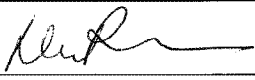
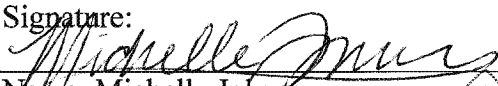



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## 1 ASSAY BACKGROUND

Thyroxine (T4) circulates bound to thyroid transport proteins especially thyroid binding globulin. When levels of binding proteins are normal, increased T4 levels may indicate hyperthyroidism, and decreased T4 levels may indicate hypothyroidism. T4 synthesis is stimulated by TSH and TRH, and T4 exerts negative feedback on both TSH and TRH release. In cases with abnormal levels of thyroid binding proteins, such as in pregnancy, abnormal T4 levels may not be a good indicator of thyroid function. Furthermore, total T4 levels may not correlate well with thyroid function in obese patients and in children. The total T4 (tT4) test measures the amount of bound and unbound T4 in circulation. Normal levels of tT4 are 4.5 – 12.5 ug/dL.

### 1.1 Theranos System Specification

This assay is designed to detect total Thyroxine (tT4) in human EDTA plasma, Li Heparin Plasma, and Serum. The assay has a reportable range of 0.8 – 27.2 ug/dL and is calibrated to the European Commission Certified Reference Material IRMM-468. No NIBSC WHO material is available for thyroxine. Samples are stable at 4C or RT for 24 hours. If samples are not analyzed within 24 hours of collection, samples should be stored at -20C or lower.

### 1.2 Reference Assay

The SIEMENS Immulite 2000 Total T4 test was used as a predicate method. The reportable range is 1 – 24 ug/dL. Hemolysis (up to 512 mg/dL hemoglobin), lipemia (up to 5000 mg/dL triglycerides), and icterus (up to 200 mg/L bilirubin), does not affect assay precision. 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 values, and a minimum of six unique standard concentrations must be within the assay range.

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### 3.2 Calibration 1 (Edison 3.X)

Of 8 levels, all had a back calculated mean value within  $100 \pm 20\%$  ( $100 \pm 25\%$  at LLOQ and ULOQ standards) of their nominal values. This calibration set was used to analyze Accuracy/Comparability (0), Dilution Linearity (0), Reference Range Verification (7), Blood Collection Device Verification (8), Analytical Sensitivity (0), Anticoagulant Comparison (10), Interference (0), and Analyte Stability (13).

**Table 1: Calibration 1 Data**

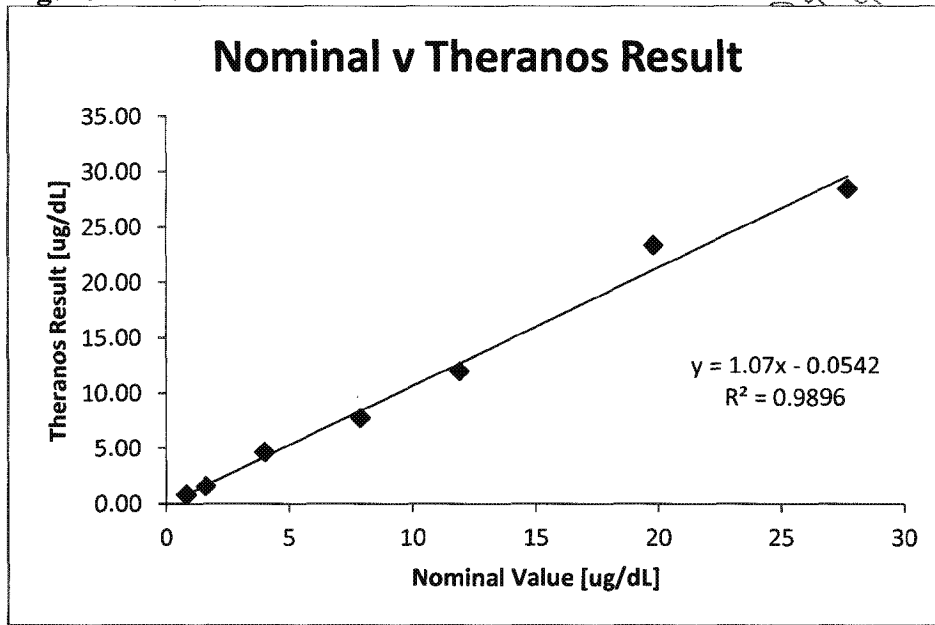
Nominal Value [ug/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			%CV
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	
27.70	4528	4739	4528	4739	4634	3%	4029	12%	23.93	22.47	28.45	16%
	3806	3700	3806	3700	3753	2%			31.19	OORH		
	3798	3605	3798	3605	3702	4%			31.30	OORH		
19.80	7146	7549					4609	11%			23.34	14%
	4242	5345	4242	5345	4794	16%			26.30	19.21		
	4551	4299	4551	4299	4425	4%			23.76	25.78		
11.90	5555	7281		7281			8125	10%		13.44	11.96	10%
	8394	9094	8394	9094	8744	6%			11.57	10.66		
	7730	11764	7730						12.61			
7.90	14118	15153	14118	15153	14636	5%	12630	19%	6.97	6.52	7.74	18%
	10662	10585	10662	10585	10624	1%			9.10	9.17		
	135	135	DARK	DARK								
4.00	19019	19583	19019	19583	19301	2%	21937	10%	5.29	5.15	4.64	10%
	23190	22664	23190	22664	22927	2%			4.41	4.51		
	22082	25082	22082	25082	23582	9%			4.62	4.11		
1.60	66878	63522	66878	63522	65200	4%	68852	5%	1.59	1.68	1.54	6%
	68029	70925	68029	70925	69477	3%			1.56	1.49		
	69964	73794	69964	73794	71879	4%			1.51	1.43		
0.80	119383	118947	119383	118947	119165	0%	115568	6%	0.77	0.77	0.81	9%
	105569	122165	105569	122165	113867	10%			0.92	0.74		
	118751	108594	118751	108594	113673	6%			0.77	0.88		
0.00	232429	248769	232429	248769	240599	5%	238972	9%	OORL	OORL	OORL	OORL
	210486	218811	210486	218811	214649	3%			OORL	OORL		
	263342	259996	263342	259996	261669	1%			OORL	OORL		

