
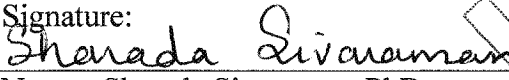



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	Validation Document	Revision: A
		Effective Date: 1/14/2014
<b>Total Testosterone ELISA Assay Validation Report on Edison 3.5 Theranos System</b>		

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## 1 ASSAY BACKGROUND

There are three types of testosterone measured in clinical settings: total testosterone (free as well as bound to SHBG and albumin), free testosterone (not bound to plasma proteins), and bioavailable testosterone (free or weakly bound to SHBG or albumin). Free testosterone can be reasonably estimated using an equation requiring total testosterone, SHBG and albumin, without the need for LC/MS/MS. LC/MS/MS is recommended however in prepubertal children (who have low levels of testosterone), infants (in whom interfering substances are common) and in females (eg in the workup of congenital adrenal hyperplasia). For most outpatient setting involving postpubertal males, however, immunoassays are appropriate.

In males, testosterone measurements are used to evaluate states of hypogonadism and as part of the workup for congenital adrenal hyperplasia (CAH) and premature adrenarche. Decreased testosterone levels are found in hypogonadism, orchiectomy, estrogen therapy, Klinefelter's syndrome, hypopituitarism, and hepatic cirrhosis. Testosterone is necessary in the development of secondary sex characteristics, the prostate, seminal vesicles and also facial, pubic, and axillary hair growth. Testosterone levels in females are found at much lower levels. Increased levels are found in polycystic ovaries, ovarian tumors, adrenal tumors, and adrenal hyperplasia.

### 1.1 Theranos System Specifications

This assay is designed to detect total Testosterone (TST) in human EDTA plasma, Li Heparin plasma, and serum. The assay has a reportable range of 30.3 – 1626 ng/dL.

### 1.2 Reference Assay

The SIEMENS Immulite 2000 Total Testosterone test was used as a predicate method. The reportable range is 20 – 1600 ng/dL. Hemolysis (up to 270uL/mL hemoglobin) and lipemia (up to 500 mg/dL triglycerides) do not affect assay precision. Bilirubin may cause elevation of values. EDTA plasma samples are not recommended for testing.

## 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.

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### 3 CALIBRATION

#### 3.1 Guidelines

- 3.1.1 In 42 CFR Part 493.1255, it is required to perform calibration procedures with at least the frequency recommended by the manufacturer, or using criteria specified by the laboratory, or when calibration verification fails to meet acceptable limits.
- 3.1.2 For the purposes of this Validation Plan, calibration will be carried out for each new lot of reagent cartridges.
- 3.1.2.1 At each level 3 cartridge replicates were tested. Any individual tip with a value less than 150RLU was considered a "Dark" tip. Any dark tips and outliers were excluded from the mean, %CV and % Recovery calculations.
- 3.1.2.2 Acceptance criteria: For each run, a minimum of 75% points of calibration standards should be within  $100 \pm 20\%$  ( $100 \pm 25\%$  at LLOQ and ULOQ standards) of their nominal value, and a minimum of six unique standard concentrations must be within the assay range.

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### 3.2 Calibration 1 (Edison 3.5, 20uL)

Of 9 Total Testosterone levels, 8 had a back calculated mean value within  $100 \pm 20\%$  ( $100 \pm 25\%$  at LLOQ and ULOQ standards) of their reported values, and all levels had CVs below 20% (25% at LLOQ). This calibration set was used to analyze Accuracy/Comparability (5), Dilution Linearity (6), Reference Range (7), Blood Collection Device Comparison (8), Analytical Sensitivity (9), Anticoagulant Comparison (10), Interference (11), Analyte Stability (13), and Reagent Stability (14).

**Table 1: Calibration 1 Data**

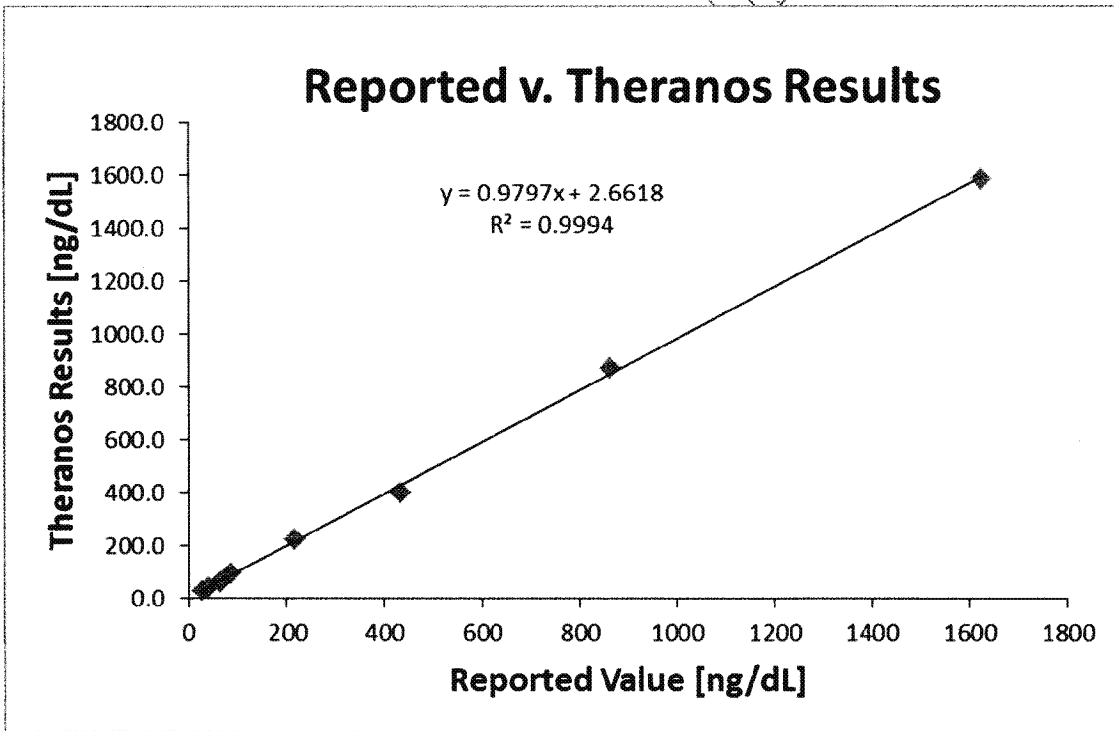
Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
1626	1380	1115	1380	1115	1248	15%	1178	12%	1323.8	1692.7	1588.1	14%
	1058	1055	1058	1055	1057	0%			1800.3	1806.3		
	1281	1668	1281						1441.4			
865	1781	1884	1781	1884	1833	4%	1993	11%	991.9	931.0	873.9	12%
	2286	2118	2286	2118	2202	5%			748.0	815.7		
	1761	2126	1761	2126	1944	13%			1004.6	812.2		
432.5	3778	3898	3778	3898	3838	2%	3868	5%	414.5	398.7	402.4	6%
	105	89	DARK	DARK								
	4104	3697	4104	3697	3901	7%			373.9	425.7		
216.3	5866	5796	5866	5796	5831	1%	6030	10%	231.6	235.6	222.6	17%
	4970	6634	4970	6634	5802	20%			291.6	193.0		
	6316	6596	6316	6596	6456	3%			207.8	194.7		
86.5	9215	10038	9215	10038	9627	6%	9912	8%	110.1	92.8	95.2	15%
	11053	12407	11053						75.1			
	9215	10038	9215	10038	9627	6%			110.1	92.8		
64.9	12974	14118	12974				11843	7%	49.8		63.6	19%
	11429	12041	11429	12041	11735	4%			69.4	61.0		
	10670	12102	10670	12102	11386	9%			81.3	60.2		
43.3	13651	15128	13651	15128	14390	7%	13518	6%	42.8	30.0	44.1	18%
	12775	13389	12775	13389	13082	3%			52.0	45.4		
	12775	13389	12775	13389	13082	3%			52.0	45.4		
30.3	15813	15094	15813	15094	15454	3%	15412	4%	25.1	30.3	27.9	16%
	15739	16226	15739	16226	15983	2%			25.6	OORL		
	14336	15265	14336	15265	14801	4%			36.4	29.0		
0	23193	24854	23193	24854	24024	5%	21796	11%	OORL	OORL	OORL	OORL
	19229	19054	19229	19054	19142	1%			OORL	OORL		
	21682	22762	21682	22762	22222	3%			OORL	OORL		

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**Table 2: Calibration 1 Summary**

Calibrator Level	Reported Value [ng/dL]	Theranos Result [ng/dL]	%CV	% Recovery
Calibrator 1	1626	1588.1	14%	98%
Calibrator 2	865	873.9	12%	101%
Calibrator 3	432.5	402.4	6%	93%
Calibrator 4	216.3	222.6	17%	103%
Calibrator 5	86.5	95.2	15%	110%
Calibrator 6	64.9	63.6	19%	98%
Calibrator 7	43.3	44.1	18%	102%
Calibrator 8	30.3	27.9	16%	92%
Calibrator 9	0	OORL	OORL	OORL

**Figure 1: Calibration 1**





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### 3.3 Calibration 2 (Edison 3.5, 7uL)

Of 9 Total Testosterone levels, 7 had a back calculated mean value within  $100 \pm 20\%$  ( $100 \pm 25\%$  at LLOQ and ULOQ standards) of reported values, and 7 levels had CVs less than 20%. This calibration set was used to analyze Precision (4).

**Table 3: Calibration Data**

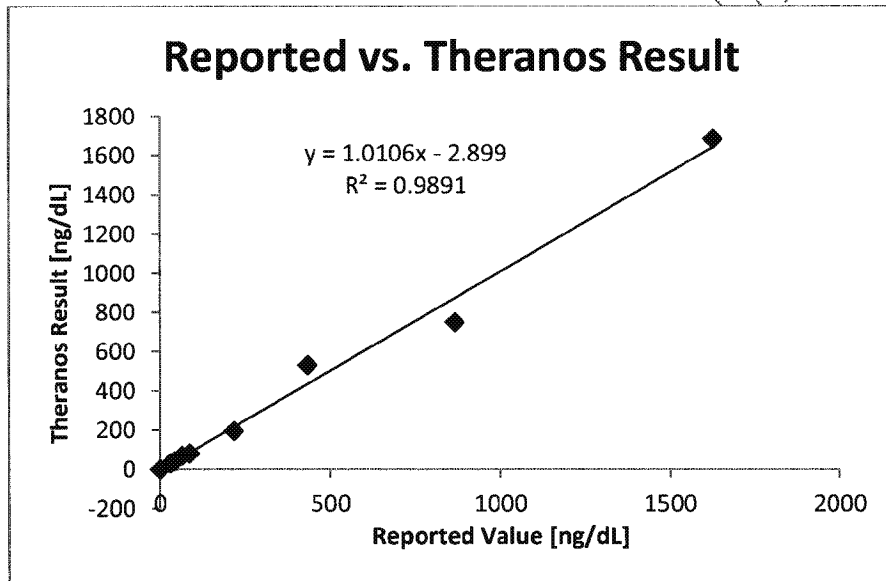
Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	
1626	1051	1104	1051	1104	1078	3%	1180	10%	OORH	OORH	1683.0	13%
	1287	1354	1287	1354	1321	4%			1458.1	1344.6		
	1135	1151	1135	1151	1143	1%			1800.5	1757.3		
865	1	1733	DARK	1733			2023	12%		929.1	748.0	17%
	2353	2170	2353	2170	2262	6%			609.2	679.5		
	1945	1913	1945	1913	1929	1%			789.6	808.1		
432.5	2505	2468	2505	2468	2487	1%	2611	5%	560.4	571.6	530.4	7%
	2561	2609	2561	2609	2585	1%			544.2	531.0		
	2704	2821	2704	2821	2763	3%			506.5	479.1		
216.3	5263	4815	5263	4815	5039	6%	5556	10%	210.4	237.2	195.3	14%
	5517	5910	5517	5910	5714	5%			197.2	179.3		
	8053	6277		6277						164.8		
86.5	8972	10084	8972	10084	9528	8%	10019	7%	96.0	78.7	79.6	12%
	9504	10196	9504	10196	9850	5%			87.2	77.2		
	10435	10923	10435	10923	10679	3%			74.1	68.1		
64.9	11815	12277	11815	12277	12046	3%	10946	9%	58.5	54.1	67.8	17%
	10217	10350	10217	10350	10284	1%			76.9	75.2		
	10070	2	10070	DARK					78.9			
43.3	11878	12855		12855			13966	6%		49.0	40.5	15%
	13737	14705	13737	14705	14221	5%			42.1	35.5		
	13658	14875	13658	14875	14267	6%			42.7	34.4		
30.3	14516	15439	14516	15439	14978	4%	15675	14%	36.7	31.0	29.7	24%
	19639	15791	19639	15791	17715	15%			OORL	29.1		
	13167	15496	13167	15496	14332	11%			46.5	30.7		
0	27146	0		DARK			23035	13%			OORL	OORL
	20719	20288	20719	20288	20504	1%			OORL	OORL		
	25378	25755	25378	25755	25567	1%			OORL	OORL		

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**Table 4: Calibration 2 Summary**

Calibrator Level	Reported Value [ng/dL]	Theranos Result [ng/dL]	%CV	% Recovery
Calibrator 1	1626	1683.0	13%	104%
Calibrator 2	865	748.0	17%	86%
Calibrator 3	432.5	530.4	7%	123%
Calibrator 4	216.3	195.3	14%	90%
Calibrator 5	86.5	79.6	12%	92%
Calibrator 6	64.9	67.8	17%	105%
Calibrator 7	43.3	40.5	15%	93%
Calibrator 8	30.3	29.7	24%	98%
Calibrator 9	0	OORL	OORL	OORL

**Figure 2: Calibration 2**



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#### 4 PRECISION

4.1 Precision was evaluated according to CLSI standard EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods.

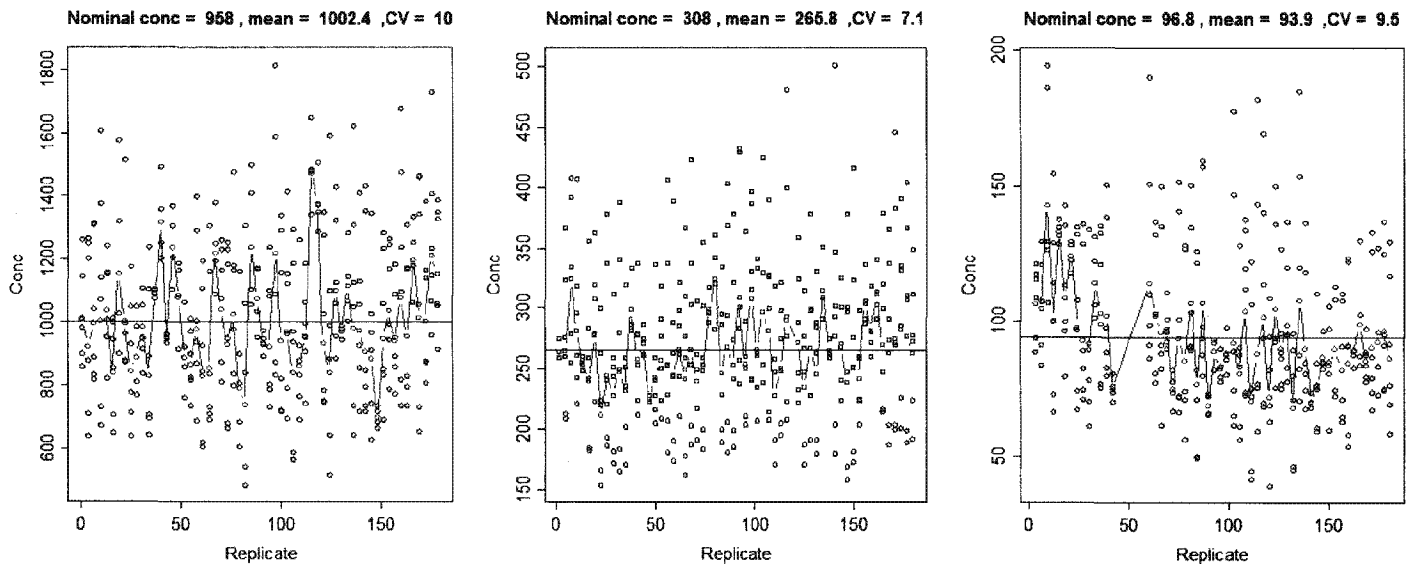
4.1.1 A total of 60 runs were performed.


