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tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

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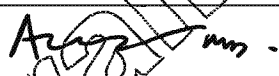
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theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table of Content

LIST OF TABLES 3

LIST OF FIGURES..... 4

1 ASSAY BACKGROUND 5

2 REGULATION AND GUIDANCE..... 5

3 CALIBRATION 6

4 REFERENCE RANGE 13

5 PRECISION..... 16

6 ACCURACY/COMPARABILITY 18

7 DILUTION LINEARITY..... 27

8 BLOOD COLLECTION DEVICE (BCD) COMPARISON..... 30

9 ANTICOAGULANT COMPARISON 33

10 ANALYTICAL SENSITIVITY..... 39

11 INTERFERENCE..... 42

12 CROSS-REACTIVITY..... 43

13 SAMPLE STABILITY..... 44

14 REAGENT STABILITY 45

15 REFERENCES 46

Theranos Internal Only

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

List of Tables

Table 1: Calibration 1 Complete Data (Edison 3.0) 6

Table 2: Calibration 1 Summary Calculated Concentration 7

Table 3: Calibration 2 Complete Data (Edison 3.0) 8

Table 4: Calibration 2 Summary Calculated Concentration 9

Table 5: Calibration 3 All Data (Edison 3.0)..... 10

Table 6: Calibration 3 Summary Calculated Concentration 10

Table 7: Calibration 4 All Data (Edison 3.5)..... 12

Table 8: Calibration 4 Summary Calculated Concentration 12

Table 9: Normal Patient Samples..... 14

Table 10: Reference Range summary 15

Table 11: Precision 16

Table 12: Clinical Sample Predicate Method Correlation Summary..... 18

Table 13: Bias Correction 21

Table 14: Ordinary linear fit CLSI guideline EP09-A2-IR section 5.1 25

Table 15: Comparability CLSI guideline EP09-A2-IR section 7 25

Table 16: Method Comparison Summary..... 26

Table 17: Sample Dilution Linearity..... 26

Table 18: Sample Dilution Linearity Summary..... 27

Table 19: Venous v. Fingerstick All Data..... 28

Table 20: Blood Collection Device Comparison Summary..... 30

Table 21: EDTA Plasma..... 31

Table 22: Li. Heparin Plasma..... 32

Table 23: Serum..... 34

Table 24: EDTA v. Li Heparin v. Serum..... 35

Table 25: 1/2LLLOQ and 1/4LLLOQ Preliminary Testing 37

Table 26: Blank and Lowest Detectable Sensitivity..... 38

Table 27: Interfering Substances 40

Table 28: Cross-reactive Samples 41

Table 29: Sample Stability Summary 42

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

List of Figures

Figure 1: Nominal v. Reported Concentration Calibration 1..... 7

Figure 2: Nominal v. Reported Concentration Calibration 2..... 9

Figure 3: Nominal v Reported Calibration 3 11

Figure 4: Edison 3.5 v Nominal and Edison 3.0 results..... 13

Figure 5: Level 1 % from Mean 16

Figure 6: Level 2 % from Mean 17

Figure 7: Level 3 % from Mean 17

Figure 8: Predicate Method Correlation 22

Figure 9: Predicate Method Correlation: Theranos Corrected 23

Figure 10: Scatter Plot CLSI guideline EP09-A2-IR section 4.2 24

Figure 11: Difference Plot CLSI guideline EP09-A2-IR section 4.2 25

Figure 12: Sample Dilution Linearity 27

Figure 13: EDTA v Li Heparin Plasma 36

Figure 14: EDTA Plasma v. Serum..... 36

Figure 15: 4C Sample Stability..... 42

Figure 16: Room Temperature Sample Stability..... 43

Figure 17: Reagent Stability over 12 Weeks 43

Theranos Internal Only

theranos	tPSA ELISA Assay Report	Document Number: Revision: A
	Validation Document	Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

1 ASSAY BACKGROUND

Prostate-specific antigen (PSA), also known as gamma-seminoprotein or kallikrein-3 (KLK3), is a glycoprotein that in humans is encoded by the KLK3 gene. KLK3 is a member of the kallikrein-related peptidase family secreted by the epithelial cells of the prostate gland. PSA exists in 3 major forms, free PSA, PSA-ACT (PSA bound to Alpha-1 Antichymotrypsin) and PSA-A2M (PSA bound to Alpha-2 Macroglobulin). Most PSA in the blood is bound to serum proteins.

PSA is often elevated in the presence of prostate cancer and in other prostate disorders. A total PSA (tPSA) level less than 4 ng/mL in serum is considered low risk of prostate cancer. When TPSA levels are between 4 and 10 ng/mL, this is called grey zone, and the ratio of free PSA to total PSA should be measured. The lower the ratio the greater is the probability of prostate cancer. Measuring the ratio of free to total PSA appears to be particularly promising for eliminating unnecessary biopsies in men for prostate cancer test.

1.1 Theranos System Specification

This assay is designed to quantitatively determine the level of TPSA in human plasma and serum. The assay has a reportable range of 0.16 to 160 ng/mL and has been calibrated using Siemens Immulite 2000 Third Generation PSA, Cat#L2K3PS2. The ULOQ for the assay is 160 ng/ml and the LLOQ is 0.16 ng/mL. The reference range for the assay is < 4 ng/ml. This assay has no cross-reactivity or interference with kallikreins 2, 4, 5 and 8.

1.2 Reference Assay

Siemens Immulite 2000 Third Generation PSA, Cat#L2K3PS2 has been used in house as predicate method. This method has a working range of 0.085-150 ng/mL. The presence of bilirubin (200mg/L), packed red blood cells (30uL/mL), and triglycerides (5000mg/dL) has no effect on the assay precision.

2 REGULATION AND GUIDANCE

The qualification/validation of the ELISA assays on the Theranos device will be in accordance with C.F.R. Ch IV, § 493.1253 "Standard: Establishment and verification of performance specifications." and outlined in CLSI guideline C28A3.

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

2 CALIBRATION

2.1.1 Acceptance criteria: For each run, a minimum of 75% of the back-calculated mean values of the total number of calibration standards in the calibration range should be within $100 \pm 20\%$ ($100 \pm 25\%$ at LLOQ and ULOQ standards) of their nominal values and a minimum of six unique standard concentrations must be within the assay range.

2.1.2 Unless otherwise stated, each level was tested in replicates of 3.

2.1.3 A point is considered to be “dark count” if it results in less than 150 RLU.

Table 1: Calibration 1 Complete Data (Edison 3.0)

This calibration set was used to calculate the concentrations in the Reference Range (3), Comparability (4), and Analytical Sensitivity (8) experiments.

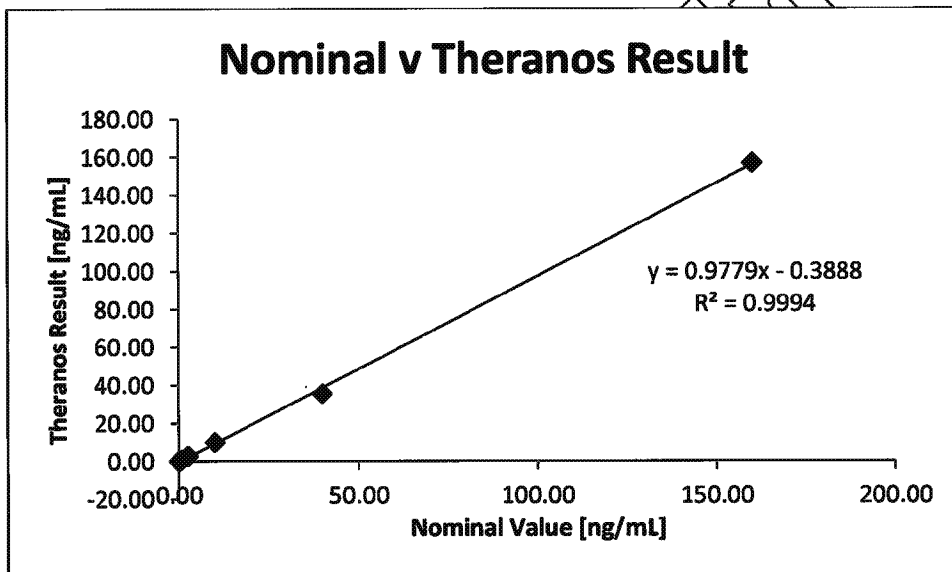
Nominal Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
160.00	512394	513890	512394	513890	513142	0%	467668	11%	OORH	OORH	156.86	23%
	375565	462970	375565	462970	419267	15%			97.65	153.15		
	442706	498484	442706	498484	470595	8%			138.11	183.53		
40.00	146237	192282	146237	192282	169259	19%	202474	18%	23.02	32.97	35.42	26%
	187093	224014	187093	224014	205554	13%			31.75	40.94		
	256256	208965	256256	208965	232610	14%			50.15	37.03		
10.00	79695	67259	79695	67259	73477	12%	70384	13%	11.34	9.43	9.90	14%
	73554	76041	73554	76041	74798	2%			10.38	10.77		
	53911	71842	53911	71842	62876	20%			7.45	10.12		
2.50	20257	18102	20257	18102	19179	8%	19428	11%	2.70	2.40	2.58	12%
	16481	20644	16481	20644	18562	16%			2.17	2.75		
	22534	18549	22534	18549	20542	14%			3.02	2.46		
0.63	4368	5061	4368	5061	4714	10%	5380	16%	0.42	0.52	0.56	23%
	5542	5048	5542	5048	5295	7%			0.59	0.52		
	7009	5250	7009	5250	6129	20%			0.81	0.55		
0.16	2771	4539	2771		2771		2644	14%	0.19		0.17	29%
	2247	2431	2247	2431	2339	6%			OORL	0.14		
	3233	2540	3233	2540	2886	17%			0.25	0.15		
0.04	1497	1328	1497	1328	1413	8%	1617	15%	OORL	OORL	OORL	OORL
	1681	2027	1681	2027	1854	13%			OORL	OORL		
	1458	1708	1458	1708	1583	11%			OORL	OORL		
0.00	1044	888	1044		1044		1733	25%	OORL	OORL	OORL	OORL
	2185	1937	2185	1937	2061	9%			OORL	OORL		
	1682	1819	1682	1819	1751	6%			OORL	OORL		

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 2: Calibration 1 Summary Calculated Concentration

Calibrator Level	Nominal Value [ng/mL]	Theranos Result [ng/mL]	%CV	%Recovery
Calibrator 1	160.00	156.86	23%	98%
Calibrator 2	40.00	35.42	26%	89%
Calibrator 3	10.00	9.90	14%	99%
Calibrator 4	2.50	2.58	12%	103%
Calibrator 5	0.63	0.56	23%	90%
Calibrator 6	0.16	0.17	29%	108%
Calibrator 7	0.04	OORL	OORL	OORL
Calibrator 8	0.00	OORL	OORL	OORL

Figure 1: Nominal v. Reported Concentration Calibration 1



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 3: Calibration 2 Complete Data (Edison 3.0)

This calibration set was used to calculate the concentrations in the Dilution Linearity (5), Blood Collection Device (6), Anticoagulants (7), and Interference (9) experiments.

Nominal Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
160.00	369916	7	369916	DARK	369916		380195	11%	150.68		158.83	13%
	342463	350072	342463	350072	346268	2%			128.72	134.36		
	396733	441790	396733	441790	419262	8%			173.87	OORH		
40.00	192095	209536	192095	209536	200816	6%	179631	11%	49.56	56.27	45.06	16%
	179495	176850	179495	176850	178173	1%			45.02	44.09		
	172014	147796	172014	147796	159905	11%			42.43	34.60		
10.00	41802	45019	41802	45019	43411	5%	49287	15%	8.04	8.70	9.59	16%
	52307	47051	52307	47051	49679	7%			10.23	9.12		
	31910	60257		60257	60257					11.94		
2.50	14512	16385	14512	16385	15449	9%	14814	17%	2.59	2.96	2.65	19%
	10981	12737	10981	12737	11859	10%			1.89	2.23		
	17559	16708	17559	16708	17134	4%			3.19	3.02		
0.63	4014	3396	4014	3396	3705	12%	4231	13%	0.50	0.38	0.54	20%
	4774	4392	4774	4392	4583	6%			0.65	0.58		
	3955	4857	3955	4837	4406	14%			0.49	0.67		
0.16	2225	2802	2225	2802	2514	16%	2259	18%	0.17	0.27	0.17	41%
	1896	2715	1896	2715	2306	25%			0.11	0.26		
	1802	2115	1802	2115	1959	11%			0.10	0.15		
0.04	1615	1402	1615	1402	1509	10%	1412	8%	0.07	0.04	0.04	33%
	1334	1451	1334	1451	1393	6%			0.03	0.05		
	1342	1325	1342	1325	1334	1%			0.04	0.03		
0.00	1453	1276	1453	1276	1365	9%	1271	7%	0.05	OORL	OORL	OORL
	1222	1251	1222	1251	1237	2%			OORL	OORL		
	1208	1214	1208	1214	1211	0%			OORL	OORL		

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

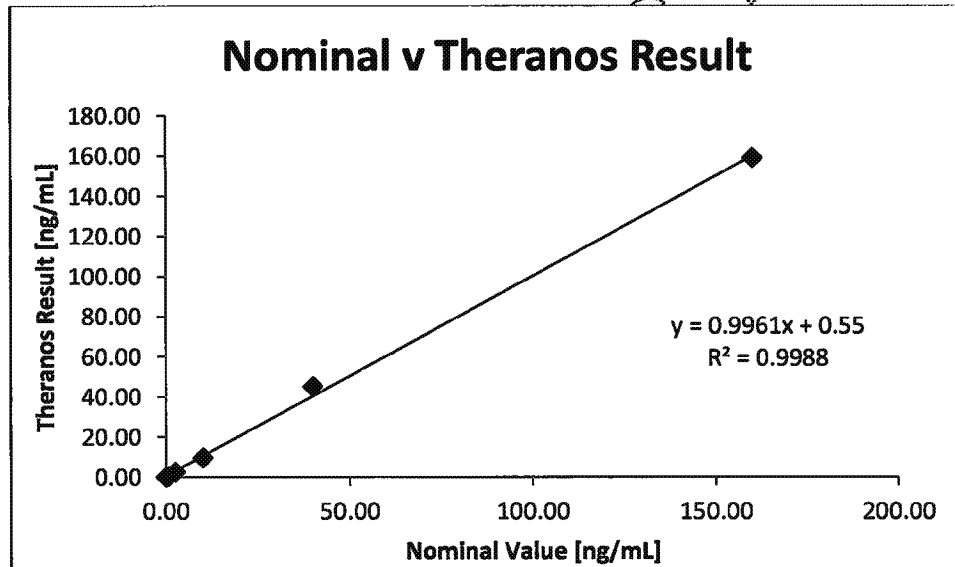
Table 4: Calibration 2 Summary Calculated Concentration

After the exclusion of all “dark count” data points, the %Recovery is within the acceptable range.