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**Table 2: Calibration 1 Summary**

Calibrator Level	Nominal Value [ug/dL]	Theranos Result [ug/dL]	%CV	% Recovery
Calibrator 1	27.7	28.45	16%	103%
Calibrator 2	19.8	23.34	14%	118%
Calibrator 3	11.9	11.96	10%	101%
Calibrator 4	7.9	7.74	18%	98%
Calibrator 5	4	4.64	10%	116%
Calibrator 6	1.6	1.54	6%	96%
Calibrator 7	0.8	0.81	9%	101%
Calibrator 8	0	OORL	OORL	OORL

**Figure 1: Calibration 1**





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### 3.3 Calibration 2 (Edison 3.X)

Of 8 levels, all had a back calculated mean value within  $100 \pm 20\%$  ( $100 \pm 25\%$  at LLOQ and ULOQ standards) of their nominal values. This calibration set was used to analyze Precision (4).

**Table 3: Calibration Data**

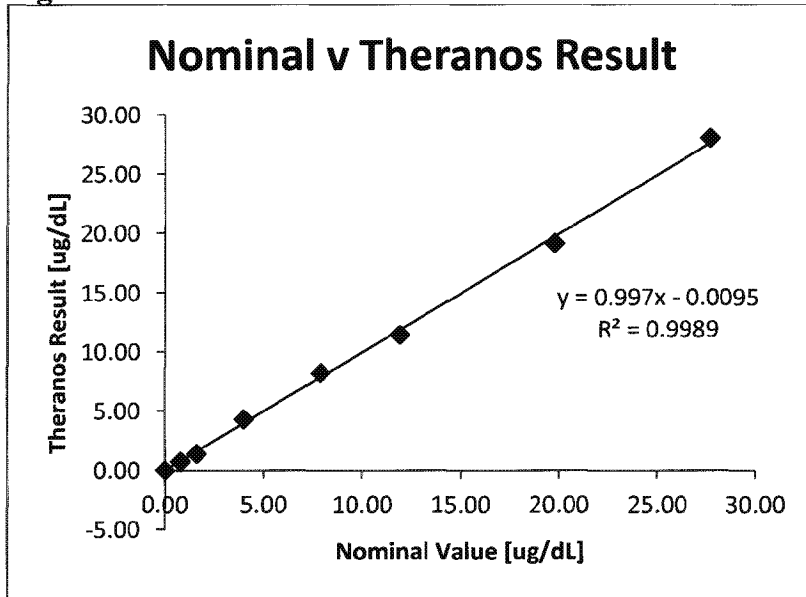
Nominal Value [ug/dl]	All Points		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip 2	Mean	%CV
27.7	4094	4428	4094	4428	4261	6%	3501	17%	23.36	21.41	28.03	19%
	2975	3166	2975	3166	3071	4%			OORH	31.74		
	3131	3209	3131	3209	3170	2%			OORH	31.20		
19.8	5660	5926	5660	5926	5793	3%	4902	22%	16.51	15.75	19.18	27%
	4748	5808	4748	5808	5278	14%			19.84	16.08		
	3575	3695	3575	3695					27.33	26.28		
11.9	7695	7181	7695	7181	7438	5%	8182	7%	12.16	13.00	11.45	8%
	8689	8365	8689	8365	8527	3%			10.81	11.21		
	8701	8458	8701	8458	8580	2%			10.80	11.09		
7.9	10811	11094	10811	11094	10953	2%	11565	7%	8.78	8.57	8.24	7%
	10889	12559	10889	12559	11724	10%			8.72	7.63		
	11359	12679	11359	12679	12019	8%			8.38	7.56		
4	23674	24253	23674	24253	23964	2%	22912	14%	4.18	4.08	4.32	16%
	26183	25396	26183	25396	25790	2%			3.79	3.90		
	17612	20354	17612	20354	18983	10%			5.55	4.84		
1.6	37694	47291					63505	14%			1.41	20%
	65953	74032	65953	74032	69993	8%			1.34	1.13		
	61360	52673	61360	52673	57017	11%			1.48	1.79		
0.8	84435	92179	84435	92179	88307	6%	93669	9%	0.92	0.78	0.76	13%
	86502	99795	86502	99795	93149	10%			0.88	0.66		
	107608	91497	107608	91497	99553	11%			OORL	0.79		
0	156474	157713	156474	157713	157094	1%	152770	16%	OORL	OORL	OORL	OORL
	169742	183917	169742	183917	176830	6%			OORL	OORL		
	123818	124958	123818	124958	124388	1%			OORL	OORL		

**Table 4: Calibration 2 Summary**

Calibrator Level	Nominal Value [ug/dL]	Theranos Result [ug/dL]	%CV	% Recovery
Calibrator 1	27.70	28.03	19%	101%
Calibrator 2	19.80	19.18	27%	97%
Calibrator 3	11.90	11.45	8%	96%
Calibrator 4	7.90	8.24	7%	104%
Calibrator 5	4.00	4.32	16%	108%
Calibrator 6	1.60	1.41	20%	88%
Calibrator 7	0.80	0.76	13%	94%
Calibrator 8	0.00	OORL	OORL	OORL

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**Figure 2: Calibration 2**



#### 4 PRECISION

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

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 22 runs were performed.

4.1.2 Precision summary

**Table 5: Acceptable Performance**

Decision Level	Notes	TAE(%)	Precision (%)	Allowable Bias (%)
10	20% or 1mcg/dL (greater)	20.00	11.9	8.1

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**Table 6: Precision summary**

Level	Reported value (ug/dL)	Mean Calculated		Median Calculated	
		Average	%CV	Average	%CV
1	11.4	9.31	12%	9.37	12%
2	2.06	2.06	11%	1.51	13%
3	1.52	1.35	16%	1.31	19%

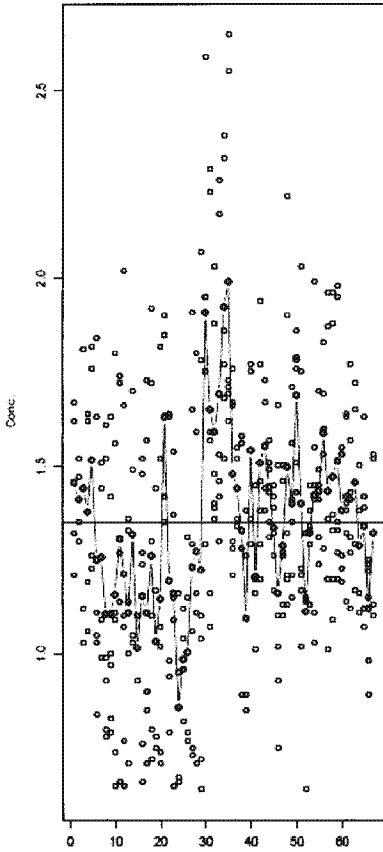
**Figure 3: Precision Plots**

The 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.

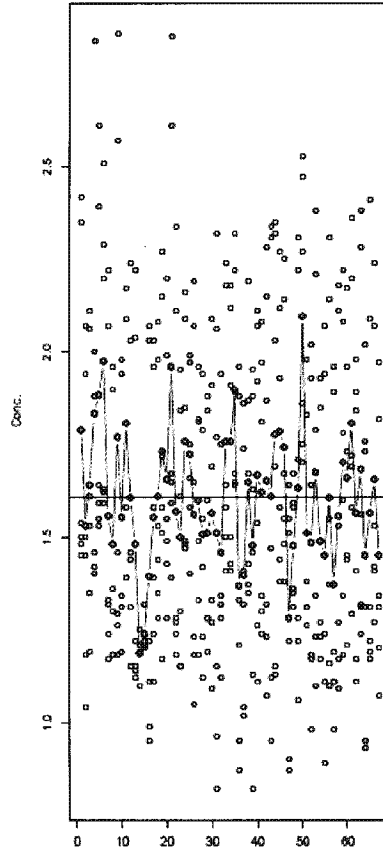
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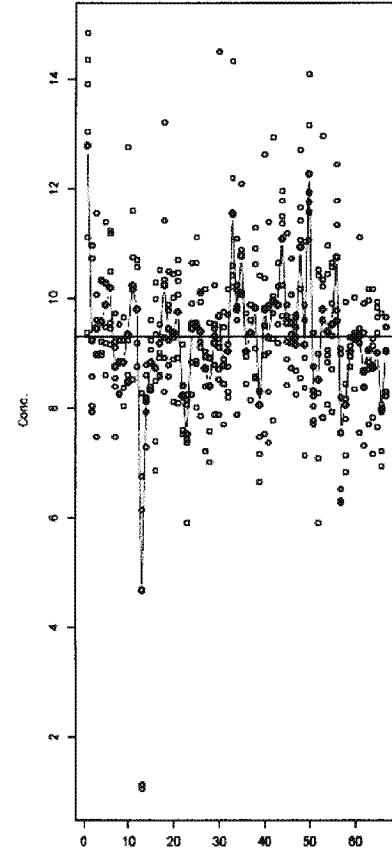
Nominal conc = 1.52, mean = 1.35, CV = 16.48%



Nominal conc = 2.06, mean = 1.61, CV = 10.62%



Nominal conc = 11.40, mean = 9.31, CV = 11.91%



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## 5 ACCURACY/COMPARABILITY

To test the accuracy of the assay on the Theranos System, 115 unique patient samples were assayed using both the predicate method (Siemens Immulite) and the Theranos System. Of these samples 62 were within the reference range (4.5 – 12.5 ug/dL), 22 were below the reference range, and 29 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. StataPro 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.

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.

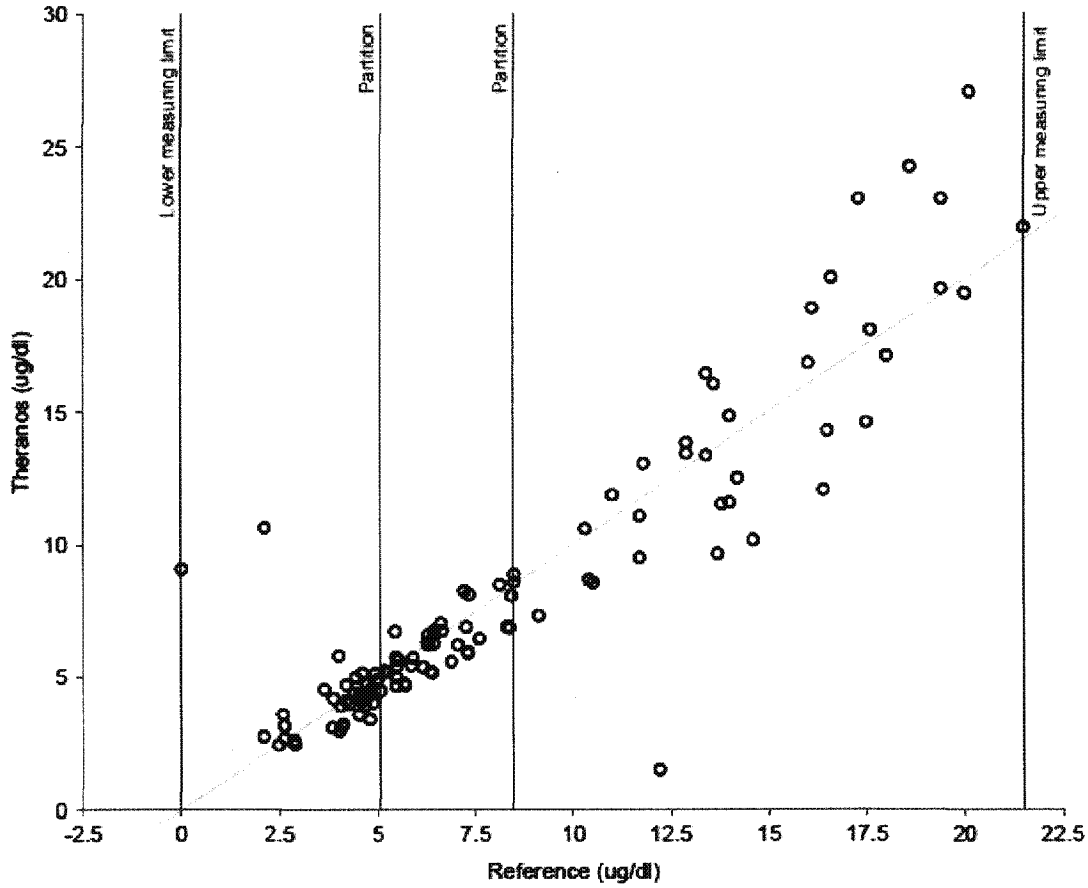
- 5.1 Default acceptance criteria for immunoassays are absolute mean bias (%RE)  $\leq 20\%$  ( $\leq 25\%$  at LLOQ) and total error (sum of the %CV and absolute %RE)  $\leq 30\%$  ( $\leq 40\%$  at the LLOQ)


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

**Scatter plot**

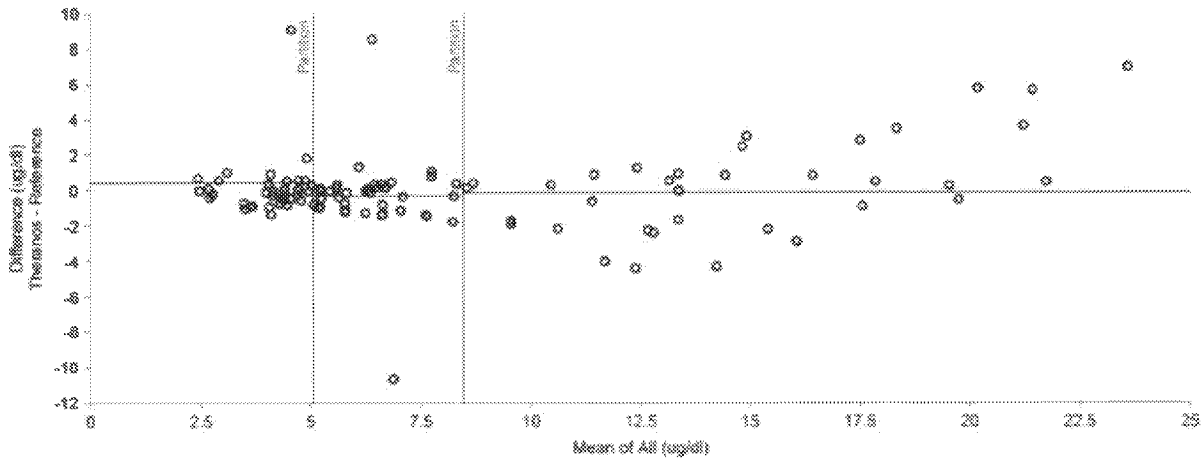
*CLSI guideline EP09-A2-IR section 4.2*



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

Difference plot  
 CLSI guideline EP09-A2-IR section 4.2



Number of samples      110  
 Test replicates        1  
 Comparative replicates   1

CLSI guideline EP09-A2-IR section 3.4 recommends a minimum of 40 samples, with 2 replicates by each measurement procedure.

Measuring interval      0 to 21.5


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

**Adequate range test**

CLSI guideline EP09-A2-IR section 4.5

$r$       0.911

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

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**Table 8: Partitioned Differences – CLSI Guideline EP09-A2-IR**

**Partitioned differences**

*CLSI guideline EP09-A2-IR section 6.2*

Partition	n	Mean difference	SD
< 5.07	36	0.412889172	2.167341055
≥ 5.07 and < 8.48	37	-0.302649393	0.720665275
≥ 8.48	37	-0.099080613	3.240428696

**Table 9: 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	5.00000000	0.412889172	0.361223580	0.320433537 to 0.505344807	0.470000000
2	7.00000000	-0.302649393	0.118476644	0.562319156 to 0.598331136	0.567000000
3	10.00000000	-0.099080613	0.532723198	0.993653837 to 0.993653837	0.810000000
4	14.00000000	-0.099080613	0.532723198	0.993653837 to 0.993653837	1.134000000

Difference is less than allowable bias: 9.4% upto 6ug/dl then 8.1%.

**6 DILUTION LINEARITY**

A high analyte sample was selected and serially diluted 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).

6.1 Each dilution level was tested on the Theranos System and compared to the nominal concentrations. For each dilution level, the recovery should be within  $100 \pm 20\%$  ( $100 \pm 25\%$  at LLOQ and ULOQ standards) of their nominal value, and when plotted, the  $R^2$  value should be equal or greater than 0.95.

For dilution level 1/12 and 1/16 the % recoveries were below the acceptance criteria.




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**Table 10: Dilution Linearity**

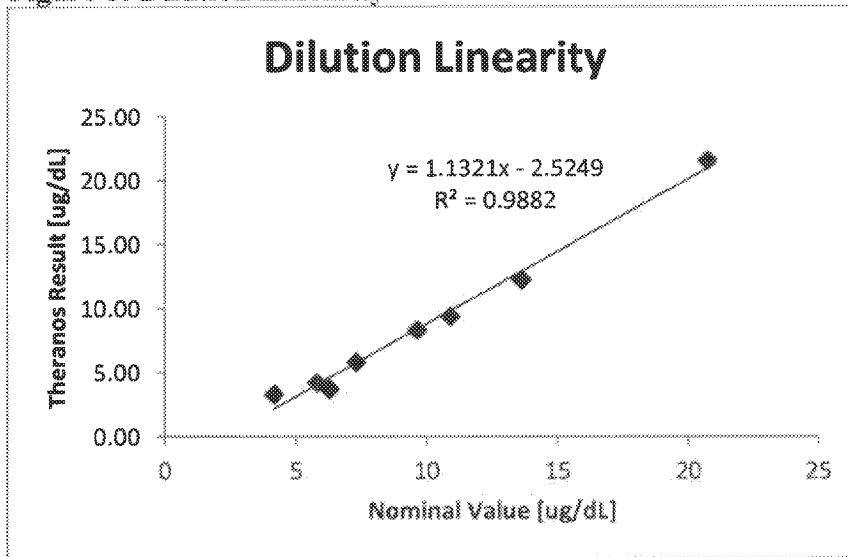
Nominal Value [ug/dl]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
20.7	4534	4044	4534	4044	4289	8%	4890	15%	23.89	28.28	21.54	20%
	4395	5095	4395	5095	4745	10%			24.97	20.42		
	5083	6190	5083	6190	5637	14%			20.48	16.11		
13.6	7326	8784	7326	8784	8055	13%	7947	14%	13.35	11.64	12.24	15%
	7863	9632	7863	9632	8748	14%			12.38	10.06		
	6512	7566	6512	7566	7039	11%			15.20	12.90		
10.9	13901	15295	13901	15295	14598	7%	10319	33%	7.07	6.47	9.40	31%
	8516	9109	8516	9109	8813	5%			11.39	10.64		
	7985	7108	7985	7108	7547	8%			12.18	13.79		
9.63	126473	127401					10912	7%			8.31	6%
	10587	10304	10587	10304	10446	2%			8.56	8.78		
	11930	10828	11930	10828	11379	7%			7.64	8.37		
7.3	16076	20291	16076	20291	18184	16%	16017	20%	5.80	4.71	5.82	19%
	13929	12149	13929	12149	13039	10%			6.61	7.51		
	17642	24932	17642						5.34			
6.28	20421	26651	20421	26651	23536	19%	26547	30%	4.68	3.68	3.70	19%
	119602	132255										
	25897	33219	25897	33219	29558	18%			3.78	3.01		
5.8	23235	25484	23235				23089	1%	4.17		4.19	1%
	12915	14436										
	22778	23254	22778	23254	23016	1%			4.24	4.17		
4.15	33527	33663	33527	33663	33595	0%	30056	15%	2.99	2.98	3.30	14%
	25708	35204	25708	35204	30456	22%			3.81	2.85		
	26857	25378	26857	25378	26118	4%			3.66	3.85		

**Table 11: Dilution Linearity Summary**

Sample ID	Nominal Value [ug/dL]	Theranos Result [ug/dL]	% Recovery
High Patient Sample	20.7	21.54	104%
1/2	13.6	12.24	90%
1/3	10.9	9.40	86%
1/4	9.63	8.31	86%
1/8	7.3	5.82	80%
1/12	6.28	3.70	59%
1/16	5.8	4.19	72%
Low Patient Sample	4.15	3.30	80%

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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, § 403.1253 “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 4.5 – 12.4 ug/dL.

Of 20 unique samples collected from reference donors, 1 patient had a tT4 level outside of the reference range.



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Overall, 95% of the patients tested fell within the reference range, and is acceptable for verification of the reference range.

**Table 12: Normal Patient Sample**

Li Heparin Reported Value [ug/dL]	All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2	Mean	%CV
9.18	23253	23098	23253	23098	23176	0%	18536	21%	4.40	4.43	5.42	19%
	14768	15835	14768	15835	15302	5%			6.68	6.26		
	15336	18924	15336	18924	17130	15%			6.43	5.32		
5.38	19790	22402	19790	22402	21096	9%	22055	8%	5.10	4.56	4.62	6%
	23800	22993	23800	22993	23397	2%			4.31	4.45		
	21707	21640	21707	21640	21674	0%			4.69	4.70		
8.76	12463	11447	12463	11447	11955	6%	14310	17%	7.83	8.50	6.88	16%
	13360	14434	13360	14434	13897	3%			7.34	6.82		
	17331	16825	17331	16825	17078	2%			5.76	5.92		
9.58	8792	9797	8792	9797	9295	8%	13716	26%	11.03	9.89	7.16	31%
	15507	17466	15507	17466	16487	8%			6.38	5.72		
	15055	15678	15055	15678	15367	3%			6.56	6.32		
6.69	19139	20210	19139	20210	19675	4%	18092	10%	5.26	5.01	5.54	10%
	17517	19284	17517	19284	18401	7%			5.71	5.22		
	15353	17047	15353	17047	16200	7%			6.44	5.85		
5.77	25871	27821	25871	27821	26846	5%	24413	26%	3.99	3.74	4.21	31%
	29629	30249	29629	30249	29939	1%			3.53	3.46		
	14790	18113	14790	18113	16453	14%			6.67	5.53		
7.49	19770	21555	19770	21555	20663	6%	20466	4%	5.11	4.72	4.95	3%
	20457	20083	20457	20083	20270	1%			4.95	5.03		
	5	5	DARK	DARK								
7.14	14243	14243	14249	14243	14246	0%	14472	19%	6.91	6.91	6.81	15%
	19654	13828	19654	13828	16741	25%			5.13	7.10		
	11873	12987	11873	12987	12430	6%			8.21	7.54		
4.96	20356	25544	20356	25544	22950	16%	24539	11%	4.97	4.04	4.19	12%
	35069	34618										
	26424	25831	26424	25831	26128	2%			3.92	4.00		
7.01			DARK	DARK			25274	15%			4.08	15%
	29083	26834	29083	26834	27959	6%			3.59	3.86		
	20162	25018	20162	25018	22590	15%			5.02	4.12		
8.39	17711	17820	17711	17820	17765	0%	15982	13%	5.65	5.62	6.21	12%
	14188	14207	14188	14207	14198	0%			6.93	6.93		
	85	95	DARK	DARK								
6.63	12610	12939	12610	12939	12775	2%	15773	15%	7.75	7.56	6.28	15%
	17384	17355	17384	17355	17370	0%			5.75	5.75		
	17027	17324	17027	17324	17176	1%			5.86	5.76		
5.42	24506	24807	24506	24807	24657	1%	30005	16%	4.20	4.15	3.49	16%
	34092	33336	34092	33336	33714	2%			3.10	3.16		
	38370	33284		33284						3.17		

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6.52	16655	16884	16655	16884	16770	1%	25211	27%	5.98	5.90	4.09	30%
	28913	27860	28913	27860	28387	3%			3.61	3.73		
	28401	32554	28401	32554	30478	10%			3.67	3.23		
7.92	77	65	DARK	DARK			25127	48%	3.17	3.82	4.10	52%
	33243	37696	33243	37696	35470	9%			6.63	6.72		
	14899	14669	14899	14669	14784	1%						
6.46	26493	26392	26493	26392	26443	0%	20412	27%	3.91	3.92	4.96	28%
	14308	14159	14308	14159	14234	1%			6.88	6.95		
	20127	20994	20127	20994	20561	3%			5.02	4.83		
11.1	16531	17825	16531	17825	17178	5%	12540	39%	6.02	5.61	7.79	61%
	5974	7004	5974	7004	6489	11%			16.79	14.02		
	13757	14146	13757	14146	13952	2%			7.14	6.95		
8.12	68	52	DARK	DARK			15766	12%			6.29	12%
	15179	13437	15179	13437	14308	9%			6.51	7.30		
	17745	16702	17745	16702	17224	4%			5.64	5.96		
8.31	13625	11872	13625	11872	12749	10%	13876	18%	7.20	8.21	7.08	16%
	12347	11493	12347	11493	11920	5%			7.90	8.47		
	16985	16933	16985	16933	16959	0%			5.87	5.89		
4.6	18973	27204	18973	27204	23089	25%	22352	14%	5.30	3.81	4.57	13%
	19133	21353	19133	21353	20243	8%			5.26	4.76		
	24555	22892	24555	22892	23724	5%			4.19	4.47		

**Table 13: Reference Range Summary**

Sample ID	Reported Value [ug/dL]	Theranos Result [ug/dL]	Corrected Theranos [ug/dL]
Patient 1	9.18	5.42	6.02
Patient 2	5.38	4.62	5.17
Patient 3	8.76	6.88	7.59
Patient 4	9.58	7.16	7.89
Patient 5	6.69	5.54	6.16
Patient 6	5.77	4.21	4.73
Patient 7	7.49	4.95	5.52
Patient 8	7.14	6.81	7.52
Patient 9	4.96	4.19	4.71
Patient 10	7.01	4.08	4.59
Patient 11	8.39	6.21	6.87
Patient 12	6.63	6.28	6.95
Patient 13	5.42	3.49	3.95
Patient 14	6.52	4.09	4.60
Patient 15	7.92	4.10	4.61
Patient 16	6.46	4.96	5.53
Patient 17	11.10	7.79	8.57
Patient 18	8.12	6.29	6.96
Patient 19	8.31	7.08	7.81
Patient 20	4.60	4.37	5.11

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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. The normal range

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 4.5 – 12.5 ug/dL.

20 unique patients each donated 2 venous tubes of blood and 2 fingerstick samples

Of 19 unique samples having venous tT4 level within reference range, all patients had tT4 levels from BCD collection within the reference range

**Table 14: Venous v. Fingerstick**

Sample ID	Sample Type	Concentration (ug/dL)			%CV	% difference	Overall	
		Tip 1	Tip 2	Mean			Mean	%CV
Patient 1	Venous Tube 1	6.26	5.81	5.58	10%	0.05	5.66	13%
	Venous Tube 2	5.14	5.10					
	Fingerstick 1	7.13	6.11					
	Fingerstick 2	5.36	5.00					
Patient 2	Venous Tube 1	5.70	5.32	5.37	4%	-0.07	5.04	17%
	Venous Tube 2	5.20	5.25					
	Fingerstick 1	6.15	6.03					
	Fingerstick 2	3.81	4.01					
Patient 3	Venous Tube 1	OORL	OORL	3.01	2%	0.29	3.69	20%
	Venous Tube 2	3.05	2.97					
	Fingerstick 1	4.23	4.34					
	Fingerstick 2	4.73	3.54					
Patient 4	Venous Tube 1	3.42	3.59	4.56	29%	-0.13	4.13	23%
	Venous Tube 2	6.19	5.02					
	Fingerstick 1	4.15	4.07					
	Fingerstick 2	3.31	4.63					
Patient 5	Venous Tube 1	4.61	4.66	4.62	1%	0.03	4.63	11%
	Venous Tube 2	4.64	4.57					
	Fingerstick 1	3.63	5.04					
	Fingerstick 2	5.33	4.99					
Patient 6	Venous Tube 1	3.84	OORL	4.14	6%	0.42	5.08	52%



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	Venous Tube 2	4.32	4.27					
	Fingerstick 1	4.90	4.39					
	Fingerstick 2	10.43	8.74	7.12	41%			
Patient 7	Venous Tube 1	6.66	5.90					
	Venous Tube 2	5.71	5.31	5.90	10%			
	Fingerstick 1	OORL	OORL			-0.12	5.63	10%
Patient 7	Fingerstick 2	5.38	5.18	5.28	3%			
	Venous Tube 1	5.31	5.38					
	Venous Tube 2	6.36	5.90	5.74	9%			
Patient 8	Fingerstick 1	6.21	5.39					
	Fingerstick 2	OORL	OORL	5.80	10%	0.01	5.72	8%
	Venous Tube 1	6.00	5.20					
Patient 9	Venous Tube 2	3.33	3.31					
	Fingerstick 1	5.76	5.35	4.46	30%	0.19	4.74	22%
	Fingerstick 2	5.51	5.47	5.52	3%			
Patient 10	Venous Tube 1	4.34	4.33					
	Venous Tube 2	4.24	4.28	4.30	1%			
	Fingerstick 1	4.93	4.32	4.71	6%	0.09	4.49	6%
Patient 10	Fingerstick 2	4.82	4.76					
	Venous Tube 1	3.19	3.13					
	Venous Tube 2	6.51	5.74	4.64	37%			
Patient 11	Fingerstick 1	4.63	4.24					
	Fingerstick 2	4.12	4.10	4.27	6%	-0.09	4.21	28%
	Venous Tube 1	5.27	5.20					
Patient 12	Venous Tube 2	3.47	3.35	4.32	24%			
	Fingerstick 1	5.32	5.93	6.80	21%	0.36	5.05	35%
	Fingerstick 2	8.49	7.47					
Patient 13	Venous Tube 1	4.43	4.26					
	Venous Tube 2	5.86	5.32	4.96	15%			
	Fingerstick 1	4.13	3.89	4.90	21%	-0.01	4.80	18%
Patient 13	Fingerstick 2	5.91	5.68					
	Venous Tube 1	3.56	3.49					
	Venous Tube 2	4.68	4.37	4.03	15%			
Patient 14	Fingerstick 1			4.33	5%	0.07	4.08	12%
	Fingerstick 2	4.49	4.18					
	Venous Tube 1	6.79	6.26					
Patient 15	Venous Tube 2	6.97	6.62	6.66	5%			
	Fingerstick 1	8.22	7.31	6.47	24%	-0.03	6.40	16%
	Fingerstick 2	4.92	5.43					
Patient 16	Venous Tube 1	3.84	3.61					
	Venous Tube 2	4.76	4.26	4.12	12%			
	Fingerstick 1	6.97	6.07	5.25	29%	0.22	4.46	27%
Patient 16	Fingerstick 2	3.94	4.05					
	Venous Tube 1	5.63	5.36					
	Venous Tube 2	4.85	4.71	5.14	8%	0.14	5.36	21%

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	Fingerstick 1	4.99	4.49	5.94	26%			
	Fingerstick 2	7.89	6.41					
Patient 18	Venous Tube 1	4.59	4.34	4.44	3%	-0.04	8.31	9%
	Venous Tube 2	4.40						
	Fingerstick 1	3.82	3.87	4.27	12%			
	Fingerstick 2	4.87	4.49					
Patient 19	Venous Tube 1	OORL	4.45	4.82	7%	-0.02	4.73	8%
	Venous Tube 2	5.15	4.85					
	Fingerstick 1	4.75	4.28	4.71	10%			
	Fingerstick 2	4.46	5.37					
Patient 20	Venous Tube 1	5.29	4.88	6.20	21%	0.16	6.54	20%
	Venous Tube 2	7.32	7.31					
	Fingerstick 1	5.85	7.57	7.38	16%			
	Fingerstick 2	7.62	8.48					

**Table 15: Venous v. Fingerstick Comparison Summary**

Sample ID	Venous Tube [ug/dL]		Fingerstick [ug/dL]	
	Original	Corrected	Original	Corrected
Patient 1	5.58	6.20	5.90	6.54
Patient 2	5.37	5.97	5.00	5.58
Patient 3	3.01	3.44	4.21	4.73
Patient 4	4.56	5.10	4.80	4.55
Patient 5	4.62	5.17	4.75	5.31
Patient 6	4.14	4.66	7.12	7.85
Patient 7	5.90	6.54	5.28	5.88
Patient 8	5.74	6.37	5.80	6.43
Patient 9	4.46	5.00	5.52	6.14
Patient 10	4.30	4.83	4.71	5.26
Patient 11	4.64	5.20	4.27	4.80
Patient 12	4.32	4.85	6.80	7.51
Patient 13	4.96	5.54	4.96	5.54
Patient 14	4.03	4.54	4.03	4.54
Patient 15	6.66	7.36	6.66	7.36
Patient 16	4.12	4.63	5.25	5.85
Patient 17	5.14	5.72	5.94	6.59
Patient 18	4.44	4.98	4.27	4.79
Patient 19	4.82	5.38	4.71	5.27
Patient 20	6.20	6.86	7.38	8.13

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## 9 ANALYTICAL SENSITIVITY

### 9.1 Verification of Limit of Blank

9.1.1 Acceptance Criteria: 90% of 60 replicates should return OORL results, and 85% