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Varicella Zoster Virus (VZV) Immunoglobulin G Assay Development Report

Theranos, Inc.

March 23, 2011

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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 Varicella Zoster virus (VZV) in human whole blood, plasma and serum. The assay has a reportable range of 0.05 to 25.0 IU/mL, and is calibrated to the British Working Standard (NIBSC 90/690). The WHO International Standard was not utilized due to its infectious status.

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

The following commercial ELISA kit has been used in house as predicate methods:

- BioQuant Varicella Zoster Virus IgG ELISA (Cat# BQ0816)

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 VZV-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 #
VZV glycoprotein Antigen (Ellen)	Genway	11-511-248136
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 1:25 and a detection antibody concentration of 100 ng/mL in blocking buffer. In addition, the positive and negative controls included in the BioQuant VZV IgG Kit were included for reference.

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

Sample#	Mean RLU	CV%
1	16886	6.8
2	39842	3.5
3	72945	4.8
4	19402	1.6
5	773	9.0
6	13428	10.4
7	5025	16.6
8	22759	5.2
9	11979	13.6
10	5710	8.3
11	10009	1.5
12	35448	3.0
13	22929	20.3
14	7737	6.0
15	15006	1.1
16	20656	0.7
17	6774	27.5
18	18432	22.3
19	29232	3.3
20	13542	12.0
21	10423	11.8
22	16359	14.6
Positive Control	30056	11.6
Negative Control	708	9.5

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

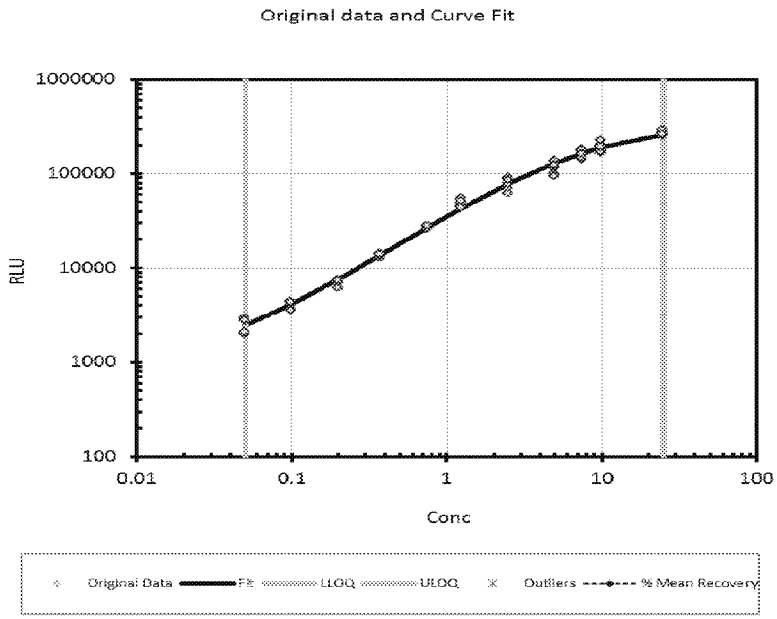
To create a set of calibration standards for the VZV IgG assay, plasma samples containing the highest levels of VZV IgG were pooled and serially diluted into assay buffer.

To assign these standards a quantitative value, a standard curve was created using the British Working Standard for VZV IgG (NIBSC 90/690) in assay buffer and this standard curve was used to calculate the concentrations of the plasma-based standards. The top standard was assigned to 11.0 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 20% of the assigned concentration.

Table [SEQ Table * ARABIC]: Standard Curve: BWS (NIBSC 90/690) in Assay Buffer

[Anti-VZV IgG] IU/mL	Mean RLU	CV %	Back-Calculated Conc., IU/mL		
			Mean Conc	CV %	% Recovery
25.00	270686	5.6	25.79	9.7	103
10.00	190662	12.3	10.34	29.9	103
7.50	165838	10.2	7.61	20.2	101
5.00	115975	14.0	4.24	21.1	85
2.50	77690	13.8	2.47	18.3	99
1.25	48785	9.1	1.43	10.8	114
0.75	27406	3.5	0.77	3.7	102
0.38	13835	3.4	0.37	3.5	100
0.20	7087	7.6	0.18	7.7	92
0.10	4100	11.0	0.10	7.6	100
0.05	2529	17.5	0.06	5.9	125
0.00	1278	29.3	OORL		