**Table 5: Precision Summary**

Level	Reported Value [ng/dL]	Theranos Result [ng/dL]	%CV
1	958.00	1002	10%
2	308.00	265.8	7.1%
3	96.80	93.9	9.5%

**Figure 3: Precision plots**

The above plot shows the profile of predicted concentrations from precision study done over multiple days. The black points denote concentrations predicted from individual Signal replicates from six tips and the green points are the means of the replicates. The horizontal black line for each level shows the concentration mean averaged across the whole dataset, which is calculated as the mean of all the green points.



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## 5 ACCURACY/COMPARABILITY

To test the accuracy of the assay on the Theranos System, 101 unique patient samples were assayed using both the predicate method (Siemens Immulite) and the Theranos System. Of these samples 21 were within the female reference range (ND– 73 ng/dL), 20 were within young male (20-49 years old) reference range (72-853 ng/dL), 20 were within old male (>50 years old) reference range (129-767 ng/dL), 40 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.

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Each sample was tested in replicates of three. Calculated concentrations are based on the average RLU of 3 cartridges excluding outliers and dark count tips.

5.1 The analysis in the report contains the following elements:

5.1.1 Repeatability plots, difference plots, and/or scatter plots

5.1.2 The result of an adequate range test (linear fit with r value) to ensure that the sample results span the measuring interval

5.1.3 The results of the calculations for the predicted bias (or difference) estimates and confidence intervals

5.1.4 Statement of performance claims

5.1.4.1 Default acceptance criteria for immunoassays are absolute mean bias (%RE)  $\leq 20\%$  ( $\leq 25\%$  at LLOQ) and total error (sum of the %CV and absolute %RE)  $\leq 30\%$  ( $\leq 40\%$  at the LLOQ)

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**Table 6: Clinical Correlation**

Sample ID	Predicate Value [ng/dL]	Theranos Result [ng/dL]	% recovery
Patient 1	>1600	OORH	NA
Patient 2	>1600	OORH	NA
Patient 3	>1600	OORH	NA
Patient 4	>1600	OORH	NA
Patient 5	>1600	OORH	NA
Patient 6	>1600	OORH	NA
Patient 7	>1600	OORH	NA
Patient 8	>1600	939.3	NA
Patient 9	>1600	1559.7	NA
Patient 10	1407	1325.1	94%
Patient 11	1509	1302.5	86%
Patient 12	>1600	OORH	NA
Patient 13	>1600	1627.4	NA
Patient 14	1203	1196.3	99%
Patient 15	1143	1532.9	134%
Patient 16	>1600	822.5	NA
Patient 17	963	1026.1	107%
Patient 18	1468	1214.2	83%
Patient 19	1404	1217.4	87%
Patient 20	1267	1185.6	94%
Patient 21	1115	1372.0	123%
Patient 22	>1600	OORH	NA
Patient 23	1032	843.7	82%
Patient 24	>1600	1787.6	NA
Patient 25	1055	1046.9	99%
Patient 26	949	920.6	97%
Patient 27	1079	1482.8	137%
Patient 28	1354	1135.4	84%
Patient 29	1197	OORL	NA
Patient 30	1005	998.9	99%
Patient 31	977	967.0	99%
Patient 32	1023	860.8	84%
Patient 33	>1600	OORH	NA
Patient 34	1171	1363.5	116%
Patient 35	1276	1072.9	84%
Patient 36	779	930.6	119%
Patient 37	1425	1073.2	75%
Patient 38	764	746.7	98%
Patient 39	677	625.9	92%
Patient 40	615	684.4	111%
Patient T1	362	665.0	184%
Patient T2	581	676.0	116%
Patient T3	352	451.4	128%

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Patient T4	350	545.0	156%
Patient T5	449	466.6	104%
Patient T6	473	273.0	58%
Patient T7	588	686.7	117%
Patient T8	<20.0	OORL	NA
Patient T9	452	714.3	158%
Patient T10	606	438.0	72%
Patient N1	115	198.0	172%
Patient N2	171	227.3	133%
Patient N3	739	732.7	99%
Patient N4	141	255.4	181%
Patient N5	430	558.1	130%
Patient N6	346	572.1	165%
Patient N7	760	1032.5	136%
Patient N8	246	302.9	123%
Patient N9	362	498.3	138%
Patient N10	479	412.0	86%
Patient N11	317	575.5	182%
Patient N12	263	198.0	75%
Patient N13	242	318.7	132%
Patient N14	200	269.8	135%
Patient N15	482	1511.1	314%
Patient N16	240	318.1	133%
Patient N17	214	257.4	120%
Patient N18	350	703.9	201%
Patient N19	293	389.6	133%
Patient N20	660	1046.4	159%
Patient N21	31	59.0	190%
Patient N22	52.2	184.5	353%
Patient N23	26.7	184.8	692%
Patient N24	49.4	71.7	145%
Patient N25	23.4	47.5	203%
Patient N26	<20	43.3	#VALUE!
Patient N27	<20	OORL	NA
Patient N28	22.1	51.6	234%
Patient N29	24.8	58.7	237%
Patient N30	41.9	59.7	143%
Patient N31	32.3	204.6	633%
Patient N32	<20.0	37.6	NA
Patient N33	36.1	58.5	162%
Patient N34	<20.0	53.8	NA
Patient N35	46.4	94.5	204%
Patient N36	22.2	58.5	263%
Patient N37	<20.0	405.5	NA
Patient N38	<20.0	84.8	NA
Patient N39	<20.0	OORL	NA

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Patient N40	<20.0	72.9	NA
Patient N41	368	428.5	116%
Patient N42	492	492.9	100%
Patient N43	277	245.8	89%
Patient N44	336	409.8	122%
Patient N45	566	497.9	88%
Patient N46	207	269.2	130%
Patient N47	336	561.0	167%
Patient N48	575	602.3	105%
Patient N49	164	133.9	82%
Patient N50	272	421.6	155%
Patient N51	121	187.2	155%

**Figure 4: Scatter Plot – CLSI Guideline EP09-A2-IR Section 4.2**

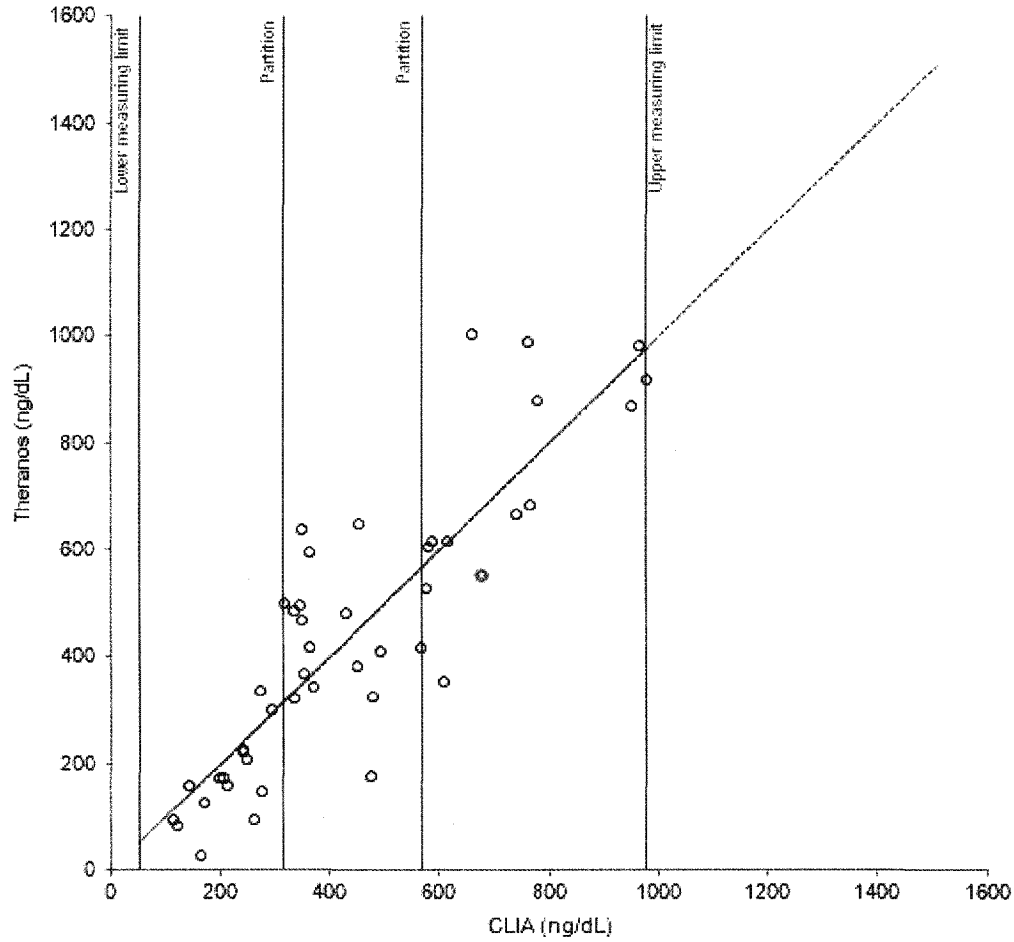
Theranos Internal Only



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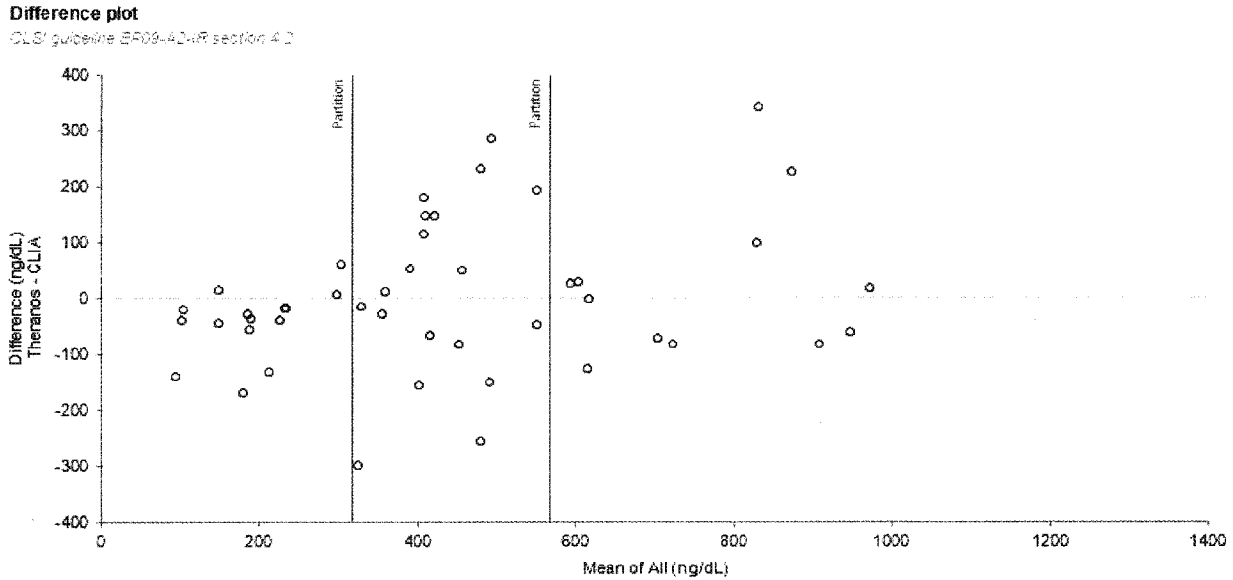
**Scatter plot**

CLSI guideline EP09-A2-1R section 4.2



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**Figure 5: Difference Plot – CLSI Guideline EP09-A2-IR Section 4.2**



**Table 7: Adequate Range Test – CLSI Guideline EP09-A2-IR Section 4.5**

**Adequate range test**

CLSI guideline EP09-A2-IR section 4.5

r 0.868

r < 0.975 indicates that the error in X is not adequately compensated by the measuring range. CLSI recommends use of partitioned biases.

**Table 8: Ordinary Linear Fit – CLSI Guideline EP09-A2-IR Section 5.1**

**Ordinary linear fit**

CLSI guideline EP09-A2-IR section 5.1

n	46		
Parameter	Estimate	SE	95% CI
Constant (intercept)	-0.00096797	42.66310898	-95.982814365 to 85.980
Proportional (slope)	1.000	0.0861	0.826 to 1.174
Sy,x	133.3551116		

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**Table 9: Partitioned Differences – CLSI Guideline EP09-A2-IR Section 6.2**

**Partitioned residuals**

*CLSI guideline EP09-A2-IR section 6.3*

Partition	n	SD
< 317	15	75.52376865
≥ 317 and < 566	16	162.2031665
≥ 566	15	148.3181935

**Table 10: 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	90.00000000	-0.00392961	19.50015321	1.327598646 to 41.819	0.090000000
2	1000.000000	-0.03387508	38.29559202	2.169752971 to 82.102	1.000000000

Difference is less than allowable bias: 0.1%.

**Table 11: Method comparison summary**

Level(ng/dL)	Precision(%)	Total Error(%)	Allowable Bias (%)
90	10	10	0.1
1000	10	10	0.1

**6 DILUTION LINEARITY**

A high analyte sample was selected and serially diluted in testosterone depleted serum using a patient sample with reported Total Testosterone value at 1468 ng/dL by the predicate method (Siemens Immulite) to a total of 8 points to test the linearity. The nominal values of each level were calculated based on the value of the high analyte sample as reported by the predicate method (Siemens Immulite).

