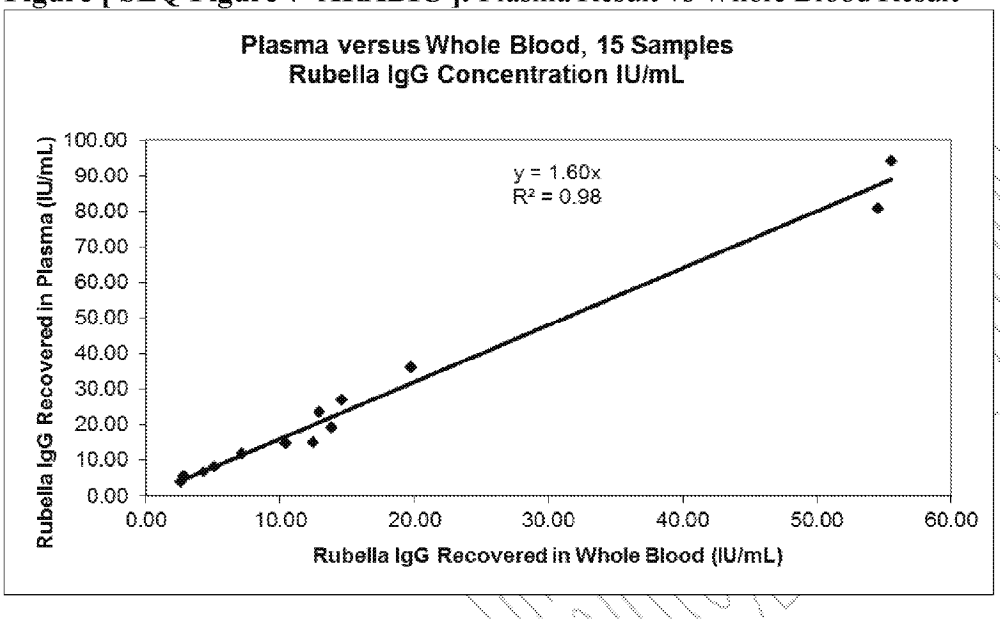
[Rubella IgG] IU/mL	Mean RLU	CV %	Back-Calculation Verification, IU/mL		
			Mean Conc.	CV %	% Recovery
170.0	543828	5.6	164.63	-	97
85.0	368888	3.9	76.92	3.5	90
42.5	255926	12.0	43.56	14.6	102
21.3	141441	23.8	23.19	16.8	109
10.6	79655	20.1	12.05	13.3	113
5.3	42138	16.3	5.73	18.6	108
2.7	18395	7.3	2.47	7.1	93
0.0	1426	13.1	OORL	-	-

Conc = 81.466 * (((760609.603 - 1415.899) / (RLU - 1415.899)) - 1) ^ (1 / -1.081)
Signal Min = 15880, Signal Max = 548299

Table [SEQ Table * ARABIC]: Results for 15 Samples: Whole Blood and Plasma

Sample #	Whole Blood				Plasma			
	Signal, RLU		Conc, IU/mL		Signal, RLU		Conc, IU/mL	
	Mean RLU	CV %	Mean Conc.	CV %	Mean RLU	CV %	Mean Conc.	CV %
1	299636	6.0	54.59	9.5	376967	3.4	80.84	4.5
2	1947	25.2	OORL	-	1809	17.2	OORL	-
3	31521	9.6	4.27	11.3	48529	6.5	6.61	2.0
4	21100	9.9	2.84	10.9	39691	5.2	5.39	2.4
5	89932	8.6	12.52	10.6	106064	13.4	14.97	10.7
6	75851	15.5	10.47	19.4	104062	17.7	14.67	3.5
7	98876	15.3	13.87	18.6	132060	11.3	19.08	12.9
8	37749	15.3	5.12	18.0	59590	17.6	8.15	19.5
9	52867	11.8	7.21	13.4	85516	17.6	11.89	20.4
10	103454	16.7	14.58	12.0	176573	16.4	26.89	14.1
11	136372	8.5	19.77	8.9	223326	11.4	36.10	11.9
12	18660	17.0	2.65	4.8	28689	24.1	3.88	27.7
13	303241	4.7	55.54	3.9	410086	4.7	94.12	-
14	92438	13.4	12.90	15.7	157440	6.9	23.34	0.1
15	2003	37.5	OORL	-	1626	8.0	OORL	-

Figure [SEQ Figure * ARABIC]: Plasma Result vs Whole Blood Result



1.8 Dilution Linearity

Dilution linearity was tested by serially diluting a high plasma sample 1:2 into a low plasma sample and measuring the recovered Rubella IgG. This experiment was performed with DAb at 250 ng/mL in Stabilizer, before the re-titration was performed. A log-log calibration was used to calculate the endogenous level of the low sample, which was below the normal LLOQ of the assay. Level 1 was 100% high sample and Level 6 was 100% low sample, while 2-5 consisted of a serial dilution of the high into the low sample. Recovery was within 20% of the nominal across the range and the correlation of recovered versus the calculated nominal concentrations was excellent, meeting the acceptance criteria for dilution linearity.

Table [SEQ Table * ARABIC]: Standard Curve: Plasma Calibrators

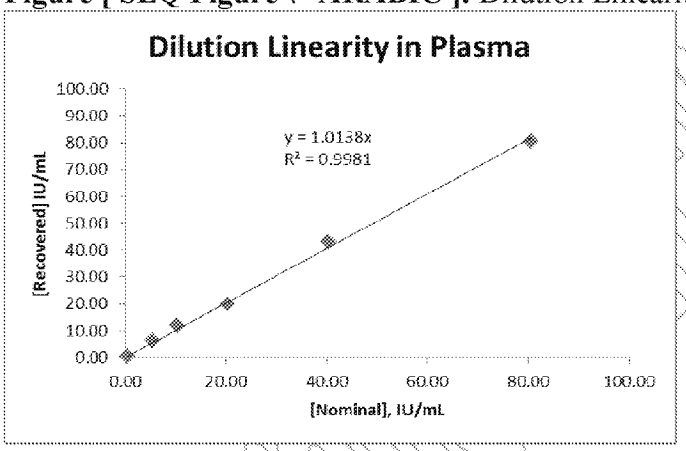
	Signal, RLU		Back-Calculation Verification, IU/mL		
IU/mL	Mean RLU	CV %	Mean Conc.	CV %	% Recovery
170.0	543828	5.6	172.3	11.7	101
85.0	368888	3.9	80.7	6.9	95
42.5	255926	12.0	43.7	19.9	103
21.3	156410	11.9	21.4	15.3	101
10.6	86761	10.3	10.6	10.9	100
5.3	42138	16.3	5.3	14.4	99
2.7	18395	7.3	2.7	5.8	100
0.0	1426	13.1	0.2	19.8	

Conc =10^(0.1967*(LOG(RLU))^3 - 2.5106*(LOG(RLU))^2 + 11.478*(LOG(RLU)) - 18.121)
Signal Min = 15835, Signal Max = 534320

Table [SEQ Table * ARABIC]: Dilution Linearity in Plasma

Level	[Nominal], IU/mL	Signal (RLU)		Concentration (IU/mL)		
		Mean RLU	CV %	Mean Conc	CV %	% Recovery
1	80.6	368631	4.2	80.6	7.6	100
2	40.5	251697	20.2	43.1	31.0	106
3	20.4	149466	0.0	20.1	0.0	98
4	10.4	97017	13.0	12.0	14.6	115
5	5.4	50680	12.8	6.2	11.8	116
6	0.4	2233	15.8	0.4	20.2	

Figure [SEQ Figure * ARABIC]: Dilution Linearity in Plasma



1.9 Inter-Lot Precision and Accuracy

Three lots of capture surface were produced and the assay run on the Theranos System on 3 sequential days, the results were compared for accuracy and precision. Plasma calibrators, and the final optimized conditions of 50 ng/mL DAb in Stabilizer were used. A combined standard curve was created from the 3 lot/day data and the back-calculated accuracy and precision was determined by lot/day and over the 3 lots/days. A positive and negative plasma control was included.

The average inter-lot/day CV was 15.8% (range 11.7 – 22.0%) and the average percentage recovery was 102% (range 95-108%). These results met the criteria for accuracy and precision, with precision less than 20% CV in the mid range and less than 25% at ULOQ and LLOQ, and accuracy within 20% of nominal in the mid range and within 25% at ULOQ and LLOQ.

Table [SEQ Table * ARABIC]: Precision and Accuracy for 3 Days/Lots, Signal (RLU)

[Rubella IgG] IU/mL	Day/Lot 1		Day/Lot 2		Day/Lot 3		Inter-Lot/Day	
	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %
170.0	145479	5.6	133311	14.0	116074	18.0	131621	14.7
85.0	82553	14.1	87014	7.0	88727	5.2	86098	8.7
42.5	54832	5.1	55874	14.5	50596	4.1	53767	9.4
21.3	27927	16.8	29278	4.7	30087	10.4	29097	10.5
10.6	16006	8.0	18225	14.1	14126	12.2	16119	15.1
5.3	7541	12.9	9343	10.7	7109	10.8	7997	16.2
2.7	3632	5.8	4397	18.4	3932	24.8	4046	17.6
0.0	1318	23.0	1078	17.3	1452	16.3	1283	21.0
Positive Control	143418	14.3	134502	15.4	137101	20.7	131621	14.7
Negative Control	1132	12.7	1092	9.0	1192	3.4	1138	4.4

N = 3 cartridges per point

Conc = 155.456 * (((251335.133 - 38.825) / (RLU - 38.825)) - 1) ^ (1 / -1.012)
Signal Min = 3306, Signal Max = 140201

Figure [SEQ Figure * ARABIC]: Standard Curve: 3 Lot Precision

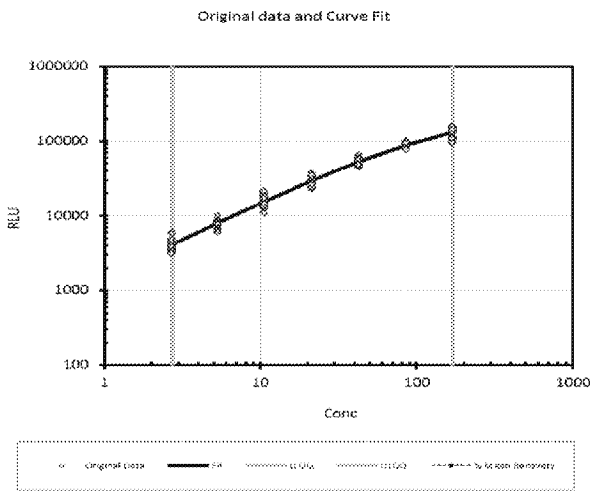


Table [SEQ Table * ARABIC]: Precision and Accuracy for 3 Days/Lots, Concentration (IU/mL)

	Day/Lot 1			Day/Lot 2			Day/Lot 3			Inter-Lot		
[RV IgG] IU/mL	**Mean Conc.**	**CV %**	**% Rec.**	**Mean Conc.**	**CV %**	**% Rec.**	**Mean Conc.**	**CV %**	**% Rec.**	**Mean Conc.**	**CV %**	**% Rec.**
170.0	188.4	0.3	111	176.4	8.3	104	132.9	29.1	78	161.2	22.0	95
85.0	96.7	18.9	114	83.3	10.9	98	85.8	7.8	101	88.6	14.0	104
42.5	44.1	6.3	104	45.3	18.1	107	39.9	5.2	94	43.1	11.8	101
21.3	20.0	18.7	94	21.0	5.2	99	21.7	11.8	102	20.9	11.7	98
10.6	10.9	8.5	103	12.5	15.0	118	9.6	12.7	90	11.0	16.0	104
5.3	5.0	13.2	94	6.2	11.1	117	4.7	11.0	89	5.3	16.7	100
2.7	2.4	5.8	89	2.9	18.6	109	3.2	16.8	120	2.9	18.5	108
0.0	OORL	-	-	OORL	-	-	OORL	-	-	OORL	-	-
Positive Control	168.7	11.5		157.5	10.5		148.4	32.3		158.1	15.6	
Negative Control	OORL			OORL			OORL			OORL		

N = 3 cartridges per point

1.10 Inter-Instrument Precision

To assess inter-instrument precision, 24 cartridges were run on 24 different instruments with a sample in the low-mid range and the precision determined. The final condition of 50 ng/mL DAb in stabilizer were used and the concentration was calculated using the standard curve generated for the 3 lot/day precision and accuracy test. The inter-instrument CV % was 12.1 which met the criteria of less than 20%.

Table [SEQ Table * ARABIC]: Inter-Instrument Precision, Signal (RLU)

Instrument			Intra-Cartridge		Inter-Instrument	
	Tip 1	Tip 2	Mean	CV %	Mean	CV %
1	9040	8541	8790	4.0	10249	11.7
2	11570	12616	12093	6.1		
3	11015	11264	11139	1.6		
4	8742	8060	8401	5.7		
5	10676	11362	11019	4.4		
6	9401	10086	9743	5.0		
7	11337	10916	11126	2.7		
8	11186	10395	10791	5.2		
9	8537	9534	9036	7.8		
10	10326	9678	10002	4.6		
11	9227	8648	8938	4.6		
12	8076	8400	8238	2.8		
13	8646	9602	9124	7.4		
14	12226	10145	11185	13.2		
15	13364	10261	11812	18.6		
16	10523	13463	11993	17.3		
17	10349	12846	11598	15.2		
18	10787	8541	9664	16.4		
19	10564	9987	10276	4.0		
20	9108	10895	10001	12.6		
21	8402	9150	8776	6.0		
22	9602	10098	9850	3.6		
23	11852	10716	11284	7.1		
24	11095	11119	11107	0.2		

Table [SEQ Table * ARABIC]: Inter-Instrument Precision, Concentration (IU/mL)

			Intra-Cartridge			Inter-Cartridge	
Instrument	**Tip 1**	**Tip 2**	**Mean**	**CV %**	**% Recovery**	**Mean**	**CV %**
1	7.5	7.1	7.3	4.2	85	8.5	12.1
2	9.7	10.6	10.1	6.4	119		
3	9.2	9.4	9.3	1.6	109		
4	7.2	6.6	6.9	6.0	81		
5	8.9	9.5	9.2	4.6	108		
6	7.8	8.4	8.1	5.2	95		
7	9.5	9.1	9.3	2.8	109		
8	9.3	8.7	9.0	5.4	105		
9	7.1	7.9	7.5	8.1	88		
10	8.6	8.0	8.3	4.8	97		
11	7.6	7.2	7.4	4.8	87		
12	6.7	6.9	6.8	2.9	80		
13	7.1	8.0	7.6	7.7	89		
14	10.3	8.4	9.3	13.7	109		
15	11.3	8.5	9.9	19.4	116		
16	8.8	11.3	10.1	18.1	118		
17	8.6	10.8	9.7	15.9	114		
18	9.0	7.1	8.0	17.1	94		
19	8.8	8.3	8.6	4.1	100		
20	7.5	9.1	8.3	13.1	97		
21	6.9	7.6	7.3	6.3	85		
22	8.0	8.4	8.2	3.7	96		
23	9.9	8.9	9.4	7.4	110		
24	9.3	9.3	9.3	0.2	109		

1.11 Clinical Samples – Correlation with Predicate Method

A set of 15 plasma samples were tested on the Theranos System and on 2 commercially available ELISA kits. The Alpco Rubella IgG kit produces a quantitative measurement in IU/mL but the BioQuant kit is not quantitative, therefore it was necessary to test the Theranos plasma standards in the BioQuant kit as samples and assign the values to Bioquant "Antibody index" on a point by point basis, since the kit's recovery of these plasma standards was not linear. A standard curve was created using these assigned values and used to calculate the Theranos result for comparison with BioQuant kit results. The correlation with both methods met the acceptance criteria with R^2 greater than 0.9 and slope within 0.75 to 1.25.

Table [SEQ Table * ARABIC]: Comparison of Sample Results: Theranos to Alpco

	Alpco Result (IU/mL)		Theranos Result (IU/mL)	
Sample #	Mean Conc.	CV %	Mean Conc.	CV %
1	115.7	1.3	83.9	6.2
2	3.0	1.5	0.3	23.7
3	13.8	5.1	6.0	5.8
4	7.7	11.0	5.0	4.5
5	24.6	5.1	13.3	15.8
6	20.8	5.9	13.0	20.3
7	41.0	6.5	17.2	13.9
8	16.9	5.9	7.2	16.8
9	16.9	3.3	10.5	19.1
10	38.5	0.7	25.3	21.1
11	52.2	5.0	35.3	17.5
12	8.9	0.3	3.8	19.9
13	128.2	0.5	98.1	8.9
14	39.8	5.8	21.5	9.2
15	4.4	12.5	0.2	11.4

Figure [SEQ Figure * ARABIC]: Correlation of Theranos Result to Alpco Result

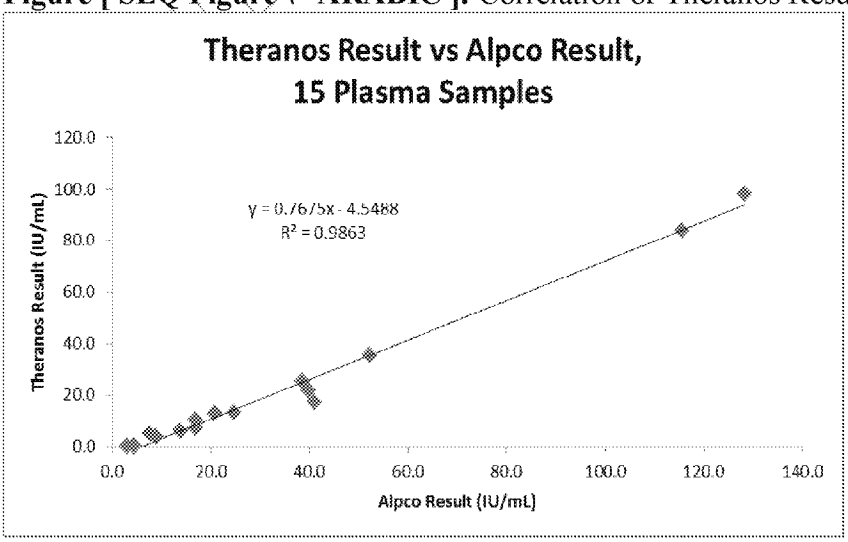
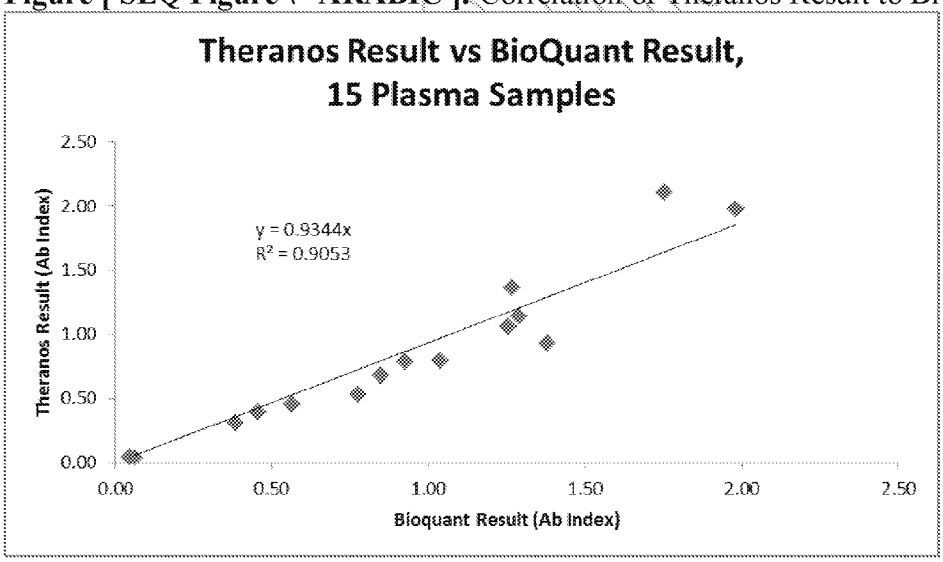


Table [SEQ Table * ARABIC]: Comparison of Sample Results: Theranos to BioQuant

Sample #	BioQuant Result (Antibody Index)		Theranos Result (Antibody Index)	
	Mean Conc.	CV %	Mean Conc.	CV %
1	1.98	5.3	1.98	2.5
2	0.06	0.0	0.04	12.4
3	0.56	2.9	0.45	4.7
4	0.45	12.2	0.39	3.8
5	1.04	3.8	0.79	9.5
6	0.92	5.3	0.78	12.7
7	1.38	4.0	0.93	8.2
8	0.78	3.3	0.52	12.7
9	0.85	8.7	0.68	12.6
10	1.29	6.3	1.15	12.1
11	1.27	5.0	1.36	8.1
12	0.38	5.3	0.31	17.6
13	1.75	6.3	2.10	3.4
14	1.25	10.8	1.06	5.0
15	0.04	11.6	0.04	5.8

Figure [SEQ Figure * ARABIC]: Correlation of Theranos Result to BioQuant Result



1.12 Stability of Assay Components

The stability of the coated surface and the working solution of detection conjugate at 50 ng/mL in a stabilizer and stored at 4°C is being monitored. As of week 8 the reagents are stable.

Table [SEQ Table * ARABIC]: Stability of Reagents: Signal (RLU)

Week	[RV IgG] IU/mL	Mean RLU	CV %
0	170.0	133311	14.3
	42.5	55874	13.8
	10.6	18225	13.0
	0.0	1078	17.3
4	170.0	135644	12.1
	42.5	51109	4.4
	10.6	15000	8.0
	0.0	1517	17.1
8	170.0	127571	5.4
	42.5	50888	16.5
	10.6	15474	13.6
	0.0	1429	9.5

N=3 Cartridges per point

Table [SEQ Table * ARABIC]: Stability of Reagents: Concentration (IU/mL)

Week	[RV IgG] IU/mL	Mean Conc.	CV %	% Recovery
0	170.0	159.8	19.2	94
	42.5	45.3	18.1	107
	10.6	12.5	15.0	118
	0.0	OORL	-	-
4	170.0	162.0	13.1	95
	42.5	40.3	6.0	95
	10.6	10.2	3.3	96
	0.0	OORL	-	-
8	170.0	172.7	8.9	102
	42.5	40.9	23.3	96
	10.6	11.2	3.0	106
	0.0	OORL		

N=3 Cartridges per point

Figure [SEQ Figure * ARABIC]: Stability of Reagents, Signal (RLU)