Figure [SEQ Figure * ARABIC]: NIBSC 90/690 Standard Curve



Calibration Equation: weighted 4 Parameter logistic:

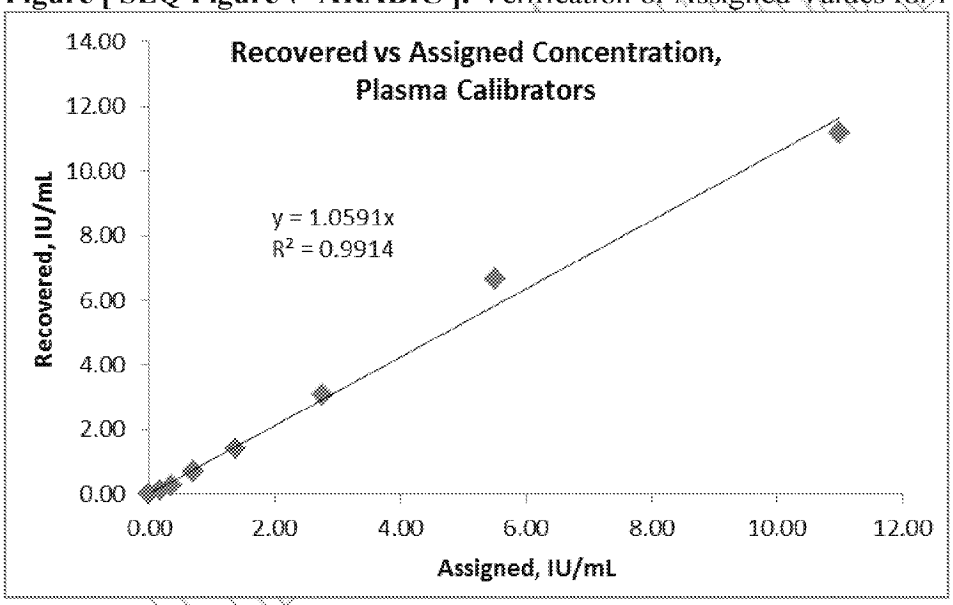
Conc = 7.594 * (((332989.857 - 893.877) / (RLU - 893.877)) - 1) ^ (1 / -1.065)

Signal Min = 2130
Signal Max = 268265

Table [SEQ Table * ARABIC]: Plasma Standards

Level	Dilution Factor	Mean RLU	CV %	Calculated Conc., IU/mL		NIBSC-Assigned Conc. IU/mL	% Recovery
				Mean Conc.	CV %		
1	1.000	200313	4.5	11.19	10.6	11.00	102
2	0.500	154988	7.2	6.67	12.9	5.50	121
3	0.250	92929	6.2	3.09	7.5	2.75	112
4	0.125	48127	9.3	1.41	11.4	1.38	102
5	0.063	24662	6.9	0.69	7.4	0.69	100
6	0.031	10439	13.2	0.28	15.6	0.34	81
7	0.016	5378	10.1	0.14	11.6	0.17	80
8	0.008	1294	20.8	0.00		0	

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



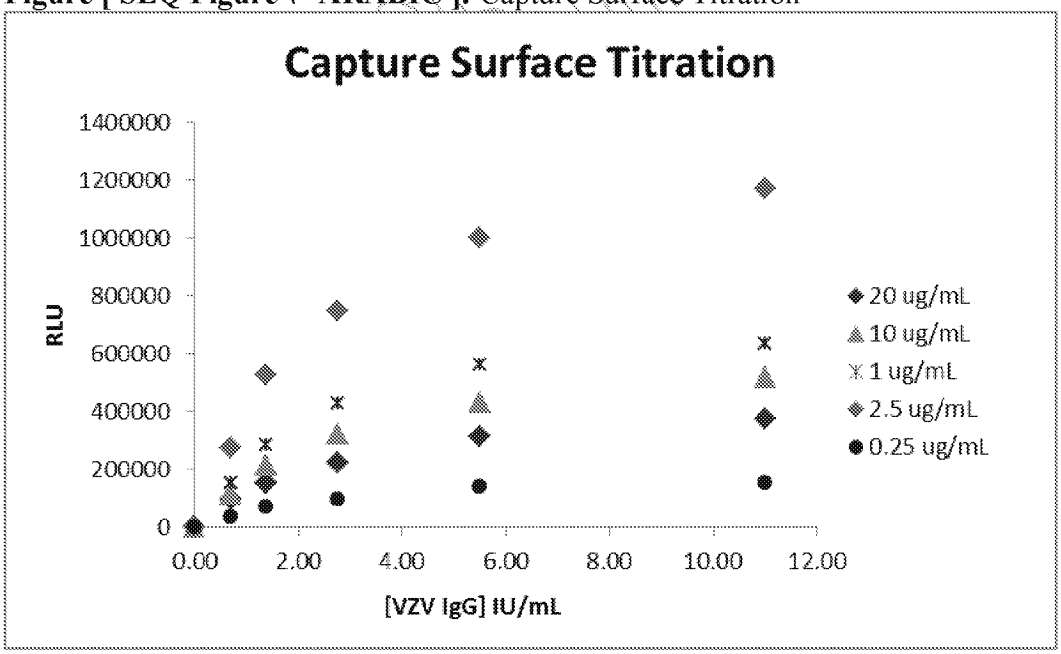
1.4 Capture Surface Titration [TC "Capture Surface Titration on the Theranos System" \f C \l "1"]

Capture surfaces were titrated with 20, 10, 2.5, 1 and 0.25 ug/mL of VZV antigen to optimize the capture surface, with the detection antibody at 100 ng/mL in blocking buffer. Based on signal to background, 2.5 ug /mL was optimal.

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

[VZV IgG] IU/mL	20 ug/mL		10 ug/mL		2.5 ug/mL		1 ug/mL		0.25 ug/mL	
	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %
11.00	375239	1.7	517585	3.9	1172444	8.7	636327	8.0	154427	14.0
5.50	315797	6.4	432566	3.9	1000088	13.9	560015	5.4	142841	12.1
2.75	223486	11.5	325070	9.7	747061	9.8	429499	10.9	96750	18.8
1.38	152376	6.5	214625	11.4	526537	17.4	283790	2.1	69084	14.4
0.69	97320	11.0	115913	5.3	277057	16.6	154384	5.8	36762	20.1
0	394	16.5	821	80.4	587	3.8	552	2.9	982	46.5
S/B	*953*		*631*		*1999*		*1154*		*157*	

Figure [SEQ Figure * ARABIC]: Capture Surface Titration



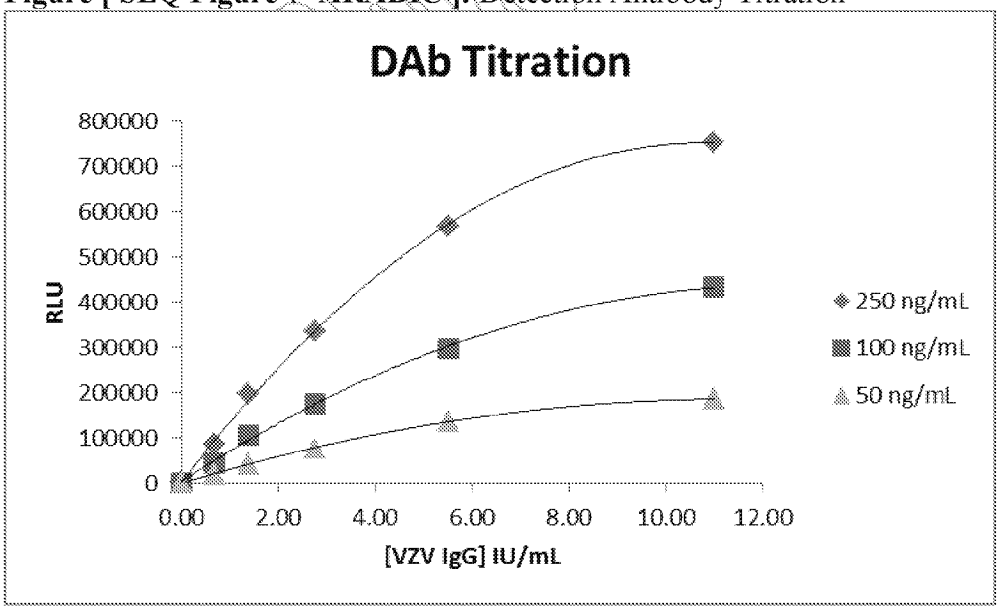
1.5 Detection Antibody Titration [TC "Detection Conjugate Titration on the Theranos System" \f C \l "1"]

The alkaline phosphatase labeled anti-human IgG detection antibody was titrated in a commercial stabilizer, with the capture surface coated at 2.5 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 %**
11.00	753058	4.8	433098	7.0	185652	5.0
5.50	568343	9.7	297405	5.8	135708	4.1
2.75	335874	1.0	176102	4.8	77803	2.7
1.38	196030	9.1	106754	5.4	42901	2.1
0.69	85647	8.3	43824	9.4	19960	0.2
0	1665	14.5	1243	6.0	692	3.0

Figure [SEQ Figure * ARABIC]: Detection Antibody Titration



1.6 Protocol Optimization

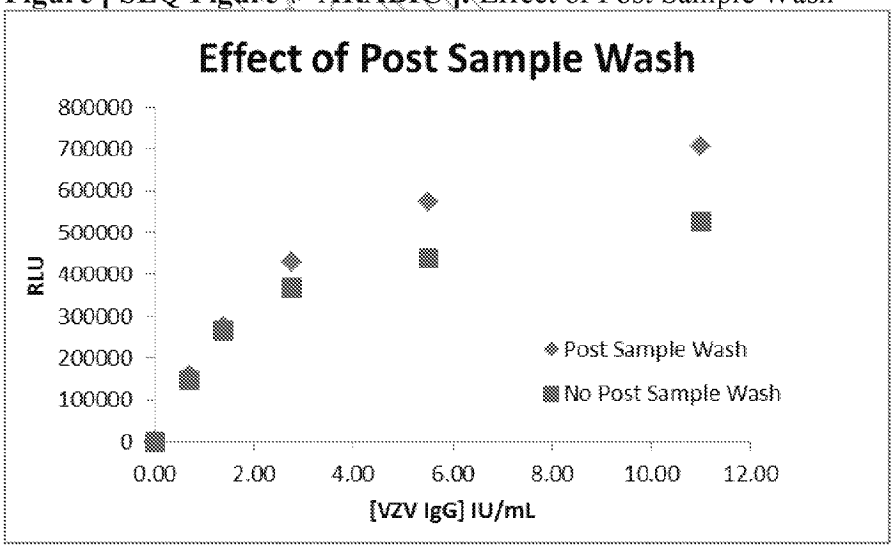
1.6.1 Post Sample Wash

The effect of a post sample wash was tested with the capture surface coated at 2.5 ug/mL VZV 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 increase in signal to background, the assay was optimized with a post sample wash.

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

[VZV IgG] IU/mL	Post Sample Wash		No Post Sample Wash	
	Mean RLU	CV %	Mean RLU	CV %
11.00	705252	6.2	526036	13.8
5.50	573549	2.4	438412	16.1
2.75	429342	10.0	367948	15.9
1.38	274055	8.3	265152	18.2
0.69	159098	4.6	145742	19.8
0	1166	26.2	1256	24.3
S/B	*605*		*419*	

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



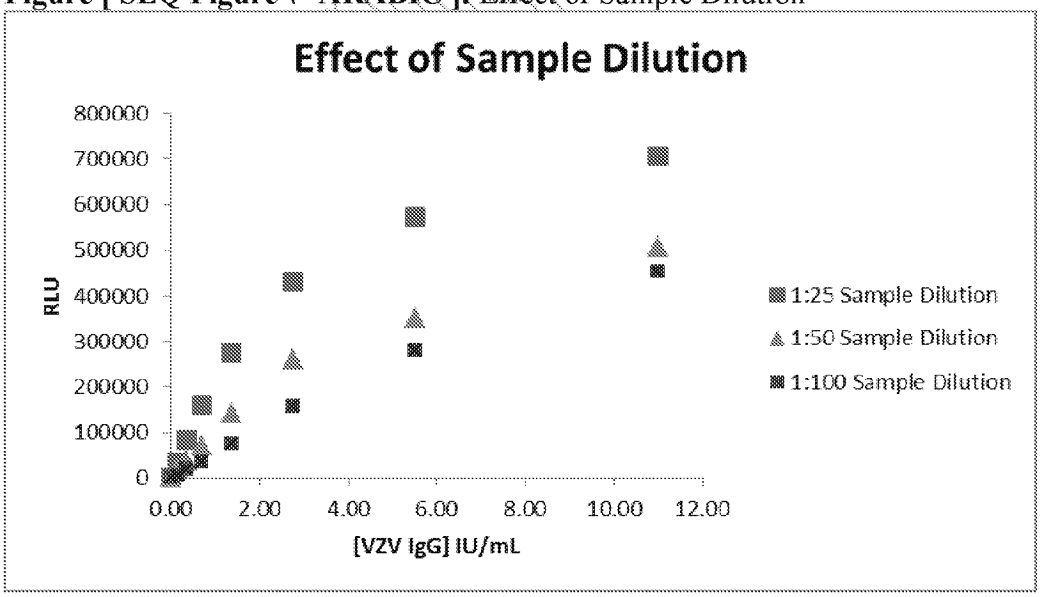
1.6.2 Sample Dilution

Sample dilutions of 1:25, 1:50 and 1:100 were tested with 250 ng/mL DAb in stabilizer. A 1:50 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

[VZV IgG] IU/mL	1:25 Dilution		1:50 Dilution		1:100 Dilution	
	Mean RLU	CV %	Mean RLU	CV %	Mean RLU	CV %
11.00	705252	6.2	506472	13.8	453010	14.7
5.50	573549	2.4	350626	11.3	278841	5.4
2.75	429342	10.0	258431	10.6	157917	3.0
1.38	274055	8.3	142718	4.7	76716	6.5
0.69	159098	4.6	71414	5.1	34932	8.4
0.34	82305	3.6	37522	5.9	18831	3.7
0.17	35690	6.6	19199	7.9	6510	13.4
0	1166	26.2	1096	40.1	786	10.0
S/B	*605*		*462*		*576*	

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 VZV IgG. To determine the hematocrit effect for this assay, plasma was prepared from these blood samples and the recovery of VZV IgG compared to the whole blood result was determined. In plasma, the measured amount of VZV IgG is equivalent to 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

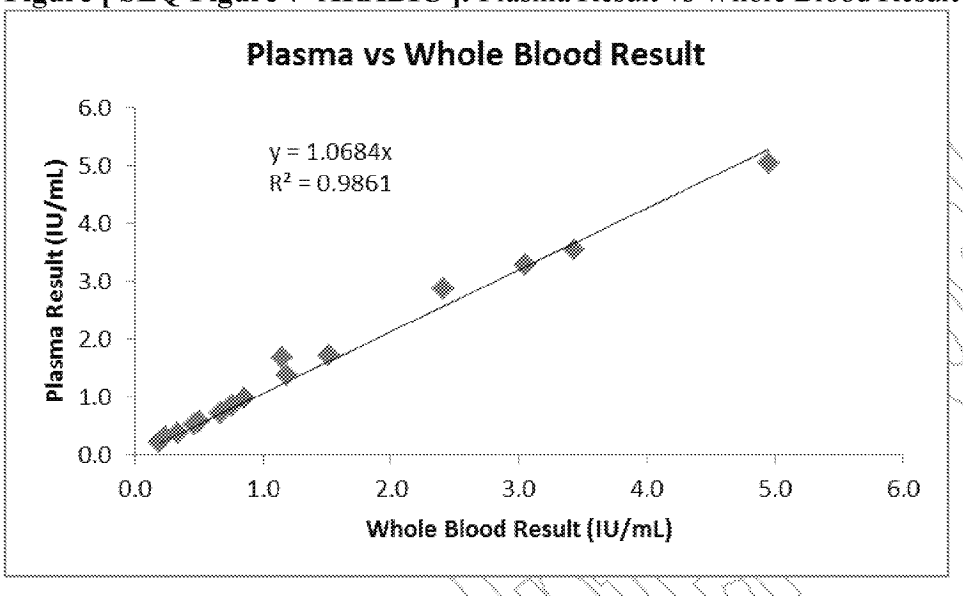
[VZV IgG] IU/mL	Mean RLU	CV %	Back-Calculation Verification, IU/mL		
			Mean Conc.	CV %	% Recovery
11.00	602146	8.5	8.7	16.2	79
5.50	499575	12.6	6.0	28.8	110
2.75	344371	5.6	3.0	8.1	110
1.38	157922	5.7	1.2	5.6	90
0.69	77204	12.2	0.6	10.7	94
0.34	38487	1.6	0.4	1.3	104
0.17	16879	17.8	0.2	14.9	104
0	1039	28.8	OORL	-	-

Conc = 3.556 * (((766018.176 - 1020.400) / (RLU - 1020.400)) - 1) ^ (1 / -1.289)
Signal Min = 12408, Signal Max = 641274

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	58085	11.7	0.5	10.0	67482	10.4	0.6	8.9
2	374917	1.1	3.4	1.6	378739	12.3	3.5	18.8
3	145638	8.8	1.1	8.5	211264	5.1	1.7	5.4
4	339588	20.4	3.1	28.4	378722	2.1	3.5	3.3
5	150854	16.2	1.2	15.9	173160	6.6	1.4	6.7
6	52118	18.7	0.5	15.8	61530	16.6	0.5	14.3
7	80174	18.4	0.7	16.1	88112	8.0	0.7	7.1
8	18263	7.4	0.2	6.3	21160	11.2	0.2	9.4
9	105941	13.4	0.9	12.3	121922	11.4	1.0	10.6
10	287933	11.6	2.4	15.0	331038	2.7	2.9	3.6
11	93119	6.4	0.8	5.7	104962	10.6	0.8	9.6
12	191799	10.6	1.5	10.9	216910	6.7	1.7	7.3
13	462842	4.9	5.0	9.4	466665	5.4	5.0	10.4
14	23111	8.0	0.2	6.8	31435	14.3	0.3	12.0
15	35878	9.6	0.3	8.1	41188	12.6	0.4	10.6

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 VZV IgG. This experiment was performed with the final conditions of DAb at 50 ng/mL in Stabilizer. 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

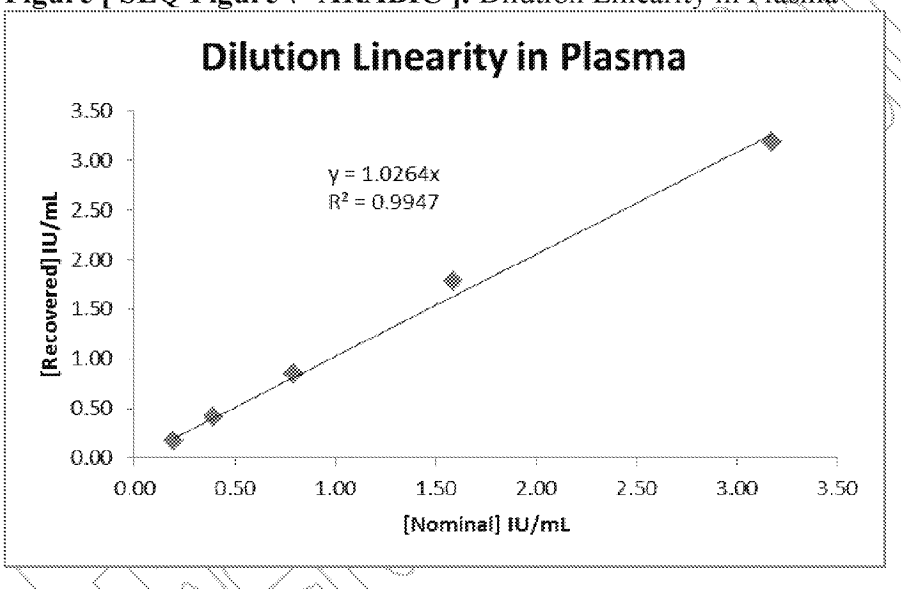
[VZV IgG] IU/mL	Signal, RLU		Back-Calculation Verification, IU/mL		
	Mean RLU	CV %	Mean Conc.	CV %	% Recovery
11.00	184104	14.1	8.24		75
5.50	116616	9.6	4.46	16.6	81
2.75	83183	5.6	2.73	7.0	99
1.38	42306	17.3	1.31	16.7	96
0.69	21616	10.1	0.71	9.0	103
0.34	10280	10.9	0.37	9.6	107
0.17	4396	22.5	0.17	21.3	98
0	1004	18.6	OORL		

Conc = 3.991 * (((218087.520 - 881.141) / (RLU - 881.141)) - 1) ^ (1 / -1.299)
Signal Min= 3542, Signal Max = 178424

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	3.18	93126	4.7	3.18	7.1	100
2	1.59	57254	7.0	1.78	7.5	112
3	0.79	26641	9.3	0.85	8.4	107
4	0.40	11656	19.7	0.41	17.5	103
5	0.20	4668	7.2	0.18	6.8	90
6	0	1204	10.9	OORL		

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 13.8% (range 7.5 – 23.7%) and the average percentage recovery was 100% (range 95-103%). 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)

[VZV 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 %
11.00	186363	9.9	200313	4.6	194296	13.3	193657	9.1
5.50	125562	1.7	154988	7.5	147560	8.9	139809	15.0
2.75	73855	13.3	92929	5.7	82435	6.7	83073	12.5
1.38	41967	13.4	48127	10.3	48380	11.9	46158	12.3
0.69	21124	11.7	24662	7.1	23331	7.2	23039	10.1
0.34	9901	8.4	10439	14.7	11048	4.3	10463	9.9
0.17	5101	9.5	5378	10.2	5008	2.0	5162	7.8
0	909	17.0	1294	4.2	918	10.1	1040	20.4
Positive Control	118195	5.9	106911	8.6	118216	6.5	113971	8.0
Negative Control	1041	29.5	1373	25.3	1230	12.1	1215	23.3

N = 3 cartridges per point

Conc = 5.836 * (((288935.779 - 479.511) / (RLU - 479.511)) - 1) ^ (1 / -1.166)
Signal Min = 4078, Signal Max = 205684

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

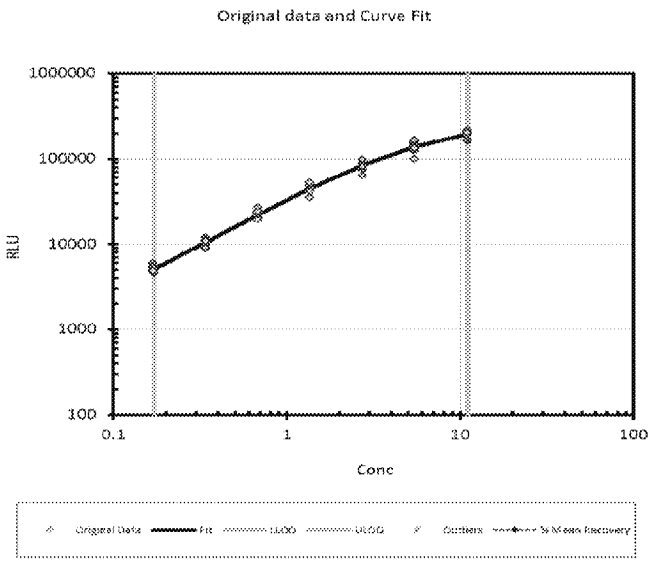


Table [SEQ Table * ARABIC]: Precision and Accuracy for 3 Days/Lots, Concentration (IU/mL)

	Day/Lot 1			Day/Lot 2			Day/Lot 3			Inter-Lot		
[VZV IgG] IU/mL	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	-	-

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 7.2 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	7822	8320	8071	4.4	9471	7.7
2	10674	10861	10767	1.2		
3	9394	11170	10282	12.2		
4	8084	8694	8389	5.1		
5	9174	9475	9325	2.3		
6	8686	8223	8454	3.9		
7	9050	9431	9240	2.9		
8	9882	9932	9907	0.4		
9	9358	8525	8942	6.6		
10	9988	10135	10062	1.0		
11	8443	8343	8393	0.8		
12	9162	9802	9482	4.8		
13	8901	9973	9437	8.0		
14	10799	10046	10422	5.1		
15	10950	10305	10628	4.3		
16	9699	9529	9614	1.3		
17	8838	10104	9471	9.5		
18	9660	7484	8572	18.0		
19	9783	8896	9339	6.7		
20	8878	9711	9295	6.3		
21	9185	9797	9491	4.6		
22	10241	9529	9885	5.1		
23	10159	9873	10016	2.0		
24	10193	9444	9818	5.4		

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	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		

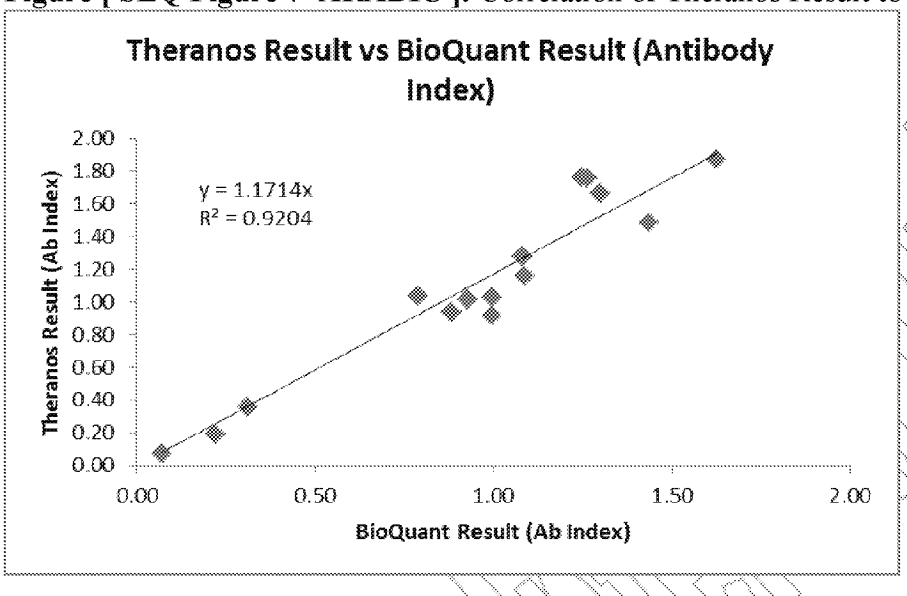
1.11 Clinical Samples – Correlation with Predicate Method

A set of 15 plasma samples were tested on the Theranos System and on 2 commercially available ELISA kits. The 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 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 BioQuant

	BioQuant Result (Antibody Index)		Theranos Result (Antibody index)	
Sample #	**Mean Conc.**	**CV %**	**Mean Conc.**	**CV %**
1	1.09	4.6	1.16	5.6
2	0.93	5.0	1.01	5.5
3	0.22	6.4	0.19	5.2
4	1.00	4.3	1.03	12.1
5	1.63	3.7	1.87	2.8
6	1.30	0.3	1.67	8.8
7	0.31	2.3	0.36	15.0
8	1.26	1.7	1.76	2.4
9	1.00	11.4	0.92	3.7
10	1.44	4.9	1.48	3.2
11	0.79	6.3	1.03	1.9
12	1.25	7.4	1.76	12.9
13	0.88	1.6	0.94	3.3
14	0.07	0.0	0.07	0.0
15	1.08	9.5	1.27	3.6

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	[VZV IgG] IU/mL	Mean RLU	CV %
0	11.00	186363	9.1
	2.75	73855	12.6
	0.69	21124	12.4
	0	909	19.0
4	11.00	183201	17.4
	2.75	96225	10.4
	0.69	19860	16.8
	0	1201	14.7
8	11.00	190306	5.1
	2.75	70648	9.6
	0.69	18788	7.1
	0	1295	32.8

N=3 Cartridges per point

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

Week	[VZV IgG] IU/mL	Mean Conc.	CV %	% Recovery
0	11.00	9.63	20.0	88
	2.75	2.32	16.1	84
	0.69	0.58	12.3	85
	0	OORL		
4	11.00	9.71	39.9	88
	2.75	3.25	15.2	118
	0.69	0.55	18.9	80
	0	OORL		
8	11.00	9.96	13.3	91
	2.75	2.20	9.0	80
	0.69	0.52	2.7	75
	0	OORL		

N=3 Cartridges per point

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