Each dilution level was tested on the Therasos System and compared to the nominal concentrations. For each dilution level, the recovery should be within 100 ± 20% (100 ± 25% at LLOQ) of their nominal value, and when plotted, the R<sup>2</sup> value should be equal or greater than 0.95.

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**Table 12: Dilution Linearity**

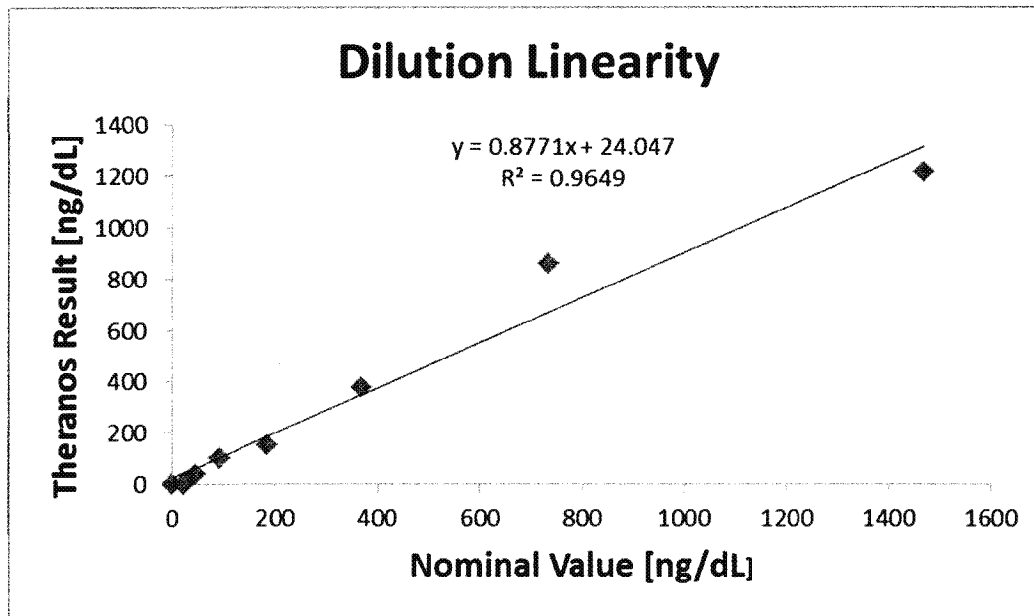
Nominal Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
1468	1567	2126	1567				1489	9%	1146.02		1214.20	12%
	684	1280		1280					1442.71			
	1570	1539	1570	1539	1555	1%			1143.54	1169.63		
734	2708	2844	2708	2844	2776	3%	2027	30%	616.04	581.98	857.37	33%
	1426	1765	1426	1765	1596	15%			1275.27	1002.03		
	1567	1850	1567	1850	1709	12%			1146.02	950.29		
367	3564	3959	3564	3959	3762	7%	4060	13%	445.12	391.11	378.95	16%
	4697	4772	4697	4772	4735	1%			514.28	307.78		
	3668	3701	3668	3701	3685	1%			429.78	425.10		
183.5	7855	7478	7855	7478	7667	3%	7736	3%	146.95	159.55	150.78	4%
	7912	7700	7912	7700	7806	2%			145.14	151.98		
	5408	4546										
91.75	7747	8396		8396			9462	7%		130.84	104.57	15%
	10038	9178	10038	9178	9608	6%			92.77	110.96		
	9972	9726	9972	9726	9849	2%			94.05	98.98		
45.88	11537	14712	11537	14712	13125	17%	13790	10%	67.84	33.28	41.41	35%
	13600	14425	13600	14425	14013	4%			43.25	35.67		
	14674	17275	14674						33.59			
22.94	13236	11369	13236	11369	12303	11%	17663	28%	46.96	70.28	OORL	OORL
	17554	18080	17554	18080	17817	2%			OORL	OORL		
	20470	25268	20470	25268	22869	15%			OORL	OORL		
0	34215	31370	34215	31370	32793	6%	26040	25%	OORL	OORL	OORL	OORL
	17789	19529	17789	19529	18659	7%			OORL	OORL		
	25376	27958	25376	27958	26667	7%			OORL	OORL		

**Table 13: Dilution Linearity Summary**

Sample ID	Nominal Value [ng/dL]	Theranos Result [ng/dL]	% Recovery
High Patient Sample	1468	1214.20	83%
1/2	734	857.37	117%
1/4	367	378.95	103%
1/8	183.5	150.78	82%
1/16	91.75	104.57	114%
1/32	45.88	41.41	90%
1/64	22.94	OORL	OORL
Testosterone-depleted serum	0	OORL	OORL

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**Figure 6: Dilution Linearity**



## 7 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 interval defined by the manufacturer in the product insert. 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.

7.1 Calculated concentrations are based on the mean RLU of 3 cartridges tested.

7.2 Acceptance Criteria: In accordance to CLSI guideline C28-A3c,

7.2.1 95% of at least 20 samples tested must be within the reference interval.

The reference interval established for the predicate method is ND – 73 ng/dL for females, 72-853 ng/dL for males (20-49 yrs), and 129-767 ng/dL for males (≥ 50 yrs).

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Of 20 unique samples collected from reference female donors, 20 collected from reference male donors (20-49 yrs) and 15 collected from reference male donors ( $\geq 50$  yrs), zero patients had Total Testosterone levels outside of the reference range. These samples were confirmed via predicate method listed in section 1.2.

Overall, 100% of the patients tested fell within the reference range, and is acceptable for verification of the reference range.

**Table 14: Normal Patient Sample (Females)**

Reported Serum Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2	Mean	%CV
32	10057	12012										
	15787	16361	15787	16361	16074	3%	14952	9%	25.28	OORL	31.36	31%
	13529	14131	13529	14131	13830	3%			43.96	38.25		
<20	16222	11836	16222	11836	14029	22%			OORL	63.68		
	14650	14754					12993	17%			49.57	15%
	11398	12514	11398	12514	11956	7%			69.85	55.05		
<20	14236	16311		16311						OORL		
	9991	9956	9991	9956	9974	0%	11718	23%	93.68	94.36	65.29	20%
	10733	11601	10733	11601	11167	5%			80.29	66.93		
<20	11298	13040	11298	13040	12169	10%			71.34	49.05		
	17454	20631	17454	20631	19043	12%	14519	25%	OORL	OORL	34.87	27%
	12379	12312	12379	12312	12346	0%			56.68	57.51		
<20	12023	13539	12023	13539	12781	8%			61.19	43.86		
	14540	15695					11876	10%			63.14	25%
	10852	11089	10852	11089	10971	2%			78.32	74.53		
<20	12747	12248	12747	12248	12498	3%			52.32	58.31		
	21464	21862					13793	15%			41.38	17%
	13464	16713	13464	16713	15089	15%			44.61	OORL		
<20	11488	13247	11488	13247	12368	10%			68.54	46.84		
	12419	13076	12419	13076	12748	4%	12164	9%	56.20	48.66	59.37	25%
	9163	10591		10591						82.69		
<20	17444	16570	17444	16570	17007	4%			OORL	OORL		
	25819	25112	25819	25112	25466	2%	19625	23%	OORL	OORL	OORL	OORL
	16363	16440	16363	16440	16402	0%			OORL	OORL		
<20	14747	13996	14747	13996	14372	4%			32.99	39.48		
	12536	12748	12536	12748	12642	1%	14124	12%	54.79	52.31	38.31	27%
	15770	16594		16594						OORL		
<20	12341	12599	12341	12599	12470	1%	12645	3%	57.15	54.04	53.51	9%

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	8079	8567																	
	13277	12362	13277	12362	12820	5%						46.53	56.89						
<20	14197	11277	14197				15141	4%				37.66		29.91	17%				
	15283	15653	15283	15653	15468	2%						28.85	26.20						
	15431	17989	15431									27.77							
<20	11944	12009	11944	12009	11977	0%	14080	25%				62.33	61.37	38.71	5%				
	11723	12073	11723	12073	11898	2%						65.22	60.54						
	16751	19981	16751	19981	18366	12%						OORL	OORL						
<20	16118	20149	16118	20149	18134	16%	14399	26%				OORL	OORL	35.95	18%				
	12265	14149	12265									58.09							
	11381	12052	11381	12052	11717	4%						70.10	60.81						
<20	14910	13703	14910	13703	14307	6%	14782	13%				31.69	42.24	32.71	27%				
	13165	12793	13165	12793	12979	2%						47.71	51.80						
	16335	17783	16335	17783	17059	6%						OORL	OORL						
<20	9464	9937					13467	7%						44.58	22%				
	14114	14297	14114	14297	14206	1%						38.40	36.78						
	13189	12267	13189	12267	12728	5%						47.45	58.07						
<20	11783	12143	11783	12143	11963	2%	11710	7%				64.40	59.64	65.40	18%				
	10438	11319	10438	11319	10879	6%						85.37	71.02						
	12823	11756	12823	11756	12290	6%						51.46	64.77						
<20	14493	15826	14493	15826	15160	6%	14636	9%				35.09	25.01	33.90	28%				
	13585	16007	13585	16007	14796	12%						43.40	OORL						
	11058	13269		13269									46.61						
<20	12520	13360	12520	13360	12940	5%	13607	7%				54.98	45.67	43.18	22%				
	10	3	DARK	DARK															
	13679	14869	13679	14869	14274	6%						42.48	32.01						
<20	9217	12189					16087	11%						OORL	OORL	OORL	OORL		
	17982	16317	17982	16317	17150	7%						OORL	OORL						
	16414	13633	16414	13633	15024	13%						OORL	42.93						
<20	10304	10158	10304	10158	10231	1%	11561	21%				87.78	90.48	67.49	47%				
	9227	10474	9227	10474	9851	9%						109.83	84.73						
	14689	14516	14689	14516	14603	1%						33.46	34.90						

**Table 15: Normal Patient Samples (Males: 20-49 yrs)**

Reported Serum Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2	Mean	%CV
627	2635	2678	2635	2678	2657	1%	3038	11%	635.8	624.0	538.8	13%
	3152	3389	3152	3389	3271	5%			515.8	473.0		
	2991	3380	2991	3380	3186	9%			548.7	474.6		
430	3162	3603	3162	3603	3383	9%	3425	10%	513.8	439.3	467.1	12%

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	3380	3995	3380	3995	3688	12%			474.6	386.7		
	2994	3413	2994	3413	3204	9%			548.0	469.0		
288	3663	3699	3663	3699	3681	1%	3959	9%	430.5	425.4	391.1	11%
	3076	3699		3699					425.4			
	4415	4319	4415	4319	4367	2%			340.6	350.4		
193	8526	8186	8526	8186	8356	3%	7179	14%	127.3	136.8	170.5	24%
	6057	6038	6057	6038	6048	0%			241.1	223.1		
	7071	7195	7071	7195	7133	1%			174.7	169.9		
279	3174	3725	3174	3725	3450	11%	3932	12%	511.5	421.7	394.4	17%
	3752	4570	3752	4570	4161	14%			418.0	325.8		
	4202	4170	4202	4170	4186	1%			362.9	366.4		
424	3865	3832	3865	3832	3849	1%	3783	3%	403.0	407.3	413.9	4%
	3644	3837	3644	3837	3741	4%			433.2	406.6		
	3648	3869	3648	3869	3759	4%			432.7	402.5		
354	5127	5542	5127	5542	5335	6%	4440	23%	279.6	251.1	338.2	34%
	4715	4853	4715	4853	4784	2%			312.7	301.0		
	3223	3178	3223	3178	3201	1%			502.3	510.8		
300	2237	2442	2237	2442	2340	6%	2816	14%	766.7	693.8	588.6	18%
	3150	3277	3150	3277	3214	3%			516.2	492.5		
	2845	2947	2845	2947	2896	2%			581.7	558.3		
281	4552	5015	4552	5015	4784	7%	4271	15%	327.4	288.0	355.4	19%
	3602	3916	3602	3916	3759	6%			439.4	396.5		
	2695	3040										
275	4043	4265	4043	4265	4154	4%	4731	13%	381.0	356.1	311.3	17%
	5003	5558	5003	5558	5281	7%			289.0	250.1		
	4300	5216	4300	5216	4758	14%			352.4	273.1		
292	5119	5286	5119	5286	5203	2%	4648	10%	280.2	268.1	318.7	12%
	4331	4322	4331	4322	4327	0%			349.2	350.1		
	4208	4620	4208	4620	4414	7%			362.2	321.2		
349	5287	4949	5287	4949	5118	5%	4466	15%	268.1	293.2	335.7	20%
	3059	3565		3565						445.0		
	4203	4325	4203	4325	4264	2%			362.8	349.8		
268.5	4347	5157	4347	5157	4752	12%	3892	20%	347.5	277.4	399.6	24%
	3379	3971	3379	3971	3675	11%			474.7	389.6		
	3026	3469	3026	3469	3248	10%			541.2	459.9		
323	3930	4266					2490	15%			678.5	18%
	2769	2799	2769	2799	2784	1%			600.3	592.9		
	2026	2366	2026	2366	2196	11%			857.7	719.3		
365.7	15	1419	DARK				3492	4%			456.3	4%
	3416	3399	3416	3399	3408	0%			468.5	471.4		
	3679	3474	3679	3474	3577	4%			428.2	459.1		
279.8	4400	4779	4400	4779	4590	6%	4282	9%	342.1	307.2	354.3	11%
	7990	7209										
	3941	4008	3941	4008	3975	1%			393.3	385.1		



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430.9	1931	2411					3932	12%			394.4	15%
	4168	4488	4168	4488	4328	5%			366.6	333.5		
	3510	3563	3510	3563	3537	1%			453.4	445.3		
169.7	3823	4587		4587			5502	23%		324.2	253.7	28%
	7363	7681	7363						163.7			
	4828	5229	4828	5229	5029	6%			303.1	272.2		
430.9	5432	4955					3541	22%			448.6	28%
	4290	4145	4290	4145	4218	2%			353.4	369.2		
	2871	2858	2871	2858	2865	0%			575.6	578.7		
294.9	3313	3156					5783	12%			236.3	18%
	4979	5468	4979	5468	5224	7%			290.8	255.9		
	6640	6051	6640	6051	6346	7%			192.7	221.4		

**Table 16: Normal Patient Samples (Males: ≥ 50 yrs)**

Reported Serum Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2	Mean	%CV
243	6999	6682					4188	14%			364.4	18%
	3509	3917	3509	3917	3713	8%			453.6	396.3		
	4754	4573	4754	4573	4664	3%			309.3	325.5		
212	2942	2969	2942	2969	2956	1%	3529	17%	559.4	553.4	450.5	20%
	4033	4379	4033	4379	4206	6%			382.2	344.3		
	3201	3649	3201	3649	3425	9%			506.4	432.5		
503	4940	4947	4940	4947	4944	0%	4195	15%	293.9	293.4	363.7	19%
	3426	3731	3426	3731	3579	6%			466.9	420.9		
	4155	3968	4155	3968	4062	3%			368.1	390.0		
336	4232	3273	4232	3273	3753	18%	3289	19%	359.6	493.2	490.3	24%
	2481	2701	2481	2701	2591	6%			681.3	617.9		
	3521	3527	3521	3527	3524	0%			451.7	450.8		
238	4501	4883	4501	4883	4692	6%	4262	15%	332.3	298.5	356.4	22%
	4731	4434	4731	4434	4583	5%			311.3	338.8		
	3198	3826	3198	3826	3512	13%			507.0	408.1		
208	3695	3677	3695	3677	3686	0%	4681	21%	425.9	428.5	315.7	28%
	4899	4229	4899	4229	4564	10%			297.2	359.9		
	5389	6195	5389	6195	5792	10%			261.1	213.9		
234	3288	3584	3288	3584	3436	6%	2954	16%	490.5	442.1	556.7	19%
	15	2398	DARK	2398						708.4		
	2690	2811	2690	2811	2751	3%			620.8	589.9		
243	5117	5730	5117	5730	5424	8%	4456	17%	280.3	239.5	336.7	21%
	4003	4086	4003	4086	4045	1%			385.7	375.9		
	3826	3971	3826	3971	3899	3%			408.1	389.6		
314	2365	2570	2365	2570	2468	6%	2644	9%	719.7	654.3	633.3	10%
	2756	2885	2756	2885	2821	3%			603.6	572.3		
	6753	44		DARK								
189	6570	6972	6570	6972	6771	4%	7069	6%	195.8	178.6	174.8	9%

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	7473	7260	7473	7260	7367	2%			159.7	167.4		
	4221	4461										
179	4158	4225	4158	4225	4192	1%	5004	13%	367.7	360.4	288.9	19%
	5196	5666	5196	5666	5431	6%			274.5	243.4		
	5224	5556	5224	5556	5390	4%			272.5	250.2		
449	2024	2360	2024	2360	2192	11%	2260	7%	858.7	721.4	757.9	9%
	2290	2365	2290	2365	2328	2%			746.6	719.7		
	1508	1730										
521	2598	2540	2598	2540	2569	2%	2472	15%	646.2	663.2	684.1	18%
	2968	2630	2968	2630	2799	9%			553.7	637.2		
	1947	2151	1947	2151	2049	7%			897.1	801.5		
244	3126	3553	3126	3553	3340	9%	3700	13%	520.9	446.8	425.3	16%
			DARK	DARK								
	3870	4249	3870	4249	4060	7%			402.3	357.8		
258	2603	2863		2863			3990	19%		577.5	387.3	27%
	4072	3917	4072	3917	3995	3%			377.6	396.3		
	4120	4977	4120	4977	4549	13%			372.0	291.0		

**Table 17: Reference Range Summary**

Female			Male (20-49 years old)			Male (>=50 years old)		
Sample ID	Reported Value [ng/dL]	Theranos Result [ng/dL]	Sample ID	Reported Value [ng/dL]	Theranos Result [ng/dL]	Sample ID	Reported Value [ng/dL]	Theranos Result [ng/dL]
F71	32.00	31.36	M81	627.00	538.81	48	243.00	364.39
F72	<20	49.57	M82	430.00	467.15	49	212.00	450.51
F73	<20	65.29	M83	288.00	391.11	50	503.00	363.70
F74	<20	34.87	M84	193.00	170.50	51	336.00	490.29
F75	<20	63.14	M85	279.00	394.44	52	238.00	356.38
F76	<20	41.38	M86	424.00	413.87	53	208.00	315.72
F77	<20	59.37	M87	354.00	338.21	54	234.00	556.70
F78	<20	OORL	M88	300.00	588.64	41	243.00	336.66
F79	<20	38.31	M89	281.00	355.41	42	314.00	633.30
F80	<20	53.51	M90	275.00	311.32	43	189.00	174.76
3	<20	29.91	M91	292.00	318.66	44	179.00	288.88
7	<20	38.71	21	349.00	335.66	45	449.00	757.93
8	<20	35.95	23	268.50	399.57	46	521.00	684.08
11	<20	32.71	24	323.00	678.53	47	244.00	425.31
12	<20	44.58	25	365.70	456.27	55	258.00	387.34
13	<20	65.40	26	279.80	354.27			
14	<20	33.90	28	430.90	394.43			
15	<20	43.18	36	169.70	253.67			
17	<20	OORL	37	430.90	448.64			
18	<20	67.49	38	294.90	236.31			

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## 8 BLOOD COLLECTION DEVICE (BCD) COMPARISON

Because the sample volume obtained from a fingerstick is sufficient only for testing on the Theranos System but not in the predicate method, a second verification of the reference range was performed using matched fingerstick blood and venous blood.

8.1 Calculated concentrations are based on the mean RLU of 3 cartridges tested.

8.2 Acceptance Criteria: In accordance to CLSI guideline C28-A3c,

8.2.1 95% of at least 20 samples tested must be within the reference interval.

The reference interval established for the predicate method is ND – 73 ng/dL for females, 72-853 ng/dL for males (20-49 ys), and 129-767 ng/dL for males ( $\geq 50$  yrs).

Although samples from 3 separate subject categories were used for this exercise there were not enough sample numbers from the older males and female categories to perform a reference range verification. Hence only the 20-49 year old males subject category was used for verification of reference range.

All 20 samples fall within the reference range and pass the acceptance criteria in both the venous and fingerstick sample category.

Overall, 86% of the patients tested for BCD fell within the reference range, and is acceptable for verification of the reference range.

**Table 18: Venous v. Fingerstick**

Female		All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV
		Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	
F71	Venous Tube 1	14100	15513	14100	15513	14807	7%	14921	7%	38.53	27.18	35.14	20%
	Venous Tube 2	16099	13970	16099	13970	15035	10%			OORL	39.72		
	Fingerstick 1	14389	14191	14389	14191	14290	1%	15311	9%	35.98	37.71	33.65	
	Fingerstick 2	15501	17164	15501	17164	16333	7%			27.26	OORL		
F72	Venous Tube 1	11513	12690	11513	12690	12102	7%	11416	11%	68.18	52.98	71.23	27%
	Venous Tube 2	9772	11687	9772	11687	10730	13%			98.04	65.72		
	Fingerstick 1	12572	12306	12572	12306	12439	2%	11329	12%	54.36	57.58	72.82	
	Fingerstick 2	9819	10617	9819	10617	10218	6%			97.09	82.25		
F73	Venous Tube 1	7818	9425	7818	9425	8622	13%	9004	20%	148.13	105.38	121.30	34%
	Venous Tube 2	7442	11331	7442	11331	9387	29%			160.82	70.85		
	Fingerstick 1	12224	13393	12224	13393	12809	6%	11200	17%	58.61	45.33	77.05	
	Fingerstick 2	9206	9978	9206	9978	9592	6%			110.31	93.93		
F74	Venous Tube 1	14254	10737	14254	10737	12496	20%	12168	13%	37.15	80.22	61.49	32%
	Venous Tube 2	11110	12572	11110	12572	11841	9%			74.21	54.36		
	Fingerstick 1	16580	16006	16580	16006	16293	2%	14242	17%	OORL	OORL	59.62	
	Fingerstick 2	12900	11481	12900	11481	12191	8%			50.59	68.64		
F75	Venous Tube 1	12635	13284	12635	13284	12960	4%	14788	15%	53.62	46.45	50.04	10%
	Venous Tube 2	17044	16190	17044	16190	16617	4%			OORL	OORL		
	Fingerstick 1	10060	10487	10060	10487	10274	3%	10570	5%	92.34	84.50	83.46	
	Fingerstick 2	10359	11373	10359	11373	10866	7%			86.78	70.22		



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F76	Venous Tube 1	17152	16726	17152	16726	16939	2%	18769	11%	OORL	OORL	OORL	NA
	Venous Tube 2	20769	20430	20769	20430	20600	1%			OORL	OORL		
	Fingerstick 1	13376	15934	13376	15934	14655	12%	16342	14%	45.50	24.29	34.90	43%
	Fingerstick 2	17249	18810	17249	18810	18030	6%			OORL	OORL		
F77	Venous Tube 1	9743	10586	9743	10586	10165	6%	11474	14%	98.63	82.78	71.31	33%
	Venous Tube 2	12837	12731	12837	12731	12784	1%			51.30	52.51		
	Fingerstick 1	12960	12083	12960	12083	12522	5%	12474	4%	49.93	60.41	55.78	12%
	Fingerstick 2	11915	12939	11915	12939	12427	6%			62.61	50.16		
F78	Venous Tube 1	17718	17354	17718	17354	17536	1%	16961	6%	OORL	OORL	27.65	NA
	Venous Tube 2	17326	15447	17326	15447	16387	8%			OORL	27.65		
	Fingerstick 1	14971	14853	14971	14853	14912	1%	14168	6%	31.21	32.14	38.35	20%
	Fingerstick 2	13482	13366	13482	13366	13424	1%			44.43	45.61		
F79	Venous Tube 1	10351	10626	10351	10626	10489	2%	11010	8%	86.93	82.09	76.60	18%
	Venous Tube 2	12054	33043	12054						60.78	NA		
	Fingerstick 1	9897	9126	9897	9126	9512	6%	9433	4%	95.53	112.18	105.47	8%
	Fingerstick 2	9276	6021	9276						108.71	NA		
F80	Venous Tube 1	8945	10007		10007			10736	7%	NA	93.37	80.49	15%
	Venous Tube 2	11471	10791	11471	10791	11131	4%			68.79	79.32		
	Fingerstick 1	10258	5665	10258				11084	7%	88.62	NA	75.19	16%
	Fingerstick 2	11299	11694	11299	11694	11497	2%			71.32	65.62		
3	Venous Tube 1	15425	17227	15425	17227	16326	8%	14356	17%	27.81	OORL	47.20	38%
	Venous Tube 2	11863	12909	11863	12909	12386	6%			63.31	50.49		
	Fingerstick 1	14202	14024	14202	14024	14113	1%	14543	3%	37.61	39.22	34.81	12%
	Fingerstick 2	14900	15045	14900	15045	14973	1%			31.77	30.64		
7	Venous Tube 1	17865	14		DARK			11429	2%	NA	NA	69.44	5%
	Venous Tube 2	11258	11600	11258	11600	11429	2%			71.94	66.94		
	Fingerstick 1	11594	11783	11594	11783	11689	1%	11032	7%	67.03	64.40	76.19	17%
	Fingerstick 2	10075	10675	10075	10675	10375	4%			92.06	81.26		
8	Venous Tube 1	16908	18598	16908	18598	17753	7%	16512	11%	OORL	OORL	36.94	NA
	Venous Tube 2	14278	16264	14278	16264	15271	9%			36.94	OORL		
	Fingerstick 1	11929	9787	11929	9787	10858	14%	11253	9%	62.43	97.74	73.24	23%
	Fingerstick 2	11969	11227	11969	11327	11648	4%			61.90	70.91		
11	Venous Tube 1	13404	13136	13404	13136	13270	1%	14103	12%	45.22	48.02	46.98	3%
	Venous Tube 2	16708	13165	16708	13165	14937	17%			OORL	47.71		
	Fingerstick 1	16458	18401	16458	18401	17430	8%	14897	23%	OORL	OORL	60.42	52%
	Fingerstick 2	10597	14131	10597	14131	12364	20%			82.59	38.25		
12	Venous Tube 1	12512	12496	12512	12496	12504	0%	12931	8%	55.07	55.27	50.92	20%
	Venous Tube 2	12316	14400	12316	14400	13358	11%			57.46	35.89		
	Fingerstick 1	16714	15557	16714	15557	16136	5%	15231	8%	OORL	26.87	33.34	18%
	Fingerstick 2	14606	14047	14606	14047	14327	3%			34.15	39.01		
13	Venous Tube 1	9332	10300	9332	10300	9816	7%	10562	13%	107.45	87.85	85.37	27%
	Venous Tube 2	12053	23	12053	DARK					60.80	NA		
	Fingerstick 1	11321	11538	11321	11538	11430	1%	12090	10%	70.99	67.82	61.32	23%
	Fingerstick 2	14844	13411		13411					NA	45.15		
14	Venous Tube 1	16639	18668	16639	18668	17654	8%	16041	13%	OORL	OORL	36.13	27%
	Venous Tube 2	13613	15244	13613	15244	14429	8%			43.12	29.13		
	Fingerstick 1	14111	13803	14111	13803	13957	2%	14258	3%	38.43	41.28	37.25	11%
	Fingerstick 2	14199	14918	14199	14918	14559	3%			37.64	31.63		
15	Venous Tube 1	11262	11520	11262	11520	11391	2%	11387	3%	71.88	68.08	70.11	6%
	Venous Tube 2	11046	11718	11046	11718	11382	4%			75.21	65.29		
	Fingerstick 1	12766	13228	12766	13228	12997	3%	14650	20%	52.11	47.04	49.57	7%
	Fingerstick 2	17956	1	17956	DARK					OORL	NA		
17	Venous Tube 1	8568	11689		11689			11050	6%	NA	65.69	75.67	15%
	Venous Tube 2	11185	10277	11185	10277	10731	6%			73.05	88.27		



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		All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration		Mean	%CV
		Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2		
	Fingerstick 1	7921	9526	7921	9526	8724	13%	8469	11%	144.86	103.19	130.58	18%
	Fingerstick 2	15915	7959		7959					NA	143.68		
18	Venous Tube 1	10639	10891	10639	10891	10765	2%	10765	2%	81.87	77.68	79.78	4%
	Venous Tube 2			DARK	DARK					NA	NA		
	Fingerstick 1	11403	11167	11403	11167	11285	1%	11285	1%	69.78	73.33	71.55	4%
	Fingerstick 2	6160	6977							NA	NA		
Male (20-49 years old)													
M81	Venous Tube 1	3130	3461	3130	3461	3296	7%	3278	7%	520.07	461.22	494.37	8%
	Venous Tube 2	3470	3049	3470	3049	3260	9%			459.77	536.42		
M82	Fingerstick 1	3218	2701	3218	2701	2960	12%	2846	10%	503.25	617.89	586.65	12%
	Fingerstick 2	2916	2550	2916	2550	2733	9%			565.24	660.24		
M82	Venous Tube 1	2978	3323	2978	3323	3151	8%	2892	18%	851.49	484.33	585.27	21%
	Venous Tube 2	3022	2246	3022	2246	2634	21%			542.07	763.21		
	Fingerstick 1	3064	3682	3064	3682	3373	13%	3758	15%	533.33	427.79	425.86	19%
	Fingerstick 2	3889	4397	3889	4397	4143	9%			399.89	342.45		
M83	Venous Tube 1	11220	14195	11220				10838	6%	72.52	NA	78.74	15%
	Venous Tube 2	10068	11286	10068	11286	10677	8%			92.19	71.52		
	Fingerstick 1	14550	14265							NA	NA		
	Fingerstick 2	11604	10748	11604	10748	11176	5%	11176	5%	66.88	80.03	73.46	13%
M84	Venous Tube 1	5524	6487	5524	6487	6006	11%	5765	8%	252.24	199.66	239.10	11%
	Venous Tube 2	5480	5568	5480	5568	5524	1%			255.08	249.45		
	Fingerstick 1	7529	7717	7529	7717	7623	2%	6957	11%	157.77	151.42	181.93	18%
	Fingerstick 2	6426	6154	6426	6154	6290	3%			202.53	216.00		
M85	Venous Tube 1	2571	3259	2571	3259	2915	17%	3482	21%	654.05	495.72	477.67	27%
	Venous Tube 2	3981	4116	3981	4116	4049	2%			388.42	372.49		
	Fingerstick 1	3255	3330	3255	3330	3293	2%	3108	10%	496.44	483.11	529.25	13%
	Fingerstick 2	2664	3184	2664	3184	2924	13%			627.82	509.64		
M86	Venous Tube 1	3482	3912	3482	3912	3697	8%	3669	7%	457.86	396.97	431.48	8%
	Venous Tube 2	3428	3853	3428	3853	3641	8%			466.57	404.53		
	Fingerstick 1	3797	4420	3797	4420	4109	11%	4622	15%	411.92	340.15	328.31	20%
	Fingerstick 2	4792	5480	4792	5480	5136	9%			306.08	255.08		
M87	Venous Tube 1	4236	4721	4236	4721	4479	8%	4320	6%	359.18	312.18	351.49	8%
	Venous Tube 2	4147	4177	4147	4177	4162	1%			368.98	365.63		
	Fingerstick 1	3464	3368	3464	3368	3416	2%	3613	7%	460.73	476.59	439.54	8%
	Fingerstick 2	3718	3903	3718	3903	3811	3%			422.71	398.11		
M88	Venous Tube 1	3621	3735	3621	3735	3678	2%	3562	7%	436.61	420.35	447.75	9%
	Venous Tube 2	3184	3706	3184	3706	3445	11%			509.64	424.39		
	Fingerstick 1	3138	3567	3138	3567	3353	9%	3045	13%	518.50	444.67	545.21	15%
	Fingerstick 2	2667	2808	2667	2808	2738	4%			627.00	590.67		
M89	Venous Tube 1	3368	3676	3368	3676	3522	6%	3383	7%	476.59	428.64	476.19	8%
	Venous Tube 2	3096	3391	3096	3391	3244	6%			526.83	472.71		
	Fingerstick 1	3536	3103	3536	3103	3320	9%	3320	9%	449.41	525.43	487.42	11%
	Fingerstick 2	6	2	DARK	DARK					NA	NA		
M90	Venous Tube 1	3798	3703	3798	3703	3751	2%	4456	27%	411.78	424.81	356.03	30%
	Venous Tube 2	5868	6131	5868						231.50	NA		
	Fingerstick 1	3797	3802	3797	3802	3800	0%	4189	16%	411.92	411.25	371.65	19%
	Fingerstick 2	5957	4967		4967					NA	291.79		
M91	Venous Tube 1	4707	5563	4707	5563	5135	12%	5025	7%	313.40	249.76	288.82	10%
	Venous Tube 2	4863	4965	4863	4965	4914	1%			300.16	291.95		
	Fingerstick 1	4183	3708	4183	3708	3946	9%	3974	6%	364.97	424.11	390.58	8%
	Fingerstick 2	3831	4175	3831	4175	4003	6%			407.41	365.85		
21	Venous Tube 1	4549	4318	4549	4318	4434	4%	4245	14%	327.72	350.50	365.96	20%
	Venous Tube 2	3380	4734	3380	4734	4057	24%			474.56	311.05		



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	Fingerstick 1	4053	3974	4053	3974	4014	1%			379.79	389.27		
	Fingerstick 2	3853	3684	3853	3684	3769	3%	3891	4%	404.53	427.50	400.27	5%
23	Venous Tube 1	8477	8854	8477						128.61	NA	197.38	31%
	Venous Tube 2	6155	5598	6155	5598	5877	7%	6743	23%	215.95	247.57		
	Fingerstick 1	6183	6489	6183	6489	6336	3%			214.51	199.56	247.05	19%
	Fingerstick 2	4856	5212	4856	5212	5034	5%	5685	14%	300.74	279.37		
24	Venous Tube 1	5331	4826	5331	4826	5079	7%			265.02	303.23	373.98	28%
	Venous Tube 2	3343	3553	3343	3553	3448	4%	4263	23%	480.86	446.80		
	Fingerstick 1	5643	5604	5643	5604	5624	0%	4774	21%	244.78	247.19	320.79	27%
	Fingerstick 2	3966	3881	3966	3881	3924	2%			390.25	400.91		
25	Venous Tube 1	2852	3259	2852	3259	3056	9%			580.08	495.72	451.00	24%
	Venous Tube 2	4265	4119	4265	4119	4192	2%	3624	19%	356.07	372.15		
	Fingerstick 1	3382	2860	3382	2860	3121	12%			474.22	578.19	481.14	14%
	Fingerstick 2	3660	3590	3660	3590	3625	1%	3373	11%	430.93	441.21		
26	Venous Tube 1	4941	2325	4941						293.85	NA	418.59	28%
	Venous Tube 2	3097	3630	3097	3630	3364	11%	3889	24%	526.63	435.29		
	Fingerstick 1	4493	4595	4493	4595	4544	2%			333.03	323.45	341.21	7%
	Fingerstick 2	4485	4098	4485	4098	4292	6%	4418	5%	333.80	374.56		
28	Venous Tube 1	2756	3035	2756	3035	2896	7%			603.63	539.34	571.48	8%
	Venous Tube 2	0	2	DARK	DARK			2896	7%	NA	NA		
	Fingerstick 1	8	4	DARK	DARK					NA	NA	440.47	18%
	Fingerstick 2	3248	4024	3248	4024	3636	15%	3636	15%	497.72	383.23		
36	Venous Tube 1			DARK	DARK					NA	NA	243.76	4%
	Venous Tube 2	5550	5774	5550	5774	5662	3%	5662	3%	250.58	236.93		
	Fingerstick 1	5451	5482	5451	5482	5467	0%			256.97	254.95	244.04	6%
	Fingerstick 2	5896	5819	5896	5819	5858	1%	5662	4%	229.92	234.31		
37	Venous Tube 1	2669	2636	2669	2636	2653	1%			626.46	635.52	562.68	14%
	Venous Tube 2	3207	3328	3207	3328	3268	3%	2960	12%	505.30	483.46		
	Fingerstick 1	3589	2857	3589	2857	3223	16%			441.36	578.89	467.83	21%
	Fingerstick 2	4024	1391	4024				3490	17%	383.23	NA		
38	Venous Tube 1	3990	4851	3990	4851	4421	14%			387.32	301.15	296.59	23%
	Venous Tube 2	5263	5928	5263	5928	5596	8%	5008	16%	269.75	228.13		
	Fingerstick 1	7060	8062							NA	NA	273.83	2%
	Fingerstick 2	5157	5255	5157	5255	5206	1%	5206	1%	277.36	270.31		
Male (>=50 years old)	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV	
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
48	Venous Tube 1	3446	4284	3446	4284	3865	15%			463.64	354.06	370.80	17%
	Venous Tube 2	4415	4580	4415	4580	4498	3%	4181	12%	340.65	324.83		
	Fingerstick 1	9519	9146							NA	NA	234.57	0%
	Fingerstick 2	5825	5804	5825	5804	5815	0%	5815	0%	233.96	235.18		
49	Venous Tube 1	3507	3682	3507	3682	3595	3%			453.91	427.79	378.64	19%
	Venous Tube 2	4778	4572	4778	4572	4675	3%	4135	15%	307.27	325.57		
	Fingerstick 1	3835	4282	3835	4282	4059	8%			406.88	354.27	448.84	19%
	Fingerstick 2	3033	3266	3033	3266	3150	5%	3604	16%	539.75	494.45		
50	Venous Tube 1	3014	3544	3014	3544	3279	11%			543.76	448.17	548.08	19%
	Venous Tube 2	2577	5	2577	DARK			3045	16%	652.30	NA		
	Fingerstick 1	2688	2667	2688	2667	2678	1%			621.34	627.00	602.34	9%
	Fingerstick 2	2630	3111	2630	3111	2871	12%	2774	8%	637.19	523.83		
51	Venous Tube 1	2038	2088	2038	2088	2063	2%			851.99	828.97	830.55	11%
	Venous Tube 2	1880	2399	1880	2399	2140	17%	2101	10%	933.21	708.04		
	Fingerstick 1	2668	2452	2668	2452	2560	6%			626.73	690.58	568.47	19%
	Fingerstick 2	3288	3431	3288	3431	3360	3%	2960	16%	490.50	466.08		
52	Venous Tube 1	5529	6607	5529	6607	6068	13%			251.92	194.17	274.99	23%
	Venous Tube 2	4580	4535	4580	4535	4558	1%	5313	18%	324.83	329.03		



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53	Fingerstick 1	4321	4547	4321	4547	4434	4%	4226	6%	350.19	327.91	361.67	8%
	Fingerstick 2	3929	4105	3929	4105	4017	3%			394.84	373.75		
	Venous Tube 1	5593	5672	5593	5672	5633	1%	5167	12%	247.88	243.01	280.67	17%
	Venous Tube 2	4378	5023	4378	5023	4701	10%			344.36	287.43		
	Fingerstick 1	1523	1500	1523	1500	1512	1%			1183.54	1204.12		
Fingerstick 2	1098	1308	1098	1308	1203	12%	1357	15%	1723.41	1407.35	1379.61	18%	
54	Venous Tube 1	3752	3791	3752	3791	3772	1%	4337	15%	418.07	412.72	356.22	19%
	Venous Tube 2	4803	5003	4803	5003	4903	3%			305.75	288.97		
	Fingerstick 1	3565	2694	3565	2694	3130	20%	3453	17%	431.87	619.74	475.33	22%
	Fingerstick 2	3463	4088	3463	4088	3776	12%			460.89	375.71		
41	Venous Tube 1	4815	5059	4815	5059	4937	3%	5377	10%	304.15	284.67	264.48	13%
	Venous Tube 2	5727	5905	5727	5905	5816	2%			239.71	229.42		
	Fingerstick 1	3366	3642		3642			4575	18%	NA	433.54	335.29	25%
	Fingerstick 2	5131	4951	5131	4951	5041	3%			279.27	293.06		
42	Venous Tube 1	3152	3202	3152	3202	3177	1%	8153	3%	515.78	506.24	516.12	4%
	Venous Tube 2	3006	3252	3006	3252	3129	6%			545.46	496.99		
	Fingerstick 1	3547	3973	3547	3973	3760	8%	3915	6%	447.71	389.39	398.18	8%
	Fingerstick 2	4049	4091	4049	4091	4070	1%			380.26	375.36		
43	Venous Tube 1	4714	4577	4714	4577	4646	2%	4664	6%	312.79	325.11	318.22	8%
	Venous Tube 2	4361	5004	4361	5004	4683	10%			346.08	288.90		
	Fingerstick 1	10	0	DARK	DARK			5895	5%	NA	NA	230.46	8%
	Fingerstick 2	5669	6121	5669	6121	5895	5%			243.20	217.72		
44	Venous Tube 1	7414	6023	7414	6023	6719	15%	6110	16%	161.82	222.92	224.50	23%
	Venous Tube 2	5000	6002	5000	6002	5501	13%			289.21	224.06		
	Fingerstick 1	5788	6098	5788	6098	5943	4%	5545	10%	236.11	218.93	253.54	14%
	Fingerstick 2	4831	5461	4831	5461	5146	9%			302.81	256.31		
45	Venous Tube 1	1929	1731	1929	1731	1830	8%	1830	8%	906.52	1024.24	965.38	9%
	Venous Tube 2	1401	1364							NA	NA		
	Fingerstick 1	2625	2273	2625	2273	2449	10%	2354	8%	638.59	752.91	727.27	8%
	Fingerstick 2	2316	2202	2316	2202	2259	4%			737.03	780.54		
46	Venous Tube 1	7580	4482		4482			4253	5%	NA	334.09	358.08	6%
	Venous Tube 2	4190	4086	4190	4086	4138	2%			364.20	375.94		
	Fingerstick 1	3846	3628	3846	3628	3737	4%	3741	3%	405.44	435.58	419.81	4%
	Fingerstick 2	3749	3214	3749						418.42	NA		
47	Venous Tube 1	7052	6854					4035	1%	NA	NA	382.03	2%
	Venous Tube 2	4075	3994	4075	3994	4035	1%			377.22	386.84		
	Fingerstick 1	5282	4834	5282	4834	5058	6%	4643	12%	268.42	302.56	323.69	16%
	Fingerstick 2	3958	4498	3958	4498	4228	9%			391.23	332.55		
55	Venous Tube 1	3168	3482	3168	3482	3325	7%	2913	18%	512.69	457.86	583.96	23%
	Venous Tube 2	2256	2747	2256	2747	2502	14%			759.36	605.92		
	Fingerstick 1	3059	3168	3059	3168	3114	2%	2777	14%	534.36	512.69	609.02	16%
	Fingerstick 2	2419	2461	2419	2461	2440	1%			701.36	687.69		

**Table 19: Venous v. Fingerstick Comparison Summary**

Sample ID	Female		Male (20-49 years old)			Male (>=50 years old)		
	Venous Tube	Fingerstick	Sample ID	Venous Tube	Fingerstick	Sample ID	Venous Tube	Fingerstick
F71	35.14	33.69	M81	494.37	586.65	48	370.80	234.57
F72	71.23	72.82	M82	585.27	425.86	49	378.64	448.84
F73	121.30	77.05	M83	78.74	73.46	50	548.08	602.34
F74	61.49	59.62	M84	239.10	181.93	51	830.55	568.47
F75	50.04	83.46	M85	477.67	529.25	52	274.99	361.67
F76	CURL	34.90	M86	431.48	328.31	53	280.67	1379.61





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F77	71.31	55.78	M87	351.49	439.54	54	356.22	475.33
F78	27.65	38.35	M88	447.75	545.21	41	264.48	335.29
F79	76.60	105.47	M89	476.19	487.42	42	516.12	398.18
F80	80.49	75.19	M90	356.03	371.65	43	318.22	230.46
3	47.20	34.81	M91	288.82	390.58	44	224.50	253.54
7	69.44	76.19	21	365.96	400.27	45	965.38	727.27
8	36.94	73.24	23	197.38	247.05	46	358.08	419.81
11	46.98	60.42	24	373.98	320.79	47	382.03	323.69
12	50.92	33.34	25	451.00	481.14	55	583.96	609.02
13	85.37	61.32	26	418.59	341.21			
14	36.13	37.25	28	571.48	440.47			
15	70.11	49.57	36	243.76	244.04			
17	75.67	130.58	37	562.68	467.83			
18	79.78	71.55	38	296.59	273.83			

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## 9 ANALYTICAL SENSITIVITY

In accordance to CLSI guideline EP17-A2 for analytical sensitivity verification, 60 replicates of a blank sample and 60 replicates of the LLOQ were tested.

### 9.1 Verification of Limit of Blank

9.1.1 Acceptance Criteria: the percentage of measured blanks of the total blanks replicates should be equal or greater than 90%

9.1.2 When the results are calculated by cartridge, for a total of 60 replicates, 93% replicates returned OORL results. By grouping the results into 20 replicates of 3 cartridges, 100% returned OORL results.

### 9.2 Verification of Limit of Detection

9.2.1 Acceptance Criteria: the percentage of measureable results to the total LLOQ replicates should be equal or greater than 90%

9.2.2 When the results are calculated by cartridge, for a total of 60 replicates, 92% replicates returned quantifiable results. By grouping the results into 20 replicates of 3 cartridges, 95% returned quantifiable results.

9.3 The LLOQ sample was diluted 1:1 and 20 replicates of the 1/2xLLOQ sample were tested. Of 20 replicates, 95% returned quantifiable results, and the sample was diluted again. Of 20 replicates at 1/4xLLOQ, 63% were quantifiable, and the sample was diluted. Of 20 replicates at 1/8xLLOQ 50% returned quantifiable results.

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**Table 20: Blank Replicates**

All Tips		Intra-Cartridge			Inter-Cartridge		
Tip1	Tip2	Mean	%CV	Result	Mean	%CV	Result
17845	18686	18266	3%	OORL	21211	13%	OORL
23924	7	23924		OORL			
23659	21943	22801	5%	OORL			
21379	22093	21736	2%	OORL	19599	13%	OORL
16114	16777	16446	3%	OORL			
20069	21159	20614	4%	OORL			
23364	23587	23476	1%	OORL	21191	10%	OORL
18790	20538	19664	6%	OORL			
18919	21949	20434	10%	OORL			
20256	23363	21810	10%	OORL	20074	11%	OORL
20724	19727	20226	3%	OORL			
16687	19685	18186	12%	OORL			
22388	30322	26355	21%	OORL	24077	13%	OORL
24837	22584	23711	7%	OORL			
22185	22143	22164	0%	OORL			
20530	23560	22045	10%	OORL	19479	12%	OORL
19487	18949	19218	2%	OORL			
16778	17571	17175	3%	OORL			
31913	31	31913		OORL	26848	15%	OORL
24046	22166	23106	6%	OORL			
30187	25927	28057	11%	OORL			
15012	18337	16675	14%	OORL	19068	17%	OORL
22743	23034	22889	1%	OORL			
17311	17969	17640	3%	OORL			
17315	16923	17119	2%	OORL	19860	12%	OORL
23114	21343	22229	6%	OORL			
19811	20653	20232	3%	OORL			
24901	23442	24172	4%	OORL	22981	22%	OORL
22591	13517	18054	36%	OORL			
27373	26060	26717	3%	OORL			
18591	19374	18983	3%	OORL	20440	9%	OORL
19711	23528	21620	12%	OORL			
20222	21215	20719	3%	OORL			
18307	23367	20837	17%	OORL	23369	31%	OORL
18129	18337	18233	1%	OORL			
25277	36795	31036	26%	OORL			
23559	27190	25375	10%	OORL	20243	21%	OORL
17307	18698	18003	5%	OORL			
16882	17823	17353	4%	OORL			
21065	21206	21136	0%	OORL	20192	13%	OORL
21330	23530	22430	7%	OORL			
16753	17267	17010	2%	OORL			
19038	14316	16677	20%	OORL	18391	16%	OORL

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20964	21843	21404	3%	OORL			
15503	18679	17091	13%	OORL			
21415	23974	22695	8%	OORL			
19285	21160	20223	7%	OORL	21282	8%	OORL
19970	21887	20929	6%	OORL			
16851	19594	18223	11%	OORL			
13305	14550	13928	6%	40.11	19812	31%	OORL
27404	27167	27286	1%	OORL			
22295	24710	23503	7%	OORL			
24235	25097	24666	2%	OORL	24551	7%	OORL
23444	27524	25484	11%	OORL			
14308	16813	15561	11%	26.84			
22754	22288	22521	1%	OORL	19643	17%	OORL
20647	21049	20848	1%	OORL			
16415	17276	16846	4%	OORL			
14894	15897	15396	5%	28.02	15981	6%	OORL
14923	16478	15701	7%	25.87			

**Table 21: LLOQ Replicates**

All Tips		Intra-Cartridge			Inter-Cartridge		
Tip1	Tip2	Mean	%CV	Result	Mean	%CV	Result
14392	13470	13931	5%	40.08			
12450	14413	13432	10%	44.94	14506	10%	34.99
15939	16370	16155	2%	OORL			
16500	16876	16688	2%	OORL			
12448	11724	12086	4%	60.37	15184	16%	29.58
17057	16500	16779	2%	OORL			
9876	2168	9876		95.94			
13823	12638	13231	6%	47.01	11679	13%	65.83
11061	10997	11029	0%	75.48			
18506	22530	20518	14%	OORL			
12391	13695	13043	7%	49.02	16073	23%	OORL
14658	14660	14659	0%	33.71			
10455	12082	11269	10%	71.78			
11271	11099	11185	1%	73.05	10641	11%	81.84
8492	10446	9469	15%	104.42			
10550	14235	12393	21%	56.52			
10242	11902	11072	11%	74.80	12177	13%	59.21
12927	13204	13066	1%	48.78			
14112	15099	14606	5%	34.15			
19693	19688	19691	0%	OORL	14098	38%	38.55
9087	6908	7998	19%	142.49			
10534	10907	10721	2%	80.49			
7342	6480	6911	9%	181.10	8148	25%	137.95
6371	7255	6813	9%	185.19			
8789	9406	9098	5%	112.85	10970	20%	76.42

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9190	11133	10162	14%	90.42			
13350	13949	13650	3%	42.77			
16013	14976	15495	5%	27.31			
7929	8731	8330	7%	132.69	12653	28%	53.41
13096	15171	14134	10%	38.23			
9738	12185	10962	16%	76.55			
7060	8673	7867	14%	146.58	10460	24%	84.97
10966	14140	12553	18%	54.59			
12734	13209	12972	3%	49.80			
8882	10114	9498	9%	103.79	11725	15%	65.19
12527	12884	12706	2%	52.80			
8431	10630	9531	16%	103.09			
8684	9896	9290	9%	108.40	9996	12%	93.59
11036	11296	11166	2%	73.34			
13027	11125	12076	11%	60.50			
9139	9543	9341	3%	107.25	10488	16%	84.48
8717	11379	10048	19%	92.58			
11455	11525	11490	0%	68.51			
7733	9675	8704	16%	122.58	10980	19%	76.26
11460	14029	12745	14%	52.35			
11090	11148	11119	0%	74.07			
7652	6867	7260	8%	167.46	8861	21%	118.60
8150	8257	8204	1%	136.33			
11648	10742	11195	6%	72.90			
14154	12429	13292	9%	46.38	12125	10%	59.87
11145	12632	11889	9%	62.97			
8194	8621	8408	4%	130.52			
7366	7563	7465	2%	160.03	7863	6%	146.69
7565	7869	7717	3%	151.42			
8167	9730	8949	12%	116.43			
8403	9571	8987	9%	115.49	9652	13%	100.51
10719	11324	11022	4%	75.59			
7357	7637	7497	3%	158.89			
11353	13632	12493	13%	55.31	9470	28%	104.40
7183	9659	8421	21%	130.15			

**Table 22: Diluted LLOQ Replicates**

1/2 LLOQ					1/4 LLOQ					1/8 LLOQ				
All Tips		Intra-Cartridge			All Tips		Intra-Cartridge			All Tips		Intra-Cartridge		
Tip1	Tip2	Mean	%CV	Result	Tip1	Tip2	Mean	%CV	Result	Tip1	Tip2	Mean	%CV	Result
14558	9469	12014	30%	61.31	14210	13154	13682	5%	42.45	12980	15824	14402	14%	35.87
15082	15644	15363	3%	28.26	9462	8268	8865	10%	118.49	9129	11519	10324	16%	87.42
14321	14336	14329	0%	36.50	18103	18898	18501	3%	OORL	10693	11966	11330	8%	70.87
10644	10511	10578	1%	82.93	16741	19458	18100	11%	OORL	18626	18885	18756	1%	OORL
8735	13243	10989	29%	76.11	14897	14034	14466	4%	35.33	21035	22133	21584	4%	OORL
12293	8965	10629	22%	82.04	16010	18553	17282	10%	OORL	12671	15046	13859	12%	40.76



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15213	16149	15681	4%	26.00	11093	9458	10276	11%	88.30	13415	18142	15779	21%	25.33
13385	14693	14039	7%	39.08	11961	12879	12420	5%	56.18	18790	22693	20742	13%	OORL
10442	11754	11098	8%	74.39	88	69			NA	16611	17784	17198	5%	OORL
14307	13993	14150	2%	38.08	12192	11911	12052	2%	60.82	16730	17205	16968	2%	OORL
14986	14510	14748	2%	32.98	8768	8881	8825	1%	119.50	15453	25377	20405	34%	OORL
9427	10256	9842	6%	96.63	16156	26	16156		OORL	15574	18819	17197	13%	OORL
10026	10533	10280	3%	88.23	11623	13266	12445	9%	55.89	13358	13406	14382	10%	36.04
13836	12537	13187	7%	47.48	15270	17618	16444	10%	OORL	12321	14118	13170	10%	47.66
15546	15875	15711	1%	25.80	14085	17560	15823	16%	25.04	17497	18518	17008	4%	OORL
12619	12669	12644	0%	53.52	12831	13748	13290	5%	46.40	16933	18677	17805	7%	OORL
9427	10256	9842	6%	96.63	15863	16387	16125	2%	OORL	16459	14913	15676	7%	26.04
20645	22041	21343	5%	OORL	17066	18180	17623	4%	OORL	18024	20318	19171	8%	OORL
14217	14400	14309	1%	36.68	7746	8915	8331	10%	132.68	14017	14899	14458	4%	35.39
15177	14265	14721	4%	33.20	15022	13912	14467	5%	35.31	10704	11907	11306	8%	71.23

**Table 23: Analytical Sensitivity Summary**

Blank Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% OORL	Mean	%CV
Intra-Cartridge	60	20979	18%	OORL	93%	30.21	22%
Inter-Cartridge	20	20914	12%	OORL	100%	NA	NA

LLOQ Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% Quantifiable	Mean	%CV
Intra-Cartridge	60	11372	26%	78.23	92%	88.55	47%
Inter-Cartridge	20	11387	20%	70.01	95%	79.60	41%

1/2 LLOQ Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% Quantifiable	Mean	%CV
Intra-Cartridge	20	13275	21%	46.55	95%	55.57	46%

1/4 LLOQ Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% Quantifiable	Mean	%CV
Intra-Cartridge	19	13956	23%	39.85	83%	68.03	55%

1/8 LLOQ Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% Quantifiable	Mean	%CV
Intra-Cartridge	20	16076	20%	OORL	50%	47.66	45%

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## 10 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. Percentage of recovery compared to CLIA reported EDTA plasma sample value was used to compare anticoagulant effect. The average recoveries were within 20% of reported value. It indicated all three matrices performed equivalently in the Theranos Total Testosterone assay.

**Table 24: EDTA Plasma**

Serum Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV	%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
243	3613	4136		4136			5134	20%	NA	370.22	279.03	28%	115%
	4217	4875	4217	4875	4546	10%			361.24	299.18			
	6087	6356	6087	6356	6222	3%			219.51	205.89			
212	2904	3177	2904	3177	3041	6%	3906	18%	567.97	510.97	397.77	25%	188%
	4315	4517	4315	4517	4416	3%			350.82	330.74			
	4421	4100	4421	4100	4261	5%			340.05	374.33			
503	2700	3051	2700	3051	2876	9%	3045	15%	618.15	536.01	537.32	17%	107%
	3439	3749	3439	3749	3594	6%			464.78	418.42			
	2684	2645	2684	2645	2665	1%			622.41	633.02			
336	4110	3970	4110	3970	4040	2%	3456	14%	373.18	389.76	461.97	17%	137%
	2962	3316	2962	3316	3139	8%			554.98	485.56			
	2938	3442	2938	3442	3190	11%			560.29	464.29			
32	11371	13746	11371	13746	12558	4%	13796	31%	70.25	NA	41.35	22%	129%
	17899	18871	17899	18871	18385	4%			OORL	OORL			
	10560	10278	10560	10278	10419	2%			83.23	88.26			
<20	16348	16309	16348	16309	16429	1%	15007	11%	OORL	OORL	30.93	18%	NA
	13192	13980	13192	13980	13586	4%			47.42	39.63			
			DARK	DARK					NA	NA			
<20	15537	15737	15537	15737	15637	1%	14820	9%	27.01	25.62	32.41	29%	NA
	13850	13164	13850	13164	13507	4%			40.84	47.72			
	13935	16696	13935	16696	15316	13%			40.04	OORL			
627	3674	3783	3674	3783	3729	2%	3692	12%	428.93	413.80	426.37	13%	68%
	3669	4445	3669	4445	4057	14%			429.64	337.69			
	3230	3351	3230	3351	3291	3%			501.02	479.49			
430	2931	3286	2931	3286	3109	8%	3382	12%	561.86	490.86	474.22	14%	110%
	3058	3322	3058	3322	3190	6%			534.56	484.51			
	3790	3905	3790	3905	3848	2%			412.86	397.86			
288	4402	4774	4402	4774	4588	6%	4277	9%	341.95	307.61	354.80	11%	123%
	3980	3952	3980	3952	3966	0%			388.54	391.98			
	2276	2805							NA	NA			
193	8412	8650	8412	8650	8531	2%	7703	13%	130.40	123.98	151.89	21%	79%
	14095	15537							NA	NA			
	6731	7018	6731	7018	6875	3%			188.70	176.77			
279	3722	4066		4066			4435	8%	NA	378.27	338.63	10%	121%
	4398	4367	4398	4367	4383	1%			342.35	345.47			

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	4321	5025	4321	5025	4673	11%			350.19	287.27			
424	4313	4192	4313	4192	4253	2%	3553	17%	351.02	363.97	446.80	22%	105%
	2883	2954	2883	2954	2919	2%			572.81	556.74			
	3245	3731	3245	3731	3488	10%			498.27	420.91			
354	3638	4308	3638	4308	3973	12%	4415	11%	434.12	351.54	340.62	15%	96%
	4136	4956	4136	4956	4546	13%			370.22	292.66			
	4769	4685	4769	4685	4727	1%			308.04	315.34			
300	3993	4406	3993	4406	4200	7%	3883	11%	386.96	341.55	400.72	14%	134%
	3746	4036	3746	4036	3891	5%			418.84	381.80			
	3946	3168	3946	3168	3557	15%			392.72	312.69			
281	3524	3735	3524	3735	3630	4%	3947	11%	451.26	420.35	392.59	13%	140%
	1687	1555							NA	NA			
	4016	4513	4016	4513	4265	8%			384.19	331.12			
275	3700	3513	3700	3513	3607	4%	4494	17%	425.24	452.97	332.95	24%	121%
	4473	4792	4473	4792	4633	5%			334.96	306.08			
	5008	5477	5008	5477	5243	6%			288.59	255.27			
341	4408	4244	4408	4244	4326	2%	4078	9%	341.35	358.32	376.91	13%	111%
	4223	4377	4223	4377	4300	3%			360.59	344.46			
	3739	3475	3739	3475	3607	5%			419.80	458.97			
303	4243	4650	4243	4650	4447	6%	4688	18%	358.43	318.46	315.07	26%	104%
	5466	5562	5466	5562	5514	1%			255.99	249.82			
	2803	3519		3519					NA	452.04			
<20	17522	16509	17522	16509	17016	4%	19304	14%	OORL	OORL	OORL	OORL	OORL
	22067	21119	22067	21119	21593	3%			OORL	OORL			
	373	149		DARK					NA	NA			

**Table 25: Li Heparin Plasma**

Serum Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration				
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	%Recovery
243	6036	6486	6036	6486	6261	5%	5593	16%	222.22	199.70	247.88	26%	102%
	5232	5999	5232	5999	5616	10%			271.94	224.22			
	3652	4212		4212					NA	361.78			
212	3159	3104	3159	3104	3132	1%	3518	18%	514.42	525.23	452.19	21%	213%
	2837	3388	2837	3388	3113	13%			583.65	473.21			
	4365	4255	4365	4255	4310	2%			345.68	357.14			
503	2273	2899	2273	2899	2586	17%	3089	21%	752.91	569.12	528.29	28%	105%
	1725	2011							NA	NA			
	3384	3799	3384	3799	3592	8%			473.88	411.65			
336	2774	2890	2774	2890	2832	3%	3399	22%	599.09	571.19	471.37	25%	140%
	2930	432	2930						562.09	NA			
	4296	4105	4296	4105	4201	3%			352.80	373.75			
32	11857	12535	11857	12535	12196	4%	12580	7%	63.39	54.80	54.27	19%	170%
	12015	13912	12015	13912	12964	10%			61.29	40.26			
	9246	8497							NA	NA			
<20	12706	14992	12706	14992	13849	12%	18325	25%	52.80	31.05	OORL	OORL	OORL
	17230	17192	17230	17192	17211	0%			OORL	OORL			

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	23424	24406	23424	24406	23915	3%			OORL	OORL				
<20	11786	11299	11786	11299	11543	3%	12845	19%	64.36	71.32	51.22	53%	NA	
	8873	10273		10273		NA			88.35					
	15276	15589	15276	15589	15433	1%			28.90	26.64				
	3153	3188	3153	3188	3171	1%			515.58	508.88				
627	1664	1944					3236	2%	NA	NA	499.87	3%	80%	
	3280	3324	3280	3324	3302	1%			491.93	484.16				
	4487	3473	4487	3473	3980	18%			333.61	459.29				
430	3581	4048	3581	4048	3815	9%	3826	10%	442.56	380.38	408.09	12%	95%	
	3514	3852	3514	3852	3683	6%			452.82	404.66				
	3901	2867	3901	2867	3384	22%			398.36	576.54				
288	3210	3261	3210	3261	3236	1%	3699	26%	504.74	495.35	425.43	28%	148%	
	5254	1555	5254						270.38	NA				
	7602	7298	7602	7298	7450	3%			155.27	166.03				
193	8725	8296	8725	8296	8511	4%	7980	8%	122.03	133.66	143.02	14%	74%	
	4281	4530							NA	NA				
	5963	5749	5963	5749	5856	3%			226.19	238.40				
279	3602	3679	3602	3679	3641	1%	4500	24%	439.42	428.21	332.33	29%	119%	
	4313	3696	4313	3696	4005	11%			351.02	425.80				
	4295	3848	4295	3848	4072	8%			352.90	405.18				
424	2645	3257	2645	3257	2951	15%	3698	17%	633.02	496.08	425.59	25%	100%	
	4108	4032	4108	4032	4070	1%			373.41	382.28				
	3575	3862	3575	3862	3719	5%			443.46	403.36				
354	2329	2880		2880			3785	16%	NA	573.51	413.47	22%	117%	
	4186	4424	4186	4424	4305	4%			364.64	339.76				
	3334	3466	3334	3466	3400	3%			482.42	460.41				
300	3467	3445	3467	3445	3456	0%	3421	2%	460.25	463.80	467.79	2%	156%	
	3391	3108	3391						472.71	NA				
	3136	3349		3349					NA	479.83				
281	4810	4585	4810	4585	4698	3%	4664	18%	304.57	324.37	317.22	28%	113%	
	4842	5733	4842	5733	5288	12%			301.90	239.35				
	13741	15407							NA	NA				
275	4242	3922	4242	3922	4082	6%	4585	13%	358.53	395.71	324.37	18%	118%	
	4895	5281	4895	5281	5088	5%			297.55	268.49				
	4377	4201	4377	4201	4289	3%			344.46	362.99				
341	4728	12	4728	DARK			4107	12%	311.57	NA	373.57	15%	110%	
	3574	3653	3574	3653	3614	2%			443.61	431.94				
	4699	4251	4699	4251	4475	7%			314.10	357.57				
303	5263	5415	5263	5415	5339	2%	4855	9%	269.75	259.35	300.85	12%	99%	
	4841	4659	4841	4659	4750	3%			301.98	317.65				
	17209	17637	17209	17637	17423	2%			OORL	OORL				
<20	11165	14254	11165	14254	12710	17%	16199	18%	73.36	37.15	OORL	OORL	OORL	
	18374	18553	18374	18553	18464	1%			OORL	OORL				



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**Table 26: Serum**

Serum Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration				%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	
243	3609	3898	3609	3898	3754	5%	4652	17%	438.38	398.74	318.26	24%	131%
	4841	4499	4841	4499	4670	5%			301.98	332.45			
	5633	5433	5633	5433	5533	3%			245.40	258.16			
212	2909	5	2909	DARK			3142	6%	566.83	NA	517.67	7%	244%
	3139	3392	3139	3392	3266	5%			518.31	472.54			
	3129	5793	3129						520.27	NA			
503	8752	9679					2626	9%	NA	NA	638.38	10%	127%
	2901	2456	2901	2456	2679	12%			568.66	689.29			
	2426	2720	2426	2720	2573	8%			699.05	612.90			
336	3179	3235	3179	3235	3207	1%	3319	14%	510.59	500.10	485.00	15%	144%
	3142	3420	3142	3420	3281	6%			517.72	467.89			
	2792	4147	2792	4147	3470	28%			594.61	368.98			
32	10736	13370		13370			13319	5%	NA	45.57	46.09	15%	144%
	12415	13320	12415	13320	12868	5%			56.24	46.08			
	13131	14358	13131	14358	13745	6%			48.07	36.25			
<20	10961	11983		11983			13660	10%	NA	61.71	42.66	32%	NA
	13698	15622	13698	15622	14660	9%			42.29	26.41			
	12773	14224	12773	14224	13499	8%			52.05	37.42			
<20	13858	12255	13858	12255	13057	9%	11703	12%	40.76	58.22	65.51	28%	NA
	12072	10675	12072	10675	11374	9%			60.55	81.26			
	10024	11331	10024	11331	10678	9%			93.04	70.85			
627	3089	3042	3089	3042	3066	1%	3404	16%	528.24	537.88	470.51	16%	75%
	3128	3136	3128	3136	3132	0%			520.47	518.90			
	3623	4407	3623	4407	4015	14%			436.31	341.45			
430	2715	2846	2715	2846	2781	3%	2988	10%	614.20	581.50	549.36	11%	128%
	3690	3529	3090	3529	3310	9%			528.04	450.49			
	2922	2825	2922	2825	2874	2%			563.89	586.54			
288	3315	3721	3315	3721	3518	8%	3241	9%	485.73	422.30	499.06	11%	173%
	3031	3167	3031	3167	3099	3%			540.17	512.88			
	2835	3375	2835	3375	3105	12%			584.13	475.40			
193	6746	6820	6746	6820	6783	1%	7415	10%	188.05	184.89	161.78	16%	84%
	8132	7963	8132	7963	8048	1%			138.43	143.55			
	135	34	DARK	DARK					NA	NA			
279	5024	4553	5024	4553	4789	7%	5430	11%	287.35	327.34	258.36	17%	93%
	5106	5941	5106	5941	5524	11%			281.13	227.41			
	5869	6086	5869	6086	5978	3%			231.45	219.56			
424	4610	5252	4610	5252	4931	9%	4194	16%	322.08	270.52	363.75	19%	86%
	3492	3634	3492	3634	3563	3%			456.27	434.70			
	4159	4017	4159	4017	4088	2%			367.64	384.07			
354	5001	5982	5001				4539	25%	289.13	NA	328.63	32%	93%
	5931	1588	5931						227.96	NA			
	3573	3652	3573	3652	3613	2%			443.76	432.09			

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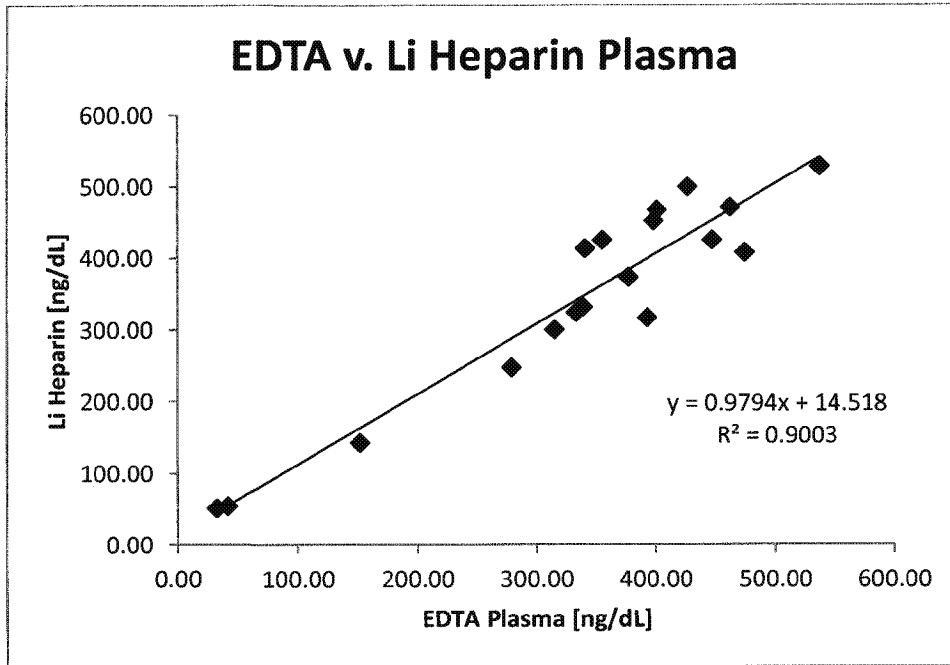
300	2700	3417	2700	3417	3059	17%	3376	12%	618.15	468.38	475.32	16%	158%
	3614	3844	3614	3844	3729	4%			437.64	405.70			
	3226	3452	3226	3452	3339	5%			501.76	462.67			
281	5272	5094	5272	5094	5183	2%	4507	12%	269.12	282.03	331.71	15%	118%
	4238	4363	4238	4363	4301	2%			358.97	345.88			
	3990	4084	3990	4084	4037	2%			387.32	376.17			
275	4293	4489	4293	4489	4391	3%	4964	11%	353.11	333.41	292.00	14%	106%
	5728	5350	5728	5350	5539	5%			239.65	263.72			
	4984	4942	4984	4942	4963	1%			290.46	293.77			
341	2908	3416	2908	3416	3162	11%	3346	7%	567.06	468.55	480.43	9%	141%
	3311	3524	3311	3524	3418	4%			486.43	451.26			
	3443	3471	3443	3471	3457	1%			464.13	459.61			
303	4139	4452	4139	4452	4296	5%	4612	18%	369.88	337.00	321.86	22%	106%
	3744	4212	3744	4212	3978	8%			419.11	361.78			
	5118	6009	5118	6009	5564	11%			280.23	223.68			
<20	14663	15447	14663	15447	15055	4%	15378	3%	33.68	27.65	28.15	12%	NA
	11399	12927							NA	NA			
	15961	15442	15961	15442	15702	2%			OORL	27.69			

**Table 27: EDTA v. Li Heparin v. Serum comparison**

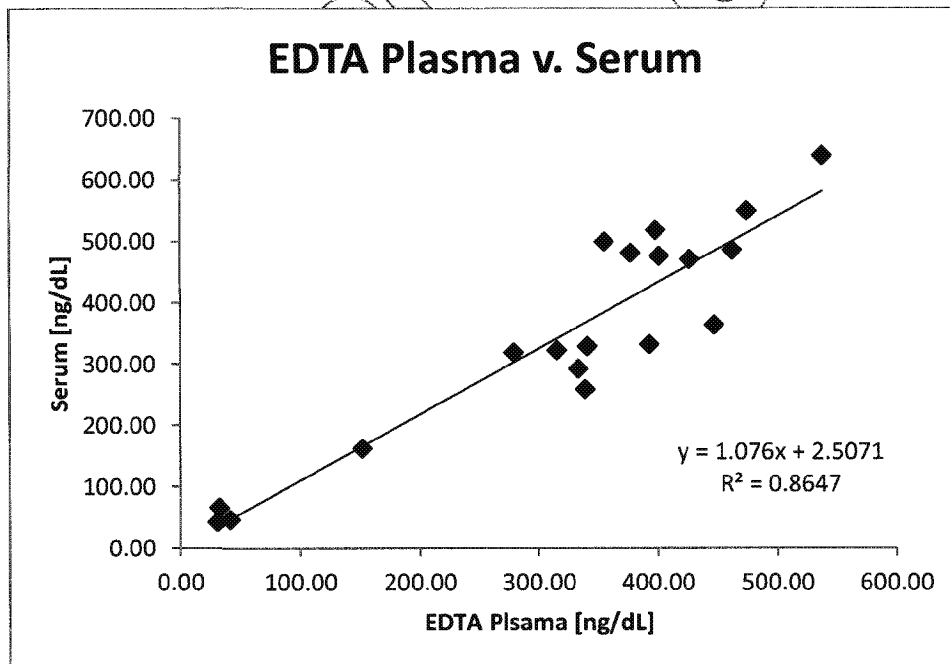
Sample ID	CLIA Reported Serum	Theranos Reported		
		EDTA	Li Heparin	Serum
Patient 48	243	279.03	247.88	318.26
Patient 49	212	397.77	452.19	517.67
Patient 50	503	537.32	528.29	638.38
Patient 51	336	461.97	471.37	485.00
Patient F71	32	41.35	54.27	46.09
Patient F72	<20	30.93	OORL	42.66
Patient F73	<20	32.41	51.22	65.51
Patient M81	627	426.37	499.87	470.51
Patient M82	430	474.22	408.09	549.36
Patient M83	288	354.80	425.43	499.06
Patient M84	193	151.89	143.02	161.78
Patient M85	279	338.63	332.33	258.36
Patient M86	424	446.80	425.59	363.75
Patient M87	354	340.62	413.47	328.63
Patient M88	300	400.72	467.79	475.32
Patient M89	281	392.59	317.22	331.71
Patient M90	275	332.95	324.37	292.00
Patient T1	341	376.91	373.57	480.43
Patient T2	303	315.07	300.85	321.86
Patient T3	<20	OORL	OORL	28.15

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**Figure 7: EDTA v. Li Heparin Plasma**



**Figure 8: EDTA Plasma v Serum**



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## 11 INTERFERENCE

The recovery of analyte spiked into hemolyzed (250mg/dL Hemoglobin), icteric (20mg/dL Bilirubin), and lipemic (542mg/dL Triglycerides) serum samples were evaluated on the Theranos System and compared to predicate method. Hemolyzed samples didn't show significant difference with hemoglobin up to 250mg/dL. Icteric samples didn't show significant difference with Bilirubin up to 20mg/dL. Lipemic samples had high recovery at low and middle Total Testosterone level with triglycerides level at 542mg/dL. Results of lipemic samples should be interpreted with cautions.

**Table 28: Hemolyzed Samples**

Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV	%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
1124	1102	1385	1102	1385	1244	16%	1274	19%	1736.09	1318.33	1451.16	17%	129%
	1469	1580	1469	1580	1525	5%			1232.97	1135.37			
	954	1151	954	1151	1053	13%			OORH	1631.11			
493	2933	3333	2933	3333	3133	9%	3031	8%	561.41	482.59	540.10	9%	110%
	2814	2790	2814	2790	2802	1%			589.21	595.10			
	3036	3282	3036	3282	3159	6%			539.13	491.57			
70.5	8976	9389	8976	9389	9183	3%	10561	16%	15.76	106.18	83.21	35%	118%
	11260	12620	11260	12620	11940	8%			71.91	59.80			
	4893	6401							NA	NA			
<20	16041	18224	16041	18224	17133	9%	20201	15%	OORL	OORL	OORL	OORL	OORL
	22843	24150	22843	24150	23497	4%			OORL	OORL			
	18601	21345	18601	21345	19973	10%			OORL	OORL			

**Table 29: Icteric Samples**

Reported Value [ng/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV	%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
>1600	1176	1452	1176	1452	1314	15%	1248	11%	1590.89	1249.36	1485.09	11%	NA
	1141	1164	1141	1164	1153	1%			1647.77	1609.95			
	1181	1375	1181	1375	1278	11%			1583.09	1329.26			
905	2271	2660	2271	2660	2466	11%	2305	10%	753.67	628.91	740.92	11%	82%
	2102	2106	2102	2106	2104	0%			822.72	820.96			
	2205	2488	2205	2488	2347	9%			779.33	679.15			
132	7270	10620	7270	10620	8945	26%	9076	23%	167.07	82.20	113.35	45%	86%
	10810	11336	10810	11336	11073	3%			79.01	70.77			
	6869	7553	6869	7553	7211	7%			182.84	156.94			
22.1	17725	20839	17725	20839	19282	11%	17832	16%	OORL	OORL	OORL	OORL	OORL
	14090	16580	14090	16580	15335	11%			38.62	OORL			
	16492	21265	16492	21265	18879	18%			OORL	OORL			

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**Table 30: Lipemic Samples**

1133	1122	1167	1122	1167	1145	3%	1303	15%	1680.36	1605.14	1413.12	17%	125%
	1473	1556	1473	1556	1515	4%			1229.17	1155.18			
	1105	1397	1105	1397	1251	17%			1710.63	1305.44			
572	1129	1320	1129	1320	1225	11%	1327	9%	1668.21	1392.71	1384.90	11%	242%
	1384	1413	1384	1413	1399	1%			1319.41	1288.63			
	1277	1436	1277	1436	1357	8%			1446.60	1265.19			
79.7	3960	4427	3960	4427	4194	8%	4586	10%	390.99	339.48	324.31	13%	407%
	5142	4387	5142	4387	4765	11%			278.36	345.45			
	4563	5035	4563	5035	4799	7%			326.41	286.50			
<20	9336	9333	9336	9333	9335	0%	10144	12%	107.36	107.43	90.76	23%	NA
	10087	0	10087	DARK					91.83	NA			
	11818	20	11818	DARK					63.92	NA			

**12 CROSSREACTIVITY**

Cross-reactivity was tested in the assay development. Three levels of each “Test Substance” were tested. The calculated concentrations for all “Test Substance” were OORL. No cross-reactivity was observed with Dihydrotestosterone (DHT), Dihydroepiandrosterone (DHEA), Progesterone and Estradiol.

**Table 31: Cross-reactive Samples**

Test Substance	[TST], ng/mL	[Test Substance], ng/mL	Signal, RLU				Conc, ng/mL		
			Tip 1 Mean RLU	CV %	Tip 2 Mean RLU	CV %	Mean Conc	CV %	% Recovery
Control	15.0	0.0	325	10.1	348	16.3	14.0	17.2	93
	10.0	0.0	396	14.9	432	13.7	10.7	20.7	107
	5.0	0.0	642	11.6	749	10.5	4.8	14.4	96
	2.5	0.0	1066	6.8	1164	2.3	2.6	3.2	104
	1.0	0.0	1950	2.7	2205	2.0	1.0	3.3	99
	0.0	0.0	5105	24.2	6265	17.9	OORL	-	-
DHT	0.0	2.5	4447	7.1	5216	6.9	OORL	-	0
	0.0	1.0	5415	4.4	6736	0.0	OORL	-	0
	0.0	0.5	4736	-	6187	8.8	OORL	-	0
	0.0	0.0	5775	3.2	6760	7.0	OORL	-	0
DHEA	0.0	30.0	6118	14.8	7086	0.6	OORL	-	0
	0.0	10.0	5766	5.1	6592	9.2	OORL	-	0
	0.0	3.3	6656	3.0	7917	2.9	OORL	-	0
	0.0	0.0	6013	6.4	7368	3.5	OORL	-	0

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Progesterone	0.0	100.0	5699	12.4	6709	17.3	OORL	-	0
	0.0	50.0	5028	1.2	6005	6.3	OORL	-	0
	0.0	25.0	5587	28.7	6656	18.6	OORL	-	0
	0.0	0.0	5667	16.2	6783	11.8	OORL	-	0
Estradiol	0.0	2.0	6118	4.6	7652	5.1	OORL	-	0
	0.0	1.0	6434	0.5	7590	2.6	OORL	-	0
	0.0	0.5	5495	10.1	6563	16.3	OORL	-	0
	0.0	0.0	5683	9.5	6617	15.2	OORL	-	0

Tip 1  $Conc = 0.579 * (((5112.115 - 144.959) / (S - 144.959)) - 1) ^ (1 / 1.018)$   
 $S_{Min} = 297; S_{Max} = 2223$

Tip 2  $Conc = 0.491 * (((6283.617 - 118.159) / (S - 118.159)) - 1) ^ (1 / 0.956)$   
 $S_{Min} = 317; S_{Max} = 2494$

### 13 SAMPLE STABILITY

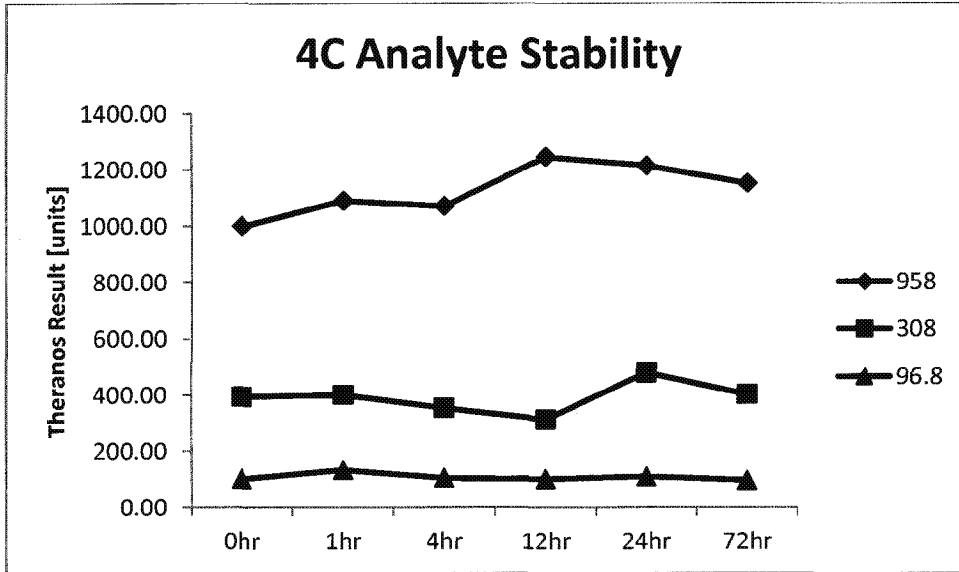
The stability of calibrators stored at 4 °C and room temperature were tested to mimic the conditions that clinical samples may be stored and handled. Samples were transferred from -80 °C to either room temperature or 4 °C at the 0hr time point, and stored at those temperatures for the remainder of testing. Overall the analyte stability data indicates that the samples can be processed up to 72 hours when stored at 4 °C and up to 72 hour when stored at room temperature.

**Table 32: Analyte Stability Summary**

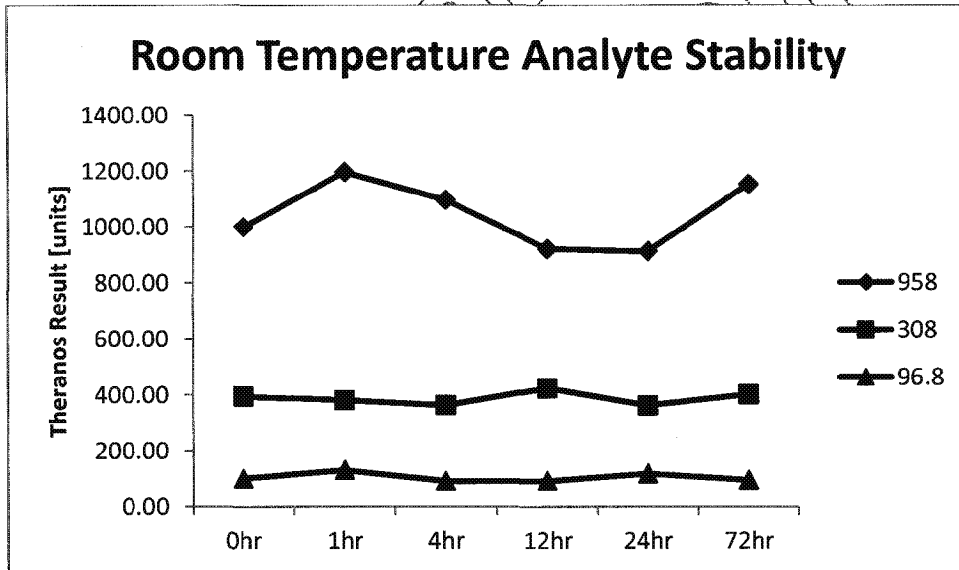
CLIA reported value (ng/dL)	Theranos Results (ng/dL)											
	4 °C						Room Temperature					
	0hr	1hr	4hr	12hr	24hr	72hr	0hr	1hr	4hr	12hr	24hr	72hr
958	999.4	1090.4	1071.1	1245.5	1214.5	1151.7	999.4	1195.8	1095.6	921.4	912.8	1151.7
308	394.8	400.6	353.6	312.4	479.5	401.8	394.8	381.5	363.0	424.7	362.6	401.8
96.8	101.9	132.7	104.6	100.3	109.7	95.8	101.9	131.9	91.5	92.1	119.4	95.8

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**Figure 9: Analyte Stability at 4 °C**



**Figure 10: Analyte Stability at Room Temperature**

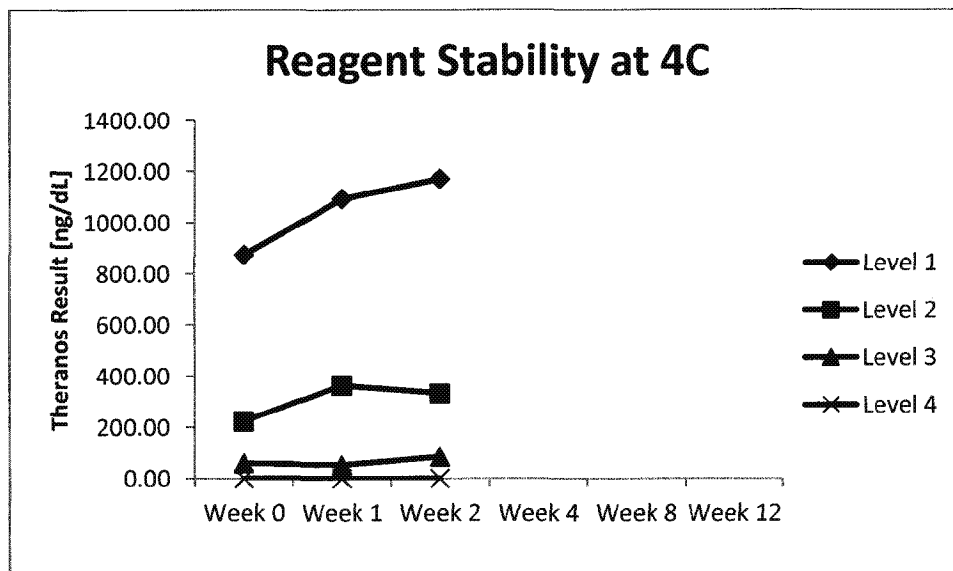


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#### 14 Reagent Stability

Reagents have been tested for up to 2 weeks of stability. Further testing is ongoing.

**Figure 11: Reagent Stability at 4°C**





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