Calibrator Level	Nominal Value [ng/mL]	Theranos Result [ng/mL]	%CV	%Recovery
Calibrator 1	160.00	158.83	13%	99%
Calibrator 2	40.00	45.06	16%	113%
Calibrator 3	10.00	9.59	16%	96%
Calibrator 4	2.50	2.65	18%	106%
Calibrator 5	0.63	0.54	20%	87%
Calibrator 6	0.16	0.17	41%	111%
Calibrator 7	0.04	0.04	33%	113%
Calibrator 8	0.00	OORL	OORL	OORL

Figure 2: Nominal v. Reported Concentration Calibration 2

This data shows the dark count excluded mean concentration calculations.



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 5: Calibration 3 All Data (Edison 3.0)

This calibration was used for the Analyte stability experiment.

Calibrator [ng/mL]	RLU Tip 1	RLU Tip 2	Inter AVG	Inter CV	Intra AVG	Intra CV	Dexter Calculated (ng/mL)		
							RLU Tip 1	RLU Tip 2	Intra AVG
160	484934	584627	534781	13%	561805	15%	137.21	OORH	OORH
	665568	646205	655887	2%			OORH	OORH	
	499634	489863	494749	1%			146.73	140.37	
40	194450	205556	200003	4%	195686	51%	30.86	33.26	31.12
	257673	14	128844	141%			45.68	OORL	
	241355	275069	258212	9%			41.57	50.32	
10	73323	78039	75681	4%	78467	14%	9.32	10.02	10.09
	99425	68050	83738	26%			13.33	8.55	
	71652	80310	75981	8%			9.08	10.36	
2.5	20420	22128	21274	6%	16928	51%	2.18	2.39	1.76
	5490	6498	5994	12%			0.45	0.56	
	25357	21674	23516	11%			2.79	2.33	
0.625	4234	3943	4089	5%	6219	28%	0.31	0.28	0.53
	7744	7910	7827	1%			0.70	0.71	
	7369	6113	6741	13%			0.65	0.52	
0.15625	3139	2503	2821	16%	3832	18%	0.20	0.13	0.19
	3760	3429	3595	7%			0.26	0.23	
	2323	3040	2682	19%			OORL	0.19	
0.039	2226	2123	2175	3%	1818	49%	OORL	OORL	OORL
	2009	2275	2142	9%			OORL	OORL	
	2275	2	1139	141%			OORL	OORL	
0	1802	1645	1724	6%	1919	12%	OORL	OORL	OORL
	1917	2281	2099	12%			OORL	OORL	
	1775	2092	1934	12%			OORL	OORL	

Table 6: Calibration 3 Summary Calculated Concentration

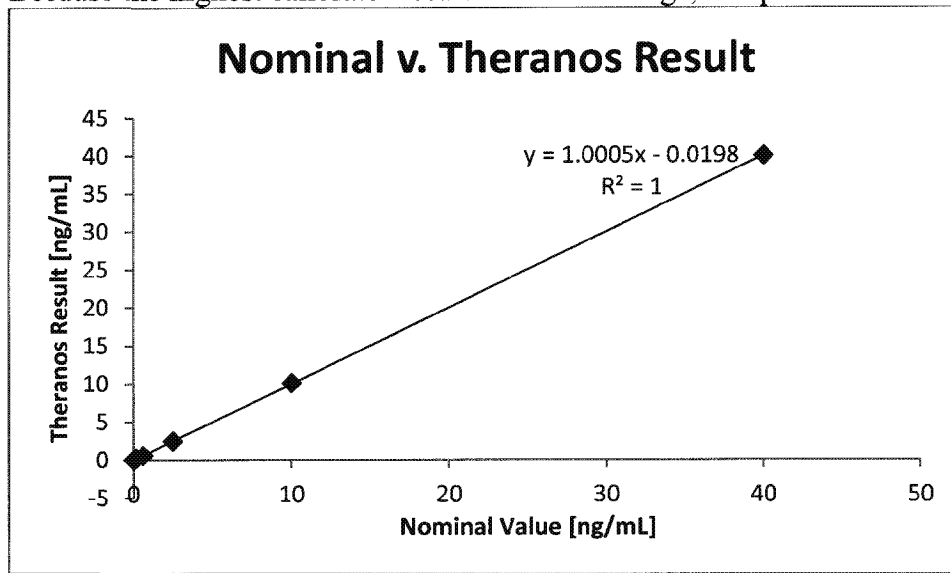
This data excludes dark counts and also the cartridge outlier highlighted in red.

Calibrator [ng/mL]	All Points		Dark Excluded	
	Result (ng/mL)	% Recovery	Result (ng/mL)	% Recovery
160	OORH	OORH	OORH	OORH
40	31.12	78%	39.98	100%
10	10.09	101%	10.09	101%
2.5	1.76	70%	2.42	97%
0.625	0.53	84%	0.53	84%
0.15625	0.19	119%	0.19	119%
0.039	OORL	OORL	OORL	OORL
0	OORL	OORL	OORL	OORL

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 3: Nominal v Reported Calibration 3

Because the highest calibrator result was out of range, this point was excluded from the result.



Theranos Only

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 7: Calibration 4 All Data (Edison 3.5)

This calibration set was used to calculate the concentrations in the Precision experiments.

Nominal Value [ng/mL]	All Points		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	
160.00	455651	499880	455651	499880	477766	7%	507100	9%	125.18	157.00	163.06	12%
	521823	589217	521823	589217	555520	9%			176.33	OORL		
	498738	477293	498738	477293	488016	3%			156.07	139.71		
40.00	261642	217029	261642	217029	239336	13%	232487	8%	45.74	34.83	38.42	11%
	230164	214979	230164	214979	222572	5%			37.87	34.37		
	228055	243050	228055	243050	235553	5%			37.37	40.98		
10.00	77397	94835	77397	94835	86116	14%	84238	10%	9.49	12.09	10.50	11%
	74962	85427	74962	85427	80195	9%			9.14	10.67		
	39422	88569		88569	88569					11.14		
2.50	18258	31559	18258	31559	24909	38%	25709	25%	1.65	3.29	2.56	31%
	21614	3817	21614		21614				2.06			
	33103	24011	33103	24011	28557	23%			3.48	2.35		
0.63	2138	88		DARK			8330	18%			0.49	34%
	6754	9090	6754	9090	7922	21%			0.31	0.58		
	7481	9995	7481	9995	8738	20%			0.39	0.68		
0.16	5216	4870	5216	4870	5043	5%	5532	9%	0.14	OORL	0.17	23%
	6962	5685	6962	5685	5685					0.19		
	6070	5818	6070	5818	5944	3%			0.23	0.21		
0.04	3552	4397	3552	4397	3975	15%	4163	11%	OORL	OORL	OORL	OORL
	4053	4826	4053	4826	4440	12%			OORL	OORL		
	972	3986		3986	3986					OORL		
0.00	4791	4932	4791	4932	4862	2%	4564	9%	OORL	OORL	OORL	OORL
	11	4031	DARK	4031	4031					OORL		
	4856	4210	4856	4210	4533	10%			OORL	OORL		

Table 8: Calibration 4 Summary Calculated Concentration

Calibrator Level	Nominal Value [ng/mL]	Theranos v.3.0 Result [ng/mL]	Theranos v.3.5 Result [ng/mL]	%CV	v.3.0 %Recovery
Calibrator 1	160.00	158.83	163.06	12%	103%
Calibrator 2	40.00	45.06	38.42	11%	85%
Calibrator 3	10.00	9.59	10.50	11%	109%
Calibrator 4	2.50	2.65	2.56	31%	97%
Calibrator 5	0.63	0.54	0.49	34%	90%
Calibrator 6	0.16	0.17	0.17	23%	100%
Calibrator 7	0.04	0.04	OORL	OORL	OORL
Calibrator 8	0.00	OORL	OORL	OORL	OORL


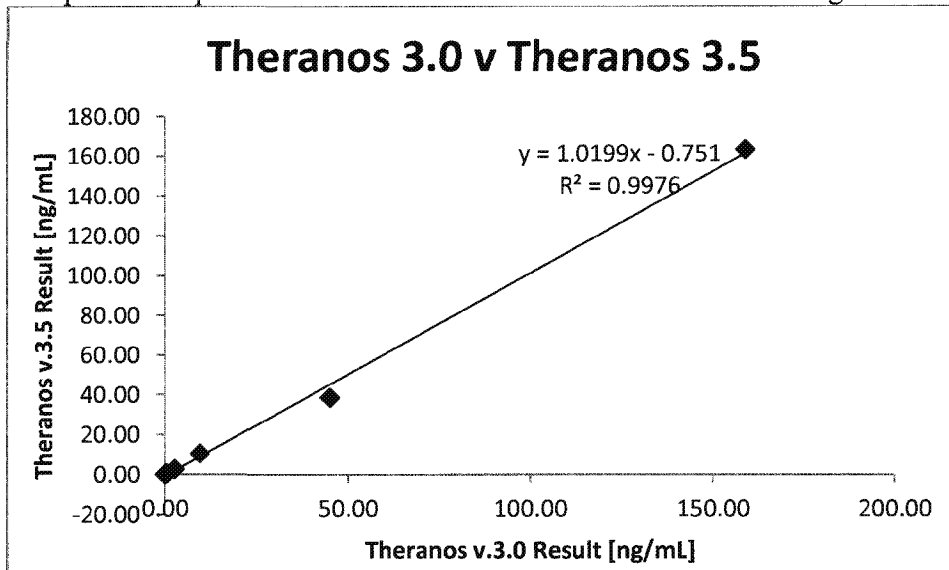
	tPSA ELISA Assay Report	Document Number: Revision: A
	Validation Document	Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 4: Edison 3.5 v Nominal and Edison 3.0 results

Version 3.5 correlates well with the Edison 3.0 Results from calibration 2. Use of the Edison 3.5 is acceptable for precision studies and also further validation testing where necessary.



4 REFERENCE RANGE

To verify the accuracy of the Theranos System, the reference range was tested and compared to the results from the predicate method. According to C.F.R. Ch IV, § 493.1253 “Standard: Establishment and verification of performance specifications” and outlined in CLSI guideline C28A3, laboratories developing test methods need to verify the measuring interval. Additionally, by verifying the measuring interval, clinical laboratories can ensure that the calibration of the measurement procedure is correctly applicable over the range in which they report patient results and that the measuring interval they are obtaining in their laboratory is comparable to the manufacturer’s claims. A measuring interval consists of all numeric values between the lower and upper numeric values for which a method can produce quantitative results suitable for clinical use.

The normal levels of tPSA in adults are less than 4ng/mL and all “normal” donors should have levels within this range.

Calculated concentrations are based on the mean RLU of 3 cartridges where any outliers and dark counts are excluded. All of the “normal” samples tested were within the reference range.

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 9: Normal Patient Samples

Reported Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2	Mean	%CV
0.804	5598	5517	5598	5517	5558	1%	5692	3%	0.60	0.59	0.61	4%
	5910	5741	5910	5741	5825	2%			0.64	0.62		
	5	39	DARK	DARK								
0.648	5675	5036	5675	5036	5355	8%	5276	16%	0.61	0.51	0.55	23%
	4451	5673	4451	5673	5062	17%			0.43	0.61		
	4300	6519	4300	6519	5410	29%			0.41	0.73		
0.56	6667	3519	6667	3519	5093	44%	4755	26%	0.75	0.29	0.47	38%
	4645	2594	4645		4645				0.46	OORL		
	5088	3858	5088	3858	4473	19%			0.52	0.34		
0.945	5356	6595	5356	6595	5975	15%	7728	19%	0.56	0.74	0.91	24%
	7945	8141	7945	8141	8043	2%			0.94	0.97		
	9261	9073	9261	9073	9167	1%			1.13	1.11		
1.09	6251	9090	6251	9090	7670	26%	8517	28%	0.69	1.11	1.03	34%
	2603	9452		9452	9452					1.16		
	11781	6013	11781	6013	8897	46%			1.50	0.66		
0.69	12	10	DARK	DARK			7953	14%			0.94	18%
	6875	7048	6875	7048	6962	2%			0.79	0.81		
	8914	8976	8914	8976	8945	0%			1.08	1.09		
1.1	7695	8111	7695	8111	7903	4%	8283	16%	0.91	0.97	0.99	19%
	9523	9511	9523	9511	9517	0%			1.17	1.17		
	6122	8739	6122	8739	7431	25%			0.67	1.06		
3.07	14944	12087	14944	12087	13315	15%	14020	17%	1.95	1.54	1.82	19%
	12115	11603	12115	11603	11859	3%			1.55	1.47		
	15900	17472	15900	17472	16686	7%			2.09	2.31		
0.919	6479	2394	6479		6479		5434	16%	0.73		0.57	23%
	5998	4756	5998	4756	5377	16%			0.66	0.47		
	4299	5640	4299	5640	4970	19%			0.41	0.60		
0.804	6133	7188	6133	7188	6661	11%	6879	9%	0.68	0.83	0.79	12%
	7587	6342	7587	6342	6965	13%			0.89	0.71		
	93	7145	DARK	7145	7145					0.83		
0.476	6307	6108	6307	6108	6207	2%	5643	14%	0.70	0.67	0.60	19%
	4770	4700	4770	4700	4735	1%			0.47	0.46		
	5456	6517	5456	6517	5986	13%			0.58	0.73		
0.79	6732	6977	6732	6977	6854	3%	7057	9%	0.76	0.80	0.81	11%
	7950	7664	7950	7664	7807	3%			0.94	0.90		
	6577	6441	6577	6441	6509	1%			0.74	0.72		
0.715	6410	6408	6410	6408	6409	0%	7292	13%	0.72	0.72	0.85	16%
	7437	8916	7437	8916	8177	13%			0.87	1.08		
	7105	7474	7105	7474	7290	4%			0.82	0.87		
0.501	7143	6954					4145	5%			0.38	9%
	4081	4475	4081	4475	4278	7%			0.37	0.43		
	3992	4031	3992	4031	4012	1%			0.36	0.37		
0.653	3668	3521	3668	3521	3595	3%	5198	29%	0.31	0.29	0.54	41%
	6574	5	6574	DARK	6574				0.74			

theranos	tPSA ELISA Assay Report					Document Number:		
	Validation Document					Revision: A		
							Effective Date:	
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System								

	5657	6571	5657	6571	6114	11%			0.61	0.74		
0.546	110	4183	DARK	4183	4183		4594	9%		0.39	0.45	14%
	4575	4606	4575	4606	4591	0%			0.45	0.45		
	4302	5305	4302	5305	4803	15%			0.41	0.55		
1.02	7602	7795	7602	7795	7699	2%	8020	10%	0.89	0.92	0.95	12%
	7018	7783	7018	7783	7401	7%			0.81	0.92		
	8611	9313	8611	9313	8962	6%			1.04	1.14		
1.06	10531	9869	10531	9869	10200	5%	9825	6%	1.32	1.22	1.22	7%
	9613	10467	9613	10467	10040	6%			1.19	1.31		
	9529	8941	9529	8941	9235	4%			1.17	1.09		
0.896	7339	8344	7339	8344	7842	9%	8917	15%	0.85	1.00	1.08	18%
	10301	9682	10301	9682	9991	4%			1.29	1.20		
	6	6	DARK	DARK								
0.39	5322	6401	5322	6401	5861	13%	6087	14%	0.56	0.72	0.67	19%
	5213	5532	5213	5532	5372	4%			0.54	0.59		
	7306	6751	7306	6751	7029	6%			0.85	0.77		

Table 10: Reference Range summary

Sample ID	Reported Value [ng/mL]	Theranos Result [ng/mL]	%CV	%Recovery
Patient 1	0.80	0.61	4%	76%
Patient 2	0.65	0.55	23%	85%
Patient 3	0.56	0.47	38%	84%
Patient 4	0.95	0.91	24%	96%
Patient 5	1.09	1.03	34%	94%
Patient 6	0.69	0.94	18%	137%
Patient 7	1.10	0.99	19%	90%
Patient 8	3.07	1.82	19%	59%
Patient 9	0.92	0.57	23%	62%
Patient 10	0.80	0.79	12%	98%
Patient 11	0.48	0.60	19%	127%
Patient 12	0.79	0.81	11%	103%
Patient 13	0.72	0.85	16%	118%
Patient 14	0.50	0.38	9%	76%
Patient 15	0.65	0.54	41%	82%
Patient 16	0.55	0.45	14%	82%
Patient 17	1.02	0.95	12%	94%
Patient 18	1.06	1.22	7%	115%
Patient 19	0.90	1.08	18%	121%
Patient 20	0.39	0.67	19%	172%

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

4 PRECISION

The precision of this assay was tested over 5 days in morning and evening shifts. One run consists of 9 total replicates at each of 3 analyte levels. During each shift 2 runs were performed. The data shows the precision of the assay on the Theranos System.

4.1 The report will include scatter plots, precision summary tables and conclusions about the performance claim(s) regarding within-run (repeatability), between-day, between-lot and within laboratory precision.

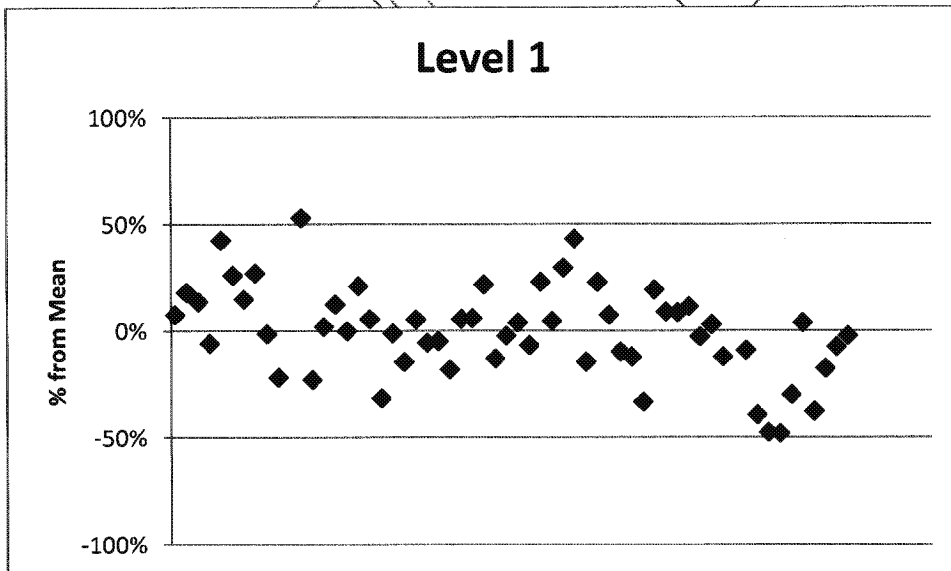
4.2 Acceptance criteria: The %CV of replicates at each concentration of the samples should not be more than 20% (25% at LLOQ and ULOQ) for ELISA assays.

The precision data is summarized in table below. The precision at 1.71 ng/ml and 14.6 ng/ml exceeded the above criteria.

Table 11: Precision

Level (ng/mL)	Precision (%)
1.71	26
7.43	16
14.6	21

Figure 5: Level 1 % from Mean



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 6: Level 2 % from Mean

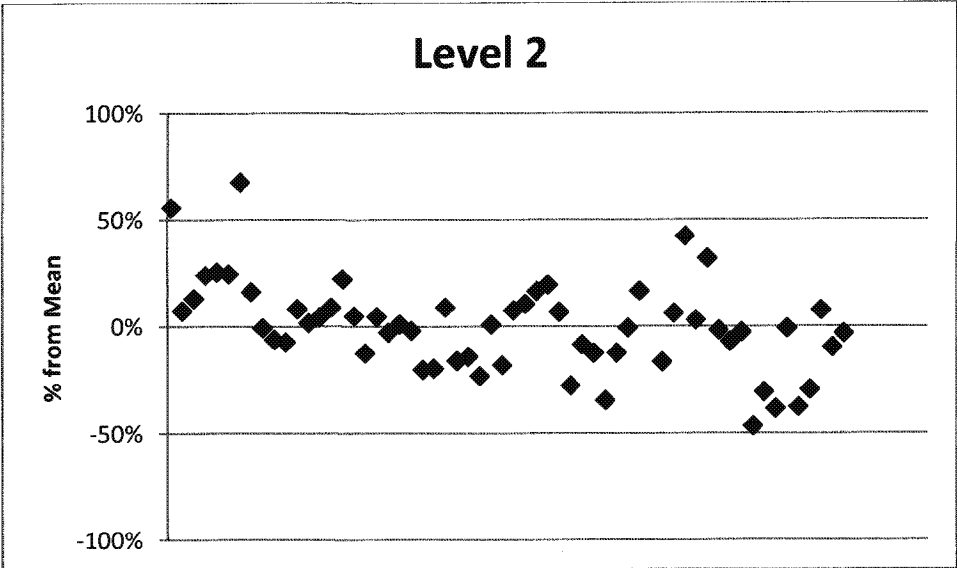
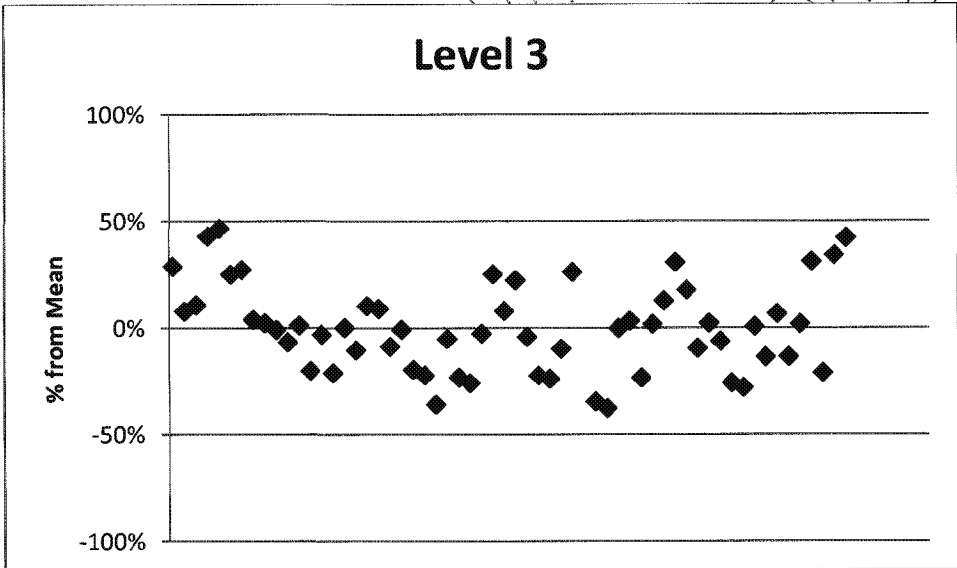


Figure 7: Level 3 % from Mean



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

5 ACCURACY/COMPARABILITY

To test the accuracy of the assay on the Theranos System, 100 unique patient samples were screened on the predicate method (Siemens, Immulite) and tested on the Theranos System. Of these samples 19 were within the reference range (0.395 and 4 ng/ml), 38 were below the reference range, and 43 were higher than the reference range. Based on the results of the data examination, either a simple linear regression or alternative procedures were used to estimate expected (average) bias and the confidence interval of expected bias at the desired medical decision level(s) as per CLSI guidance EP09-A2. StatisPro was used for bias calculations. These estimates were compared with internal criteria to judge the acceptability of the Theranos method. Each sample was run in replicate on the predicate, and the average used for comparison to the Theranos method. Some samples were stored before analysis on both methods. If the confidence interval for the predicted bias includes the defined acceptable bias or if the acceptable bias is greater than the higher limit of the confidence interval of the predicted bias, then the data do not show that the bias of the Theranos method is different from the acceptable bias or there is a high probability (97%) that the predicated bias is acceptable, respectively. The acceptable bias at each medical decision level was determined based on the total allowable error (TEa) minus the measured precision at the level closest to that decision level. Total allowable error (TEa) was taken from CLIA proficiency testing criteria for acceptable analytical performance, as printed in the Federal Register February 28, 1992;57(40):7002-186, when available.

Table 12: Clinical Sample Predicate Method Correlation Summary

Sample ID	CLIA Result (ng/mL)	Theranos (ng/mL)	% Recovery	% Recovery
Patient 1	<0.09	OORL	OORL	OORL
Patient 2	<0.09	OORL	OORL	OORL
Patient 3	<0.09	OORL	OORL	OORL
Patient 4	<0.09	OORL	OORL	OORL
Patient 5	<0.09	OORL	OORL	OORL
Patient 6	<0.09	OORL	OORL	OORL
Patient 7	<0.09	OORL	OORL	OORL
Patient 8	<0.09	OORL	OORL	OORL
Patient 9	<0.09	OORL	OORL	OORL
Patient 10	<0.09	OORL	OORL	OORL
Patient 11	<0.09	OORL	OORL	OORL
Patient 12	<0.09	OORL	OORL	OORL
Patient 13	<0.09	OORL	OORL	OORL
Patient 14	<0.09	OORL	OORL	OORL
Patient 15	<0.09	OORL	OORL	OORL
Patient 16	<0.09	OORL	OORL	OORL
Patient 17	<0.09	OORL	OORL	OORL
Patient 18	<0.09	OORL	OORL	OORL
Patient 19	<0.09	OORL	OORL	OORL
Patient 20	<0.09	OORL	OORL	OORL
Patient 21	<0.09	OORL	OORL	OORL



tPSA ELISA Assay Report

Document Number:

Revision: A

Validation Document

Effective Date:

tPSA ELISA Assay Validation Report on Edison 3.X Theranos System

Patient 22	<0.09	OORL	OORL	OORL
Patient 23	<0.09	OORL	OORL	OORL
Patient 24	<0.09	OORL	OORL	OORL
Patient 25	<0.09	OORL	OORL	OORL
Patient 26	<0.09	OORL	OORL	OORL
Patient 27	<0.09	OORL	OORL	OORL
Patient 28	<0.09	OORL	OORL	OORL
Patient 29	<0.09	OORL	OORL	OORL
Patient 30	<0.09	OORL	OORL	OORL
Patient 31	<0.09	OORL	OORL	OORL
Patient 32	<0.09	OORL	OORL	OORL
Patient 33	<0.09	OORL	OORL	OORL
Patient 34	<0.09	OORL	OORL	OORL
Patient 35	<0.09	OORL	OORL	OORL
Patient 36	<0.09	OORL	OORL	OORL
Patient 37	<0.09	OORL	OORL	OORL
Patient 38	<0.09	OORL	OORL	OORL
Patient 41	0.395	0.42	105%	105%
Patient 42	0.461	0.46	99%	99%
Patient 43	0.417	0.45	108%	108%
Patient 44	0.513	0.64	124%	124%
Patient 45	0.567	0.59	103%	103%
Patient 46	0.712	0.82	115%	115%
Patient 47	1.03	1.34	128%	128%
Patient 48	1.01	1.32	151%	151%
Patient 49	1.05	0.62	59%	59%
Patient 50	0.798	1.01	127%	127%
Patient 51	0.852	1.57	185%	185%
Patient 52	1.03	1.28	124%	124%
Patient 53	0.883	1.21	137%	137%
Patient 54	1.48	1.84	125%	125%
Patient 55	1.4	2.34	167%	167%
Patient 56	1.5	2.64	176%	176%
Patient 57	1.42	2.04	144%	144%
Patient 58	1.37	4.47	326%	326%
Patient 59	2.34	1.83	78%	78%
Patient 61	9.08	9.56	105%	105%
Patient 62	9.84	9.23	94%	94%
Patient 63	8.01	6.89	86%	86%
Patient 64	8.69	7.30	84%	84%
Patient 65	6.93	6.64	96%	96%
Patient 66	11.3	13.26	117%	117%
Patient 67	11.8	15.07	128%	128%
Patient 68	10.4	10.98	106%	106%
Patient 69	10.1	9.33	92%	92%
Patient 70	15.5	20.85	134%	134%
Patient 71	16.7	16.21	97%	97%

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

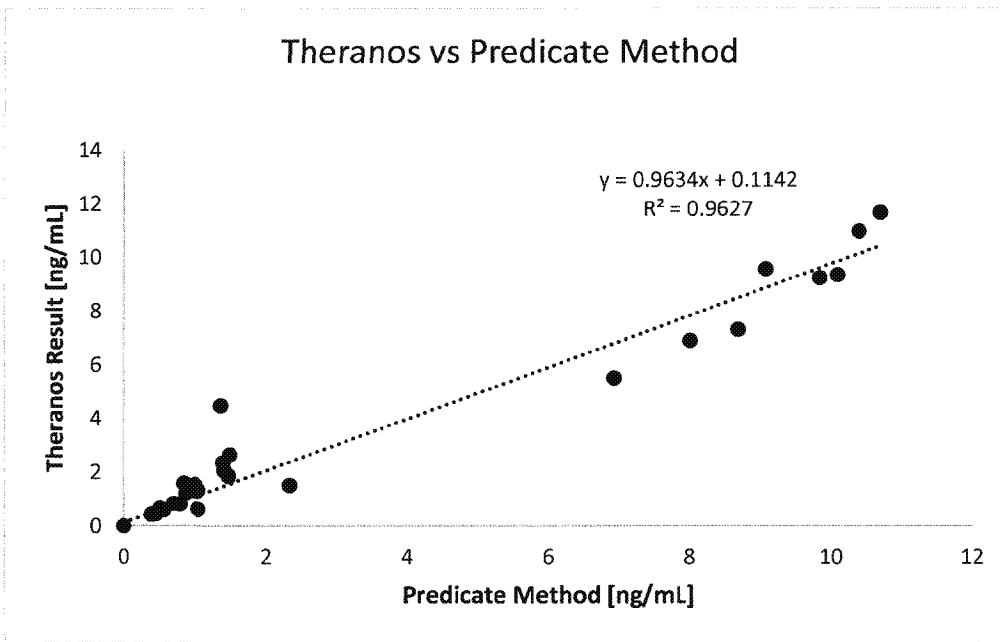
Patient 72	22.9	22.50	98%	98%
Patient 73	14.2	15.04	106%	106%
Patient 74	21.5	18.81	87%	87%
Patient 75	10.7	11.67	109%	109%
Patient 76	19.2	21.02	109%	109%
Patient 77	19.4	19.70	102%	102%
Patient 78	24.6	27.28	111%	111%
Patient 79	16.1	18.21	113%	113%
Patient 80	22.9	27.39	120%	120%
Patient 81	22.8	26.78	117%	117%
Patient 82	26.5	26.45	100%	100%
Patient 83	22.7	20.71	91%	91%
Patient 84	16.6	18.48	111%	111%
Patient 85	26	32.34	124%	124%
Patient 86	22.6	37.44	166%	166%
Patient 87	33.1	41.10	124%	124%
Patient 88	28.2	24.22	86%	86%
Patient 89	19.1	22.75	119%	119%
Patient 90	32.5	38.52	119%	119%
Patient 91	39.3	46.99	120%	120%
Patient 92	65.9	82.70	125%	125%
Patient 93	96.3	116.23	121%	121%
Patient 94	86.3	87.47	101%	101%
Patient 95	92.4	111.79	121%	121%
Patient 96	80	128.16	160%	160%
Patient 97	88	87.82	100%	100%
Patient 98	82.5	109.55	133%	133%
Patient 99	75.6	84.83	112%	112%
Patient 100	85.7	96.39	112%	112%
Patient 39	>150	OORH	OORH	OORH
Patient 39 Retest	>150	OORH	OORH	OORH
Patient 40	9.44	7.75	82%	82%
Patient 40 Retest	9.44	10.85	115%	115%
Patient 60	>150	OORH	OORH	OORH
Patient 60 Retest	>150	OORH	OORH	OORH

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

0	0	0	-0.118538509
0	0	0	-0.118538509
0	0	0	-0.118538509
0	0	0	-0.118538509
0	0	0	-0.118538509
0	0	0	-0.118538509
0	0	0	-0.118538509
0.395	0.42	0.395	0.301461491
0.461	0.46	0.461	0.341461491
0.417	0.45	0.417	0.331461491
0.513	0.64	0.513	0.521461491
0.567	0.59	0.567	0.471461491
0.712	0.82	0.712	0.701461491
1.05	1.34	1.05	1.221461491
1.01	1.52	1.01	1.401461491
1.05	0.62	1.05	0.501461491
0.798	0.81	0.798	0.691461491
0.852	1.57	0.852	1.451461491
1.03	1.28	1.03	1.161461491
0.883	1.21	0.883	1.091461491
1.48	1.84	1.48	1.721461491
1.4	2.34	1.4	2.221461491
1.5	2.64	1.5	2.521461491
1.42	2.04	1.42	1.921461491
1.37	4.47	1.37	4.351461491
2.34	1.5	2.34	1.381461491
9.08	9.56	9.08	9.441461491
9.84	9.23	9.84	9.111461491
8.01	6.89	8.01	6.771461491
8.69	7.3	8.69	7.181461491
6.93	5.5	6.93	5.381461491
10.4	10.98	10.4	10.86146149
10.1	9.33	10.1	9.211461491
10.7	11.67	10.7	11.55146149

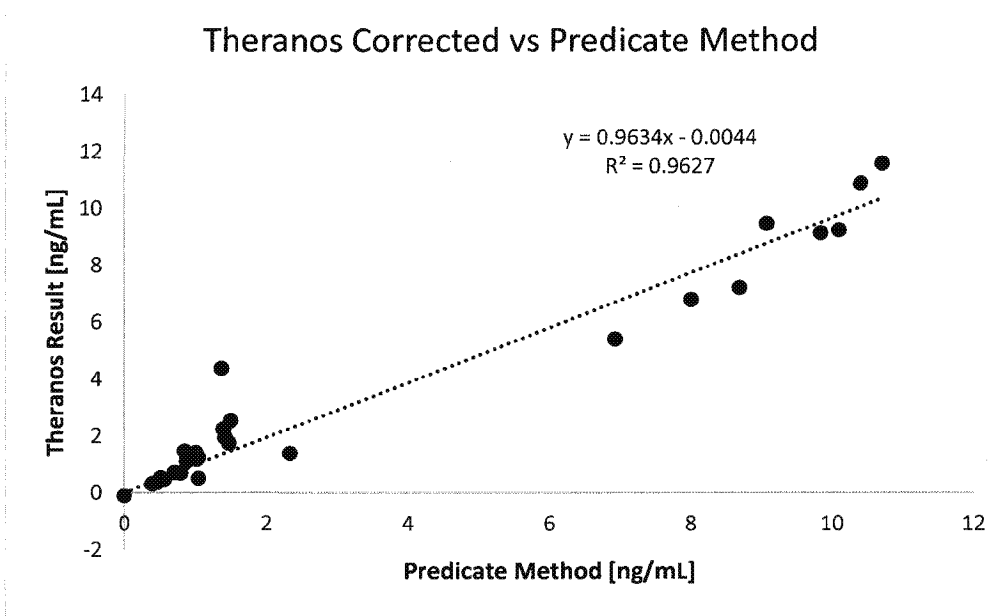
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	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 8: Predicate Method Correlation



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 9: Predicate Method Correlation: Theranos Corrected

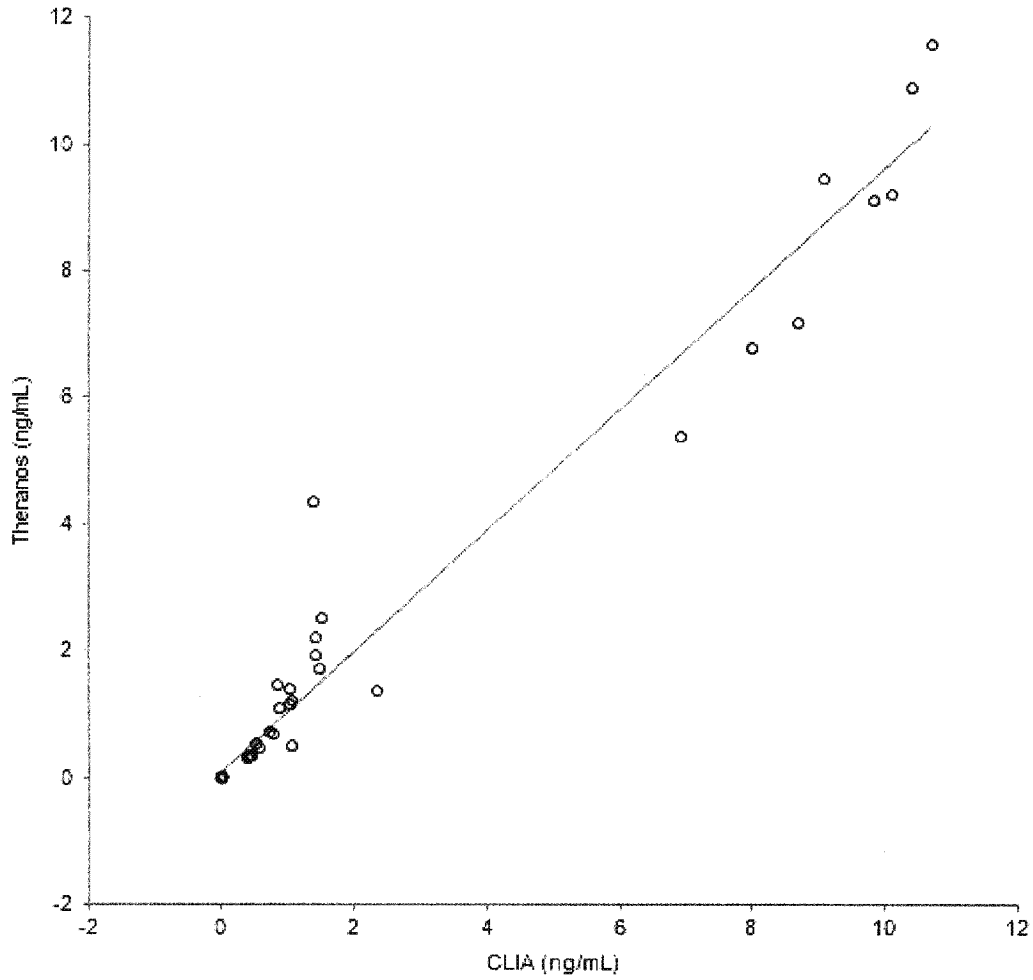


theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 10: Scatter Plot CLSI guideline EP09-A2-IR section 4.2

Scatter plot

CLSI guideline EP09-A2-IR section 4.2




	tPSA ELISA Assay Report	Document Number: Revision: A
	Validation Document	Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 11: Difference Plot CLSI guideline EP09-A2-IR section 4.2

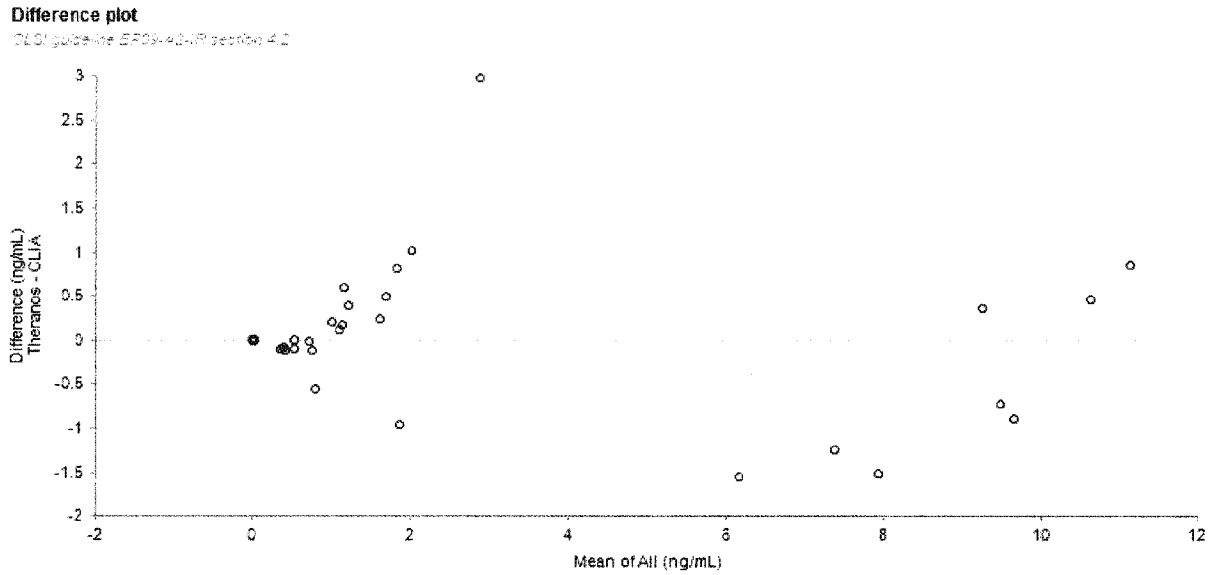


Table 14: Ordinary linear fit CLSI guideline EP09-A2-IR section 5.1

Ordinary linear fit

CLSI guideline EP09-A2-IR section 5.1

	n	65		
Parameter	Estimate	SE	95% CI	
Constant (intercept)	0.080770858	0.077566420	-0.074233279 to 0.23577	
Proportional (slope)	0.952	0.0234	0.906 to 0.999	
Sy.x	0.564222454			

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 15: Comparability CLSI guideline EP09-A2-IR section 7

Comparability

CLSI guideline EP09-A2-IR section 7

Level ID	Value	Difference	SE	95% CI	Allowable difference
1	4.00000000	-0.10971261	0.092227080	0.294013733 to 0.07458	0.160000000
2	11.30000000	-0.45734495	0.241118488	0.339181801 to 0.02449	0.565000000
3	23.00000000	-1.01450910	0.509112749	0.331889756 to 0.00287	1.150000000

Difference is less than allowable bias: 4% upto 7.43ng/mL then 5%.

Table 16: Method Comparison Summary

Level(ng/mL)	Precision (%)	Total Error (%)	Allowable Bias (%)
4	26	30	4
11.3	16	20	4
23	21	26	5

7 DILUTION LINEARITY

A serial dilution of a high patient sample with a low patient sample was performed to test dilution linearity. The nominal values were calculated from the reported value of the highest patient sample. Each dilution level was tested on the Theranos System and compared to the nominal concentrations. For each dilution level, the recovery should be within 100 ± 20% (100 ± 25% at LLOQ and ULOQ standards) of their nominal value, and when plotted, the R² value should be greater than 0.95. Calculated concentrations are based on the average RLU of 3 cartridges excluding outliers and dark count tips. When comparing the nominal values to the Theranos results, the linearity is acceptable.

Table 17: Sample Dilution Linearity

Nominal Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
69.7	414892	385326	414892	385326	400109	5%	426939	10%	63.66	56.40	66.81	18%	96%
	409118	428015	409118	428015	418567	3%			62.19	67.10			
	497345	8	497345	DARK	497345				88.07				
34.85	240472	343556	240472	343556	292014	25%	301112	12%	28.66	47.21	38.94	16%	112%
	292669	293106	292669	293106	292888	0%			37.41	37.49			
	323469	313398	323469	313398	318434	2%			43.18	41.24			
17.43	194902	166930	194902	166930	180916	11%	183747	10%	21.91	18.11	20.36	13%	117%
	184175	162493	184175	162493	173334	9%			20.42	17.53			
	179917	214062	179917	214062	196990	12%			19.84	24.66			

theranos	tPSA ELISA Assay Report		Document Number:	
	Validation Document		Revision: A	
			Effective Date:	
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System				

8.71	129078	7	129078	DARK	129078		115086	10%	13.35		11.70	11%	134%
	117165	120081	117165	120081	118623	2%			11.94	12.28			
	100178	108929	100178	108929	104554	6%			9.98	10.98			
4.36	60902	70092	60902	70092	65497	10%	60284	10%	5.72	6.69	5.66	12%	130%
	52197	63667	52197	63667	57932	14%			4.82	6.01			
	55343	59503	55343	59503	57423	5%			5.15	5.58			
2.18	33825	12	33825	DARK	33825		35677	11%	2.98		3.16	12%	145%
	29961	38853	29961	38853	34407	18%			2.60	3.48			
	35925	39820	35925	39820	37873	7%			3.19	3.58			
<0.09	2766	2858	2766	2858	2812	2%	2828	10%	OORL	0.03	OORL	OORL	OORL
	3070	3184	3070	3184	3127	3%			0.05	0.06			
	2647	2445	2647	2445	2546	6%			OORL	OORL			

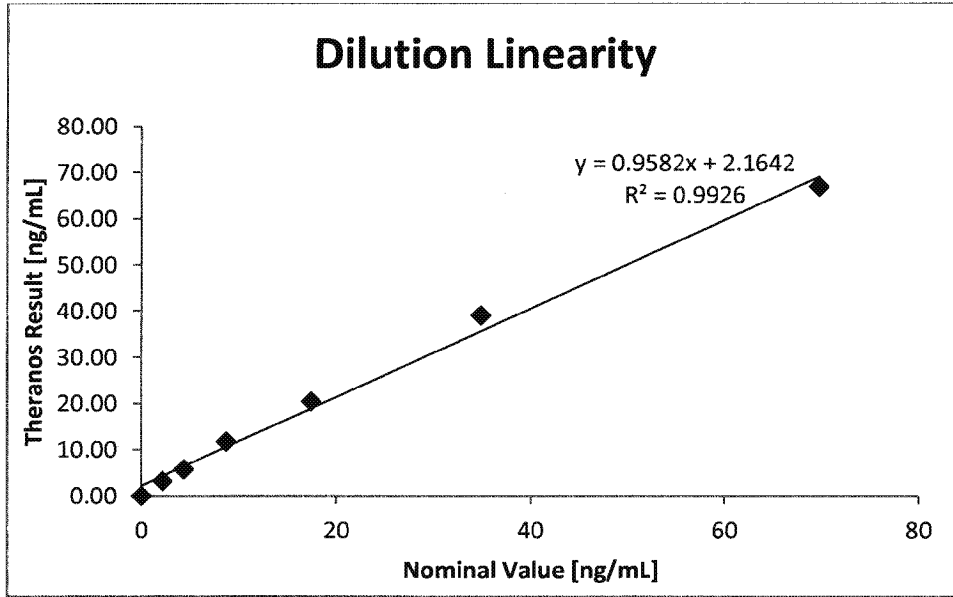
Table 18: Sample Dilution Linearity Summary

Dark tips were excluded as well as the low RLUs reported in the high calibrator level. Overall, the dilution linearity samples had an average recovery of 122%.

Sample ID	Nominal Value [ng/mL]	Theranos Result [ng/mL]	%CV	%Recovery
High Patient Sample	69.7	66.81	18%	96%
1/2	34.85	38.94	16%	112%
1/4	17.43	20.36	13%	117%
1/8	8.71	11.70	11%	134%
1/16	4.36	5.66	12%	130%
1/32	2.18	3.16	12%	145%
Low Patient Sample	<0.09	OORL	OORL	OORL

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 12: Sample Dilution Linearity



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theranos	tPSA ELISA Assay Report		Document Number:	
	Validation Document		Revision: A	
			Effective Date:	
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System				

Venous Tube 1	5322	6401	5322	6401	5861	13%	5076	20%	0.76	0.98	0.71	29%	-113%
Venous Tube 2	4539	4042	4539	4042	4291	8%			0.61	0.51			
Fingerstick 1	2218	2152	2218	2152	2185	2%	3136	41%	0.17	0.16	0.33	73%	
Fingerstick 2	2581	2553	2581	2553	2567	1%			0.23	0.23			
Fingerstick 3	5405	3905	5405	3905	4655	23%			0.78	0.48			

Table 20: Blood Collection Device Comparison Summary

Sample ID	Sample Type	Theranos Results [ng/mL]	% CV	% Difference
Patient 1	Venous Tube 1	1.12	33%	-38%
	Fingerstick 1	0.82	18%	
Patient 2	Venous Tube 1	0.92	20%	-46%
	Fingerstick 1	0.63	20%	
Patient 3	Venous Tube 1	0.80	10%	-60%
	Fingerstick 1	0.50	26%	
Patient 4	Venous Tube 1	1.23	36%	-35%
	Fingerstick 1	0.91	31%	
Patient 5	Venous Tube 1	1.28	23%	-21%
	Fingerstick 1	1.06	21%	
Patient 6	Venous Tube 1	1.34	23%	-49%
	Fingerstick 1	0.90	11%	
Patient 7	Venous Tube 1	1.14	15%	-8%
	Fingerstick 1	1.06	19%	
Patient 8	Venous Tube 1	2.51	15%	0%
	Fingerstick 1	2.52	15%	
Patient 9	Venous Tube 1	0.95	24%	11%
	Fingerstick 1	1.07	21%	
Patient 10	Venous Tube 1	1.01	10%	-10%
	Fingerstick 1	0.92	19%	
Patient 11	Venous Tube 1	0.85	13%	-85%
	Fingerstick 1	0.46	11%	
Patient 12	Venous Tube 1	1.24	16%	-2%
	Fingerstick 1	1.22	22%	
Patient 13	Venous Tube 1	0.91	9%	-13%
	Fingerstick 1	0.80	12%	
Patient 14	Venous Tube 1	0.82	40%	-21%
	Fingerstick 1	0.68	20%	
Patient 15	Venous Tube 1	0.81	56%	11%
	Fingerstick 1	0.91	6%	
Patient 16	Venous Tube 1	0.79	27%	-5%
	Fingerstick 1	0.76	17%	
Patient 17	Venous Tube 1	1.18	8%	-14%
	Fingerstick 1	1.04	18%	
Patient 18	Venous Tube 1	1.00	1%	-11%
	Fingerstick 1	0.90	16%	
Patient 19	Venous Tube 1	1.02	29%	-7%
	Fingerstick 1	0.95	23%	
Patient 20	Venous Tube 1	0.71	29%	-113%
	Fingerstick 1	0.33	73%	

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

8 ANTICOAGULANT COMPARISON

To test the effect of anticoagulants, 20 unique patients donated a total of 3 tubes, one EDTA, one Li Heparin, and one Serum. Each sample was spiked with 10ng/mL of tPSA

Table 21: EDTA Plasma

Nominal Value 10ng/mL Spiked	All Data		Dark Excluded		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery
	Tip 1	Tip 2	Tip 1	Tip 2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
10	18645	43476		43476	43476		50383	20%	8.38		9.82	22%	98%
	45828	39857	45828	39857	42843	10%			8.87	7.64			
	62739	60017	62739	60017	61378	3%			12.48	11.89			
10.878	60727	85765	60727	85765	73246	24%	63442	23%	12.04	17.76	12.64	26%	116%
	69003	49880	69003	49880	59442	23%			13.87	9.72			
	51834	89844	51834		51834				10.13				
11.91	53082	71421	53082	71421	62252	21%	58402	15%	10.39	14.42	11.54	16%	97%
	60169	56179	60169	56179	58174	5%			11.92	11.06			
	46467	63093	46467	63093	54780	21%			9.00	12.56			
10	38812	33915	38812	33915	36363	10%	45763	18%	7.43	6.43	8.86	19%	89%
	54984	53502	54984	53502	54243	2%			10.80	10.48			
	48286	45076	48286	45076	46681	5%			9.38	8.71			
16.06	23	77384	DARK	77384	77384		67373	17%		15.78	13.51	19%	84%
	53582	56526	53582	56526	55054	4%			10.50	11.13			
	73144	76230	73144	76230	74687	3%			14.81	15.52			
10	4972	50674		50674	50674		51676	11%		9.88	10.10	12%	101%
	54890	42163	54890	42163	48527	19%			10.78	8.11			
	57057	53597	57057	53597	55327	4%			11.24	10.50			
10.779	47680	50762	47680	50762	49221	4%	52670	10%	9.26	9.90	10.31	11%	96%
	58806	48549	58806	48549	53678	14%			11.62	9.44			
	74201	57554		57554	57554					11.35			
11.41	53178	45511	53178	45511	49344	11%	55103	11%	10.41	8.80	10.83	12%	95%
	54148	60278	54148	60278	57213	8%			10.62	11.94			
	62146	55358	62146	55358	58752	8%			12.35	10.88			
10.746	61259	70971	61259	70971	66115	10%	54488	19%	12.16	14.32	10.69	21%	100%
	49401	48692	49401	48692	49046	1%			9.62	9.47			
	42467	54137	42467	54137	48302	17%			8.17	10.62			
11.18			DARK	DARK			56833	24%			11.20	27%	100%
	72097	8	72097	DARK	72097				14.57				
	53495	44905	53495	44905	49200	12%			10.48	8.68			
11.42	65989	66863	65989	66863	66426	1%	58577	19%	13.20	13.39	11.57	20%	101%
	48653	41188	48653	41188	44921	12%			9.46	7.91			
	66569	62198	66569	62198	64384	5%			13.33	12.36			
12.94	54861	49759	54861	49759	52310	7%	57822	12%	10.77	9.69	11.41	13%	88%
	55365	58820	55365	58820	57092	4%			10.88	11.63			
	69806	58323	69806	58323	64065	13%			14.05	11.52			
10	36234	47207	36234	47207	41721	19%	49559	16%	6.90	9.16	9.65	18%	96%
	45453	56123	45453	56123	50788	15%			8.79	11.04			
	56941	55394	56941	55394	56168	2%			11.22	10.89			

theranos	tPSA ELISA Assay Report					Document Number:			
	Validation Document					Revision: A			
					Effective Date:				
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System									

10	2	37	DARK	DARK			50601	3%	9.78	9.57	9.87	4%	99%
	50174	49168	50174	49168	49671	1%			10.26				
11.73	52461	26	52461	DARK	52461		64037	14%	13.04		12.77	16%	109%
	65267	46638	65267		65267				16.08	12.45			
	58629	55051	58629	55051	56840	4%			11.58	10.81			
10	58762	2	58762	DARK	58762		47308	16%	11.61	7.06	9.18	18%	92%
	47937	36998	47937	36998	42468	18%			9.31	8.74			
	47657	45188	47657	45188	46422	4%			9.25	8.74			
10	55748	65004	55748	65004	60376	11%	53733	12%	10.96	12.98	10.53	13%	105%
	51735	52999	51735	52999	52367	2%			10.11	10.38			
	47162	49749	47162	49749	48455	4%			9.15	9.69			
11.13	53414	67227	53414	67227	60320	16%	61341	17%	10.46	13.47	12.17	19%	109%
	48294	58201	48294	58201	53247	13%			9.38	11.49			
	63988	76926	63988	76926	70457	13%			12.76	15.68			
10.984	46801	45254	46801	45254	46028	2%	54807	21%	9.07	8.75	10.76	23%	98%
	61677	72190	61677	72190	66934	11%			12.25	14.59			
	42806	60116	42806	60116	51461	24%			8.24	11.91			
15.39	51699	64338	51699	64338	58019	15%	70773	18%	10.10	12.83	14.27	20%	93%
	84563	77722	84563	77722	81143	6%			17.47	15.86			
	64947	81370	64947	81370	73159	16%			12.97	16.72			

Table 22: Li. Heparin Plasma

Nominal Value	All Data		Dark Excluded		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery
	Tip 1	Tip 2	Tip 1	Tip 2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
10	35866	41704	35866	41704	38785	11%	46503	19%	6.83	8.02	9.01	20%	90%
	50708	39408	50708	39408	45058	18%			9.89	7.55			
	56065	55264	56065	55264	55665	1%			11.03	10.86			
10.878	44807	47027	44807	47027	45917	3%	48997	12%	8.66	9.12	9.53	13%	88%
	46389	57677	46389	57677	52078	15%			8.99	11.40			
	33362	31204											
11.91	60122	57127	60122	57127	58625	4%	55152	15%	11.91	11.26	10.84	17%	91%
	47427	44683	47427	44683	46055	4%			9.20	8.63			
	67970	53584	67970	53584	60777	17%			13.64	10.50			
10	53856	53196	53856	53196	53526	1%	52200	5%	10.56	10.42	10.21	6%	102%
	51753	5	51753	DARK	51753				10.11				
	47472	54722	47472	54722	51097	10%			9.21	10.74			
16.06	87915	140850					62879	5%	11.91	11.26	12.51	6%	78%
	60709	85453	60709		60709				12.04				
	66794	61134	66794	61134	63964	6%			13.38	12.13			
10	55964	55022	55964	55022	55493	1%	54634	8%	11.01	10.81	10.72	9%	107%
	50274	56207	50274	56207	53240	8%			9.80	11.06			
	48761	61574	48761	61574	55168	16%			9.48	12.23			
10.779	28	26	DARK	DARK			46154	20%	9.20	6.98	8.94	22%	83%
	47399	36616	47399	36616	42007	18%			8.13	11.52			
	42248	58353	42248	58353	50301	23%							
11.41	45317	54942	45317	54942	50129	14%	49406	11%	8.76	10.79	9.62	12%	84%

theranos	tPSA ELISA Assay Report					Document Number:								
	Validation Document					Revision: A								
										Effective Date:				
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System														

	46354	43111	46354	43111	44733	5%			8.98	8.31				
	49272	57442	49272	57442	53357	11%			9.59	11.33				
10.746	17883	46541		46541	46541		56179	12%		9.02	11.06	14%	103%	
	65191	58256	65191	58256	61724	8%			13.02	11.50				
	58209	52697	58209	52697	55453	7%			11.49	10.31				
11.18	49041	68266	49041	68266	58654	23%	52269	17%	9.54	13.71	10.22	19%	91%	
	38238	49443		49443	49443				9.62	9.62				
	46121	48473	46121	48473	47297	4%			8.93	9.42				
11.42	50562	49308	50562	49308	49935	2%	51880	10%	9.86	9.60	10.14	10%	89%	
	57909	58204	57909	58204	58057	0%			11.43	11.49				
	46441	48855	46441	48855	47648	4%			9.09	9.50				
12.94	77406	2	77406	DARK	77406		68032	13%	15.79		13.65	15%	106%	
	75172	54875	75172	54875	65023	22%			15.27	10.78				
	65463	67245	65463	67245	66354	2%			13.08	13.48				
10	44465	43842	44465	43842	44153	1%	43929	7%	8.59	8.46	8.48	7%	85%	
	48067	46239	48067	46239	47153	3%			9.34	8.95				
	40477	40485	40477	40485	40481	0%			7.77	7.77				
10	37122	37917	37122	37917	37520	1%	41292	13%	7.08	7.24	7.93	14%	79%	
	2	38	DARK	DARK										
	40931	49199	40931	49199	45065	13%			7.86	9.57				
11.73	33274	42974	33274	42974	38124	18%	41279	14%	6.31	8.28	7.93	15%	68%	
	39080	48652	39080	48652	43866	15%			7.48	9.46				
	70445	42415		42415	42415				8.16					
10	13833	45082		45082	45082		47292	6%		8.71	9.17	6%	92%	
	44832	48101	44832	48101	46466	5%			8.66	9.34				
	46738	51709	46738	51709	49224	7%			9.06	10.10				
10	40069	44127	40069	44127	42098	7%	43603	13%	7.68	8.52	8.41	14%	84%	
	52735	37302	52735	37302	45019	24%			10.32	7.12				
	39988	47397	39988	47397	43692	12%			7.67	9.20				
11.13	46201	49644	46201	49644	47922	5%	49924	12%	8.95	9.67	9.73	13%	87%	
	60391	53216	60391	53216	56804	9%			11.97	10.42				
	43070	47023	43070	47023	45046	6%			8.30	9.12				
10.984	44041	47949	44041	47949	45995	6%	45152	7%	8.50	9.31	8.73	8%	79%	
	45228	49656	45228	49656	47442	7%			8.74	9.67				
	40500	43535	40500	43535	42017	5%			7.77	8.39				
15.39	61875	66644	61875	66644	64260	5%	61598	8%	12.29	13.34	12.23	9%	79%	
	67188	54467	67188	54467	60828	15%			13.47	10.69				
	59757	59657	59757	59657	59707	0%			11.83	11.81				

tPSA ELISA Assay Validation Report on Edison 3.X Theranos System

Table 23: Serum

Nominal Value	All Data		Dark Excluded		Inter-Cartridge		Intra-Cartridge		Concentration				%Recovery	
	Tip 1	Tip 2	Tip 1	Tip 2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV		
10ng/mL Spiked	89520	63104		63104	63104									
10	69800	75712	69800	75712	72756	6%	70120	10%	14.05	15.40	14.12	11%	141%	
	63665	78318	63665	78318	70991	15%			12.68	16.00				
10.878	65230	75378	65230	75378	70304	10%			13.03	15.32				
	45101	14		DARK			72273	9%			14.61	10%	134%	
	69361	79122	69361	79122	74242	9%			13.95	16.19				
11.91	79768	86735	79768	86735	83251	6%			16.34	17.99				
	79767	81891	79767	81891	80829	2%	80927	7%	16.34	16.84	16.61	8%	139%	
	86683	70720	86683	70720	78702	14%			17.98	14.26				
10	82753	66984	82753	66984	74869	15%			17.04	13.42				
	68244	79361	68244	79361	73802	11%	68516	16%	13.70	16.24	13.76	18%	138%	
	55525	58230	55525	58230	56877	3%			10.92	11.50				
16.06	92099	89342	92099	89342	90720	2%			19.29	18.62				
	66256	80598	66256	80598	73427	14%	85300	13%	13.26	16.53	17.65	15%	110%	
	83814	99692	83814	99692	91753	12%			17.29	21.18				
10	63968	61439	63968	61439	62703	3%			12.75	12.20				
	56949	65299	56949	65299	61124	10%	63828	8%	11.22	13.05	12.72	9%	127%	
	18813	71484		71484	71484					14.43				
10.779	78490	71618	78490	71618	75054	6%			18.04	14.46				
	2	26	DARK	DARK			75292	7%			15.30	8%	142%	
	70041	81020	70041	81020	75531	10%			14.11	16.63				
11.41	57950	79172	57950	79172	68561	22%			11.44	16.20				
	119396	70478		70478	70478		68972	11%		14.20	13.87	12%	122%	
	67978	69285	67978	69285	68631	1%			13.64	13.94				
10.746	73829	84169	73829	84169	78999	9%			14.97	17.38				
	69304	46085	69304		69304		74182	9%	13.94		15.05	11%	140%	
	69427	6	69427	DARK	69427				13.97					
11.18	83973	87707	83973	87707	85840	3%			17.33	18.22				
	107991	114399					75753	16%			15.41	18%	138%	
	65211	66120	65211	66120	65666	1%			13.03	13.23				
11.42	61658	68240	61658	68240	64949	7%			12.24	13.70				
	78501	72631	78501	72631	75566	5%	75715	13%	16.04	14.69	15.40	15%	135%	
	84264	88995	84264	88995	86629	4%			17.40	18.54				
12.94	89878	76624	89878	76624	83251	11%			18.75	15.61				
	55766	43862					84602	9%			17.48	11%	135%	
	92829	79078	92829	79078	85953	11%			19.47	16.18				
10	40398	45012	40398	45012	42705	8%			7.75	8.70				
	65378	72617	65378	72617	68997	7%	51960	32%	13.06	14.69	10.16	35%	102%	
	28824	59534	28824	59534	44179	49%			5.41	11.78				
10	65977	18729	65977		65977				13.20					
	10410	64526		64526	64526		61969	6%		12.87	12.31	7%	123%	
	58627	58745	58627	58745	58686	0%			11.58	11.61				
11.73	5	7	DARK	DARK										
	63111	58577	63111	58577	60844	5%	66099	14%	12.56	11.57	13.22	16%	113%	
	76608	39899	76608		76608				15.61					
10	50296	75730	50296	75730	63013	29%			9.80	15.40				
	65756	69351	65756	69351	67553	4%	60891	18%	13.15	13.95	12.08	20%	121%	
	51286	52926	51286	52926	52106	2%			10.01	10.36				
10	54157	54475	54157	54475	54316	0%			10.62	10.69				
	62211	72882	62211	72882	67546	11%	66448	18%	12.36	14.75	13.30	20%	133%	
	83868	71094	83868	71094	77481	12%			17.31	14.34				
11.13	93068	87495	93068	87495	90281	4%	77319	18%	19.53	18.17	15.77	20%	142%	

theranos	tPSA ELISA Assay Report		Document Number:	
	Validation Document		Revision: A	
			Effective Date:	
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System				

	75453	85752	75453	85752	80603	9%			15.34	17.76			
	63830	58317	63830	58317	61073	6%			12.72	11.52			
10.984	50083	60092	50083	60092	55087	13%	57447	11%	9.76	11.90	11.33	12%	103%
	53876	56520	53876	56520	55198	3%			10.56	11.13			
	66664	2	66664	DARK	66664				13.35				
15.39	71079	62596	71079	62596	66838	9%	75346	14%	14.34	12.45	15.31	16%	100%
	110486	93002											
	82501	85210	82501	85210	83855	2%			16.98	17.63			

Table 24: EDTA v. Li Heparin v. Serum

Because analyte was spiked into each sample, the % Recovery compared to the nominal value for EDTA was used to compare anticoagulant types. The average recoveries were within 20% of nominal indicating that all three matrices performed equivalently in the Theranos TPSA assay.

Sample ID	EDTA Nominal Value (10ng/mL + endogenous)	Theranos Result [ng/mL]					
		EDTA Plasma	% Recovery	Li Heparin Plasma	% Recovery	Serum	% Recovery
Patient 1	10.000	9.823	98%	9.010	90%	14.124	141%
Patient 2	10.878	12.635	116%	9.531	88%	14.611	134%
Patient 3	11.910	11.535	97%	10.836	91%	16.611	139%
Patient 4	10.000	8.856	89%	10.207	102%	13.763	138%
Patient 5	16.060	13.507	84%	12.511	78%	17.647	110%
Patient 6	10.000	10.096	101%	10.725	107%	12.720	127%
Patient 7	10.779	10.306	96%	8.937	83%	15.302	142%
Patient 8	11.410	10.825	95%	9.617	84%	13.865	122%
Patient 9	10.746	10.693	100%	11.056	103%	15.047	140%
Patient 10	11.180	11.196	100%	10.221	91%	15.408	138%
Patient 11	11.420	11.573	101%	10.139	89%	15.399	135%
Patient 12	12.940	11.410	88%	13.655	106%	17.481	135%
Patient 13	10.000	9.649	96%	8.476	85%	10.156	102%
Patient 14	10.000	9.869	99%	7.933	79%	12.312	123%
Patient 15	11.730	12.767	109%	7.930	68%	13.223	113%
Patient 16	10.000	9.178	92%	9.174	92%	12.076	121%
Patient 17	10.000	10.532	105%	8.408	84%	13.301	133%
Patient 18	11.130	12.174	109%	9.726	87%	15.770	142%
Patient 19	10.984	10.762	98%	8.729	79%	11.329	103%
Patient 20	15.390	14.271	93%	12.231	79%	15.314	100%


	tPSA ELISA Assay Report	Document Number: Revision: A
	Validation Document	Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Figure 13: EDTA v Li Heparin Plasma

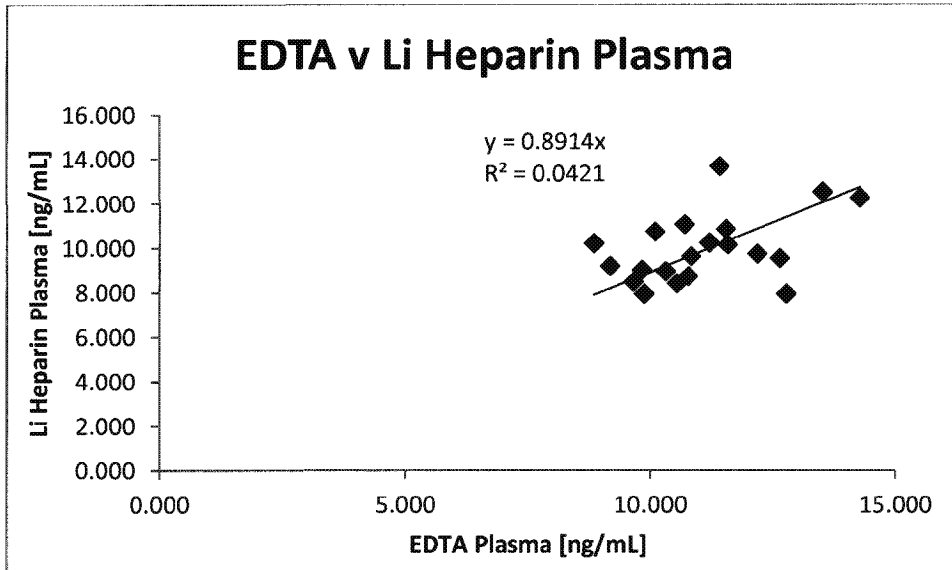
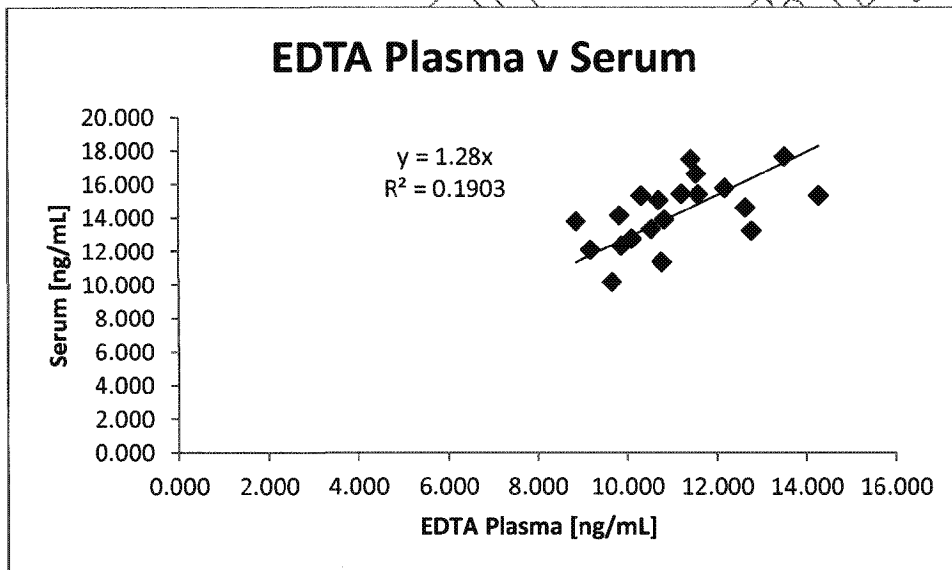


Figure 14: EDTA Plasma v. Serum



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

9 ANALYTICAL SENSITIVITY

To test the analytical sensitivity, 60 replicates of a blank sample and 60 replicates of the lowest detectable LLOQ dilution were tested. To determine the lowest detectable dilution level, 20 replicates of (a low positive sample or calibrator) were tested. This sample was then diluted 1:1 with buffer and 20 replicates of the 1/2xLLOQ sample were tested. The mean RLU was below the LLOQ so the LLOQ was used to test the analytical Sensitivity.

Table 25: 1/2LLOQ and 1/4LLOQ Preliminary Testing

1/4 LLOQ					
RLUs		Calculated From		Calculated	
Mean	%CV	Mean		Mean	%CV
2420	13%	0.14		0.16	23%
All Tips		Inter-Cartridge		Conc. (ng/mL)	
Tip1	Tip2	Mean	%CV	Tip 1	Tip 2
9	10				
3066	2878	2972	4%	0.23	0.20
13	10				
2390	2861	2625	13%	0.13	0.20
2524	2643	2584	3%	0.15	0.17
2345	2591	2468	7%	0.13	0.16
2269	2259	2264	0%	OORL	OORL
2436	2140	2288	9%	0.14	OORL
1921	2216	2069	10%	OORL	OORL
2153	2293	2223	4%	OORL	OORL
2554	2431	2492	4%	0.16	0.14
2767	2682	2724	2%	0.19	0.17
2508	2	2508		0.15	
28	23				
2572	2869	2720	8%	0.16	0.20
9	8				
2387	2046	2216	11%	0.13	OORL
1888	1915	1902	1%	OORL	OORL
2821	2520	2671	8%	0.19	0.15
2309	1760	2034	19%	OORL	OORL

1/8 LLOQ					
RLUs		Calculated From		Calculated	
Mean	%CV	Mean		Mean	%CV
2260	16%	OORL		0.16	15%
All Tips		Inter-Cartridge		Conc. (ng/mL)	
Tip1	Tip2	Mean	%CV	Tip 1	Tip 2
2458	2561	2509	3%	0.14	0.16
2232	2366	2299	4%	OORL	0.13
2131	2003	2067	4%	OORL	OORL
2416	2714	2565	8%	0.14	0.18
1845	1908	1877	2%	OORL	OORL
2603	2729	2666	3%	0.16	0.18
2255	2254	2254	0%	OORL	OORL
2234	2305	2270	2%	OORL	OORL
2704	2969	2837	7%	0.18	0.21
6	6				
2	1				
1954	2134	2044	6%	OORL	OORL
4	3				
25	26				
2048	2127	2087	3%	OORL	OORL
2439	2722	2581	8%	0.14	0.18
2008	1996	2002	0%	OORL	OORL
5	4				
1141	2053	1597		OORL	OORL
16	16				

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

Table 26: Blank and Lowest Detectable Sensitivity

After exclusion of dark count tips, 82 of the 112 tips reported OORL for the blank sample. The Theranos test will report a result in a blank sample 27% of the time. At the LLOQ 79 of the 100 tips are within the assay range and are reportable. The Theranos test will report OORL in 21% of samples at the LLOQ.

Blank					
RLUs		Calculated From Mean	Calculated		
Mean	%CV		Mean	%CV	
2098	13%	OORL	0.14	13%	
All Tips		Inter-Cartridge		Conc. (ng/mL)	
Tip1	Tip2	Mean	%CV	Tip 1	Tip 2
2342	2333	2337	0%	0.13	0.13
2099	2367	2233	8%	OORL	0.13
2892	2019	2455	25%	0.20	OORL
1927	1920	1924	0%	OORL	OORL
1855	2061	1958	7%	OORL	OORL
1963	2084	2024	4%	OORL	OORL
2340	2511	2426	5%	0.13	0.13
1741	3	1741		OORL	
2018	2222	2120	7%	OORL	OORL
1851	2331	2091	16%	OORL	0.13
1955	2108	2032	5%	OORL	OORL
2009	2011	2010	0%	OORL	OORL
2691	2632	2662	2%	0.18	0.17
2167	1706	1936	17%	OORL	OORL
1694	1958	1826	10%	OORL	OORL
2363	1980	2177	12%	0.13	OORL
2465	2328	2396	4%	0.14	0.13
2116	2414	2265	9%	OORL	0.14
2529	2398	2464	4%	0.15	0.14
1825	1910	1868	3%	OORL	OORL
2271	1896	2083	13%	OORL	OORL
2049	1993	2021	2%	OORL	OORL
2354	2487	2420	4%	0.13	0.15
1931	1988	1960	2%	OORL	OORL
10	13				
1929	2044	1986	4%	OORL	OORL
2067	2124	2096	2%	OORL	OORL
1936	1607	1771	13%	OORL	OORL
2264	2122	2193	5%	OORL	OORL
2331	1977	2154	12%	0.13	OORL
1706	1941	1824	9%	OORL	OORL
2074	2267	2171	6%	OORL	OORL
2441	2328	2385	3%	0.14	0.13
1227	1592	1410	18%	OORL	OORL

LLOQ					
RLUs		Calculated From Mean	Calculated		
Mean	%CV		Mean	%CV	
2920	24%	0.21	0.24	31%	
All Tips		Inter-Cartridge		Conc. (ng/mL)	
Tip1	Tip2	Mean	%CV	Tip 1	Tip 2
2667	2450	2509	3%	0.16	0.14
3978	3988	3979	0%	0.36	0.36
3372	3584	3478	4%	0.27	0.30
3979	4	3979		0.36	
3760	3692	3726	1%	0.33	0.32
1151	3300	2225	68%	OORL	0.26
3787	2551	3169	28%	0.33	0.16
3307	3344	3326	1%	0.26	0.27
2748	3201	2974	11%	0.18	0.25
3578	3018	3298	12%	0.30	0.22
2657	2268	2463	11%	0.17	OORL
2904	2960	2932	1%	0.20	0.21
2295	2352	2323	2%	OORL	0.13
2566	2348	2457	6%	0.16	0.13
2444	2930	2687	13%	0.14	0.21
2065	1974	2020	3%	OORL	OORL
47	33				
1443	2154	1799	28%	OORL	OORL
1741	1603	1672	6%	OORL	OORL
28	25				
3513	3763	3638	5%	0.29	0.33
3813	3233	3523	12%	0.33	0.25
3797	3265	3531	11%	0.33	0.26
3081	3102	3092	0%	0.23	0.23
2845	3955	3400	23%	0.20	0.36
3356	3491	3424	3%	0.27	0.29
7	4				
3254	2652	2953	14%	0.25	0.17
3425	3554	3490	3%	0.28	0.30
2534	2663	2598	4%	0.15	0.17
3165	2296	2731	23%	0.24	OORL
2124	2305	2214	6%	OORL	OORL
15	12				
2856	2396	2626	12%	0.20	0.14

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

2179	2027	2103	5%	OORL	OORL
2402	52	2402		0.14	
2527	2394	2461	4%	0.15	0.14
2056	1797	1926	10%	OORL	OORL
1906	1978	1942	3%	OORL	OORL
2062	2296	2179	8%	OORL	OORL
1984	2146	2065	6%	OORL	OORL
2617	2707	2662	2%	0.16	0.18
1890	1948	1919	2%	OORL	OORL
2396	2454	2425	2%	0.14	0.14
2678	2347	2513	9%	0.17	0.13
2015	1779	1897	9%	OORL	OORL
1966	1788	1877	7%	OORL	OORL
8	7				
2201	2019	2110	6%	OORL	OORL
1825	2114	1970	10%	OORL	OORL
5	3				
1351	1906	1629	24%	OORL	OORL
2384	2148	2266	7%	0.13	OORL
2013	1956	1984	2%	OORL	OORL
2151	1952	2052	7%	OORL	OORL
2231	2041	2136	6%	OORL	OORL
1925	1818	1872	4%	OORL	OORL
2055	2009	2032	2%	OORL	OORL
1777	1779	1778	0%	OORL	OORL
1919	1930	1924	0%	OORL	OORL

2099	1914	2006	7%	OORL	OORL
5	14				
25	12				
2497	2871	2684	10%	0.15	0.20
1777	2568	2173	26%	OORL	0.16
2655	2718	2686	2%	0.17	0.18
2	2				
3319	3793	3556	9%	0.26	0.33
3283	3479	3531	4%	0.26	0.29
131	3657	3657			0.31
3993	3292	3643	14%	0.36	0.26
3208	3106	3157	2%	0.25	0.23
3218	3090	3154	3%	0.25	0.23
3297	2835	3066	11%	0.26	0.19
4618	4451	4535	3%	0.45	0.43
12	16				
4096	4012	4054	1%	0.38	0.36
2748	2639	2694	3%	0.18	0.17
2842	2410	2626	12%	0.20	0.14
2160	2289	2224	4%	OORL	OORL
2237	2461	2349	7%	OORL	0.14
9	9				
3101	2882	2992	5%	0.23	0.20
2049	2804	2426	22%	OORL	0.19
1365	2325	1845	37%	OORL	0.13
2241	3122	2682	23%	OORL	0.24

Theranos

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

10 INTERFERENCE

The recovery of analyte spiked into hemolyzed (500mg/dL Hemoglobin), icteric (40mg/dL), and lipemic (1000mg/dL Triglycerides) serum samples was evaluated on the Theranos System and compared to nominal values. The acceptance criteria include recovery within 20% of nominal. Both icteric and hemolyzed samples did not pass these criteria. Samples with bilirubin levels at or greater than 40 mg/dl and hemoglobin hemoglobin levels at or greater than 500 mg/dl are not recommended for testing.

Table 27: Interfering Substances

Hemolyzed sample (hemoglobin 500mg/dL)										Dexter Calculated Result				
Nominal Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery	
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean			
50	203043	271583	203043	271583	237313	20%	235133	15%	53.72	84.76	67.09	23%	134%	
	230772	46185	230772		230772				65.16	OORL				
	11441	58661							OORL	OORL				
5	36341	44544	36341	44544	40442	14%	44764	14%	6.92	8.60	8.65	15%	173%	
	39027	53180	39027	53180	46104	22%			7.47	10.41				
	48949	46544	48949	46544	47747	4%			9.52	9.02				
1	8453	9905	8453	9905	9179	11%	9145	10%	1.38	1.67	1.52	12%	152%	
	7849	9578	7849	9578	8713	14%			1.26	1.61				
	11089	9942			9942				OORL	1.68				
0	1931	1412	1931	1412	1672	22%	1737	11%	0.12	0.04	0.09	31%		
	1663	1708	1663	1708	1686	2%			0.08	0.08				
	1841	1868	1841	1868	1855	1%			0.10	0.11				
Icteric sample (Bilirubin 40mg/dL)										Dexter Calculated Result				
Nominal Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery	
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean			
50	298141	272689	298141	272689	285415	6%	259989	9%	99.58	85.34	78.83	16%	158%	
	238138	267774	238138	267774	252956	8%			68.44	82.78				
	232558	258635	232555	250635	241595	5%			65.95	74.26				
5	30408	23199	30408	23199	26804	19%	27577	11%	5.73	4.30	5.17	12%	103%	
	28191	28511	28191	28511	28351	1%			5.29	5.35				
	21	39321	DARK											
1	10747	7101		7101	7101		8251	13%		1.12	1.34	16%	134%	
	9113	7597	9113	7597	8355	13%			1.52	1.21				
	12217	9194		9194	9194					1.53				
0	2379	2988	2379	2988	2684	16%	2649	11%	0.19	0.31	0.24	21%		
	1219	2543		2543	2543					0.22				
	2903	2433	2903	2433	2668	12%			0.29	0.20				
Lipemic sample (Triglycerides 1000mg/dL)										Dexter Calculated Result				
Nominal Value [ng/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery	
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean			
50	217042	166215	217042	166215	191628	19%	204075	12%	59.32	40.48	54.12	17%	108%	
	228287	220221	228287	220221	224254	3%			64.08	60.64				
	183399	209284	183399	209284	196342	9%			46.40	56.17				
5	29917	27884	29917	27884	28900	5%	25747	12%	5.63	5.23	4.80	13%	96%	
	22521	24327	22521	24327	23424	5%			4.17	4.52				
	24085	3	24085	DARK	24085				4.47					
1	8102	8349	8102	8349	8225	2%	7836	5%	1.31	1.36	1.26	6%	126%	
	7932	7737	7932	7737	7834	2%			1.28	1.24				

theranos	tPSA ELISA Assay Report		Document Number:	
	Validation Document		Revision: A	
			Effective Date:	
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System				

	7270	7628	7270	7628	7449	3%			1.15	1.22			
0	2768	2232	2768	2232	2500	15%	2378	12%	0.26	0.17	0.19	25%	
	2472	2602	2472	2602	2537	4%			0.21	0.23			
	2090	2102	2090	2102	2096	0%			0.15	0.15			

11 CROSSREACTIVITY

Information about cross-reacting analytes from predicate method insert.

11.1 The analysis in the report will contain the following elements:

11.1.1 A statistical summary table showing the mean, and CV of each concentration level

11.1.2 Theranos calculated concentration (all samples should be "OORL")

11.1.3 % cross-reactivity

Table 28: Cross-reactive Samples

These data were obtained from the assay development report. All the analytes tested OORL on the assay and hence there was no cross reactivity detected.

Sample ID	RLU Tip1	RLU Tip2	Inter-Cartridge		Intra-Cartridge		
			Mean	%CV	Mean	%CV	Modulation
Blank	2290	1499	1895	30%	1595	26%	1.0
	1023	1702	1363	35%			
	1648	1406	1527	11%			
Kallikrein 2 (200ng/ml)	1005	1014	1008	0%	830	35%	0.5
	1079	690	885	31%			
	382	892	597	70%			
Kallikrein 4 (200ng/ml)	1387	613	960	51%	1153	25%	0.7
	1219	1198	1209	1%			
	1444	1137	1291	17%			
Kallikrein 5 (200ng/ml)	2121	2015	2068	4%	1774	14%	1.1
	1455	1669	1562	10%			
	1678	1704	1691	1%			
Kallikrein 8 (200ng/ml)	1888	1289	1589	27%	1744	19%	1.1
	2041	1756	1899	11%			

theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

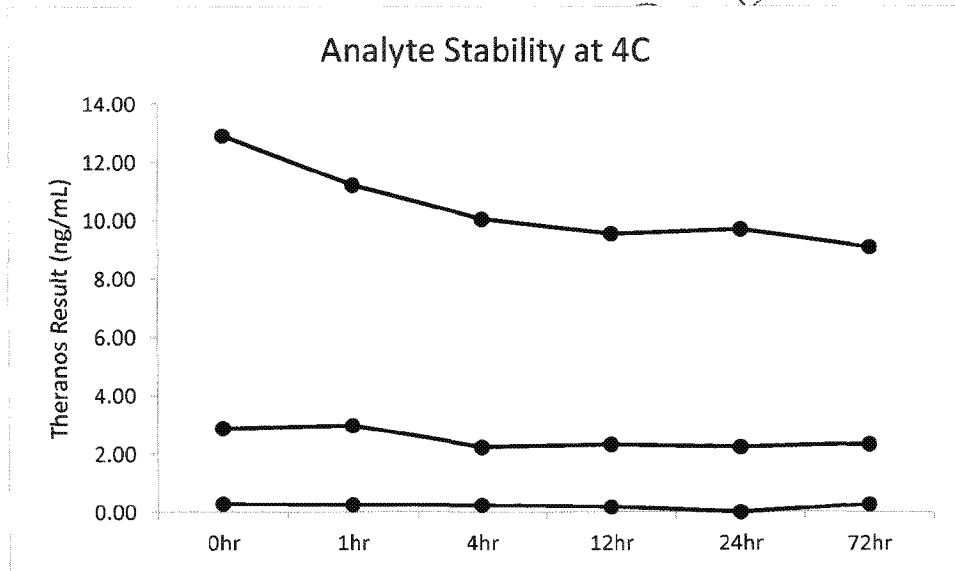
12 SAMPLE STABILITY

Overall the analyte levels in samples stored at 4C and room temperature tend to decrease over a 72 hour period. It is recommended to process the sample within one hour of collection.

Table 29: Sample Stability Summary

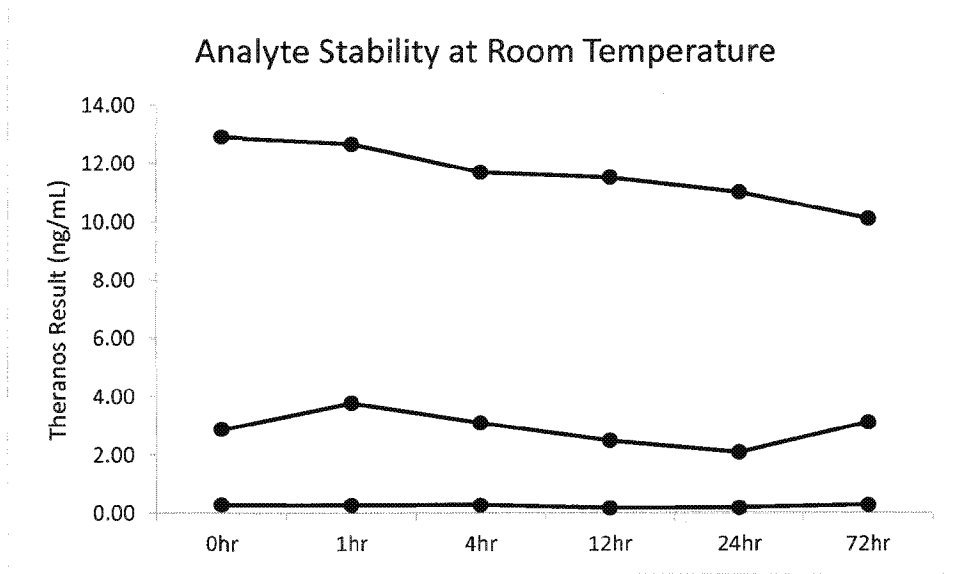
4C						
0hr	1hr	4hr	12hr	24hr	72hr	
12.89	11.20	10.04	9.54	9.69	9.09	
2.87	2.96	2.23	2.31	2.23	2.33	
0.28	0.25	0.24	0.18	0.00	0.27	
Room Temp						
0hr	1hr	4hr	12hr	24hr	72hr	
12.89	12.65	11.68	11.50	10.99	10.08	
2.87	3.76	3.09	2.48	2.08	3.10	
0.28	0.27	0.27	0.17	0.18	0.27	

Figure 15: 4C Sample Stability



theranos	tPSA ELISA Assay Report	Document Number:
	Validation Document	Revision: A
		Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

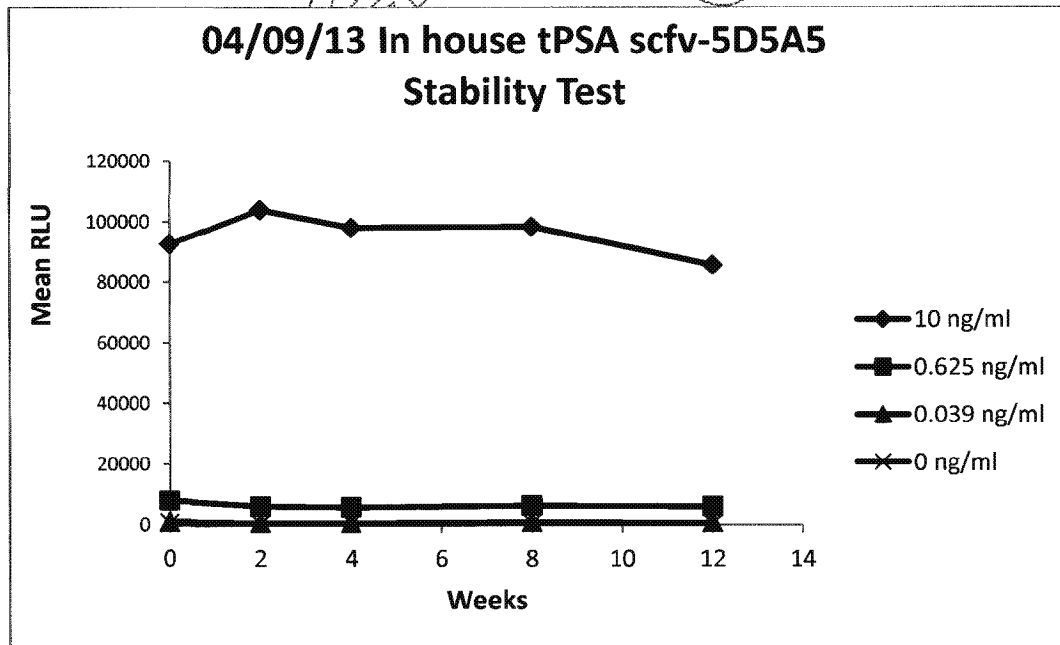
Figure 16: Room Temperature Sample Stability



13 Reagent Stability

Assay reagents are stable up to 12 weeks when stored at 4C

Figure 17: Reagent Stability over 12 Weeks



theranos	tPSA ELISA Assay Report	Document Number: Revision: A
	Validation Document	Effective Date:
tPSA ELISA Assay Validation Report on Edison 3.X Theranos System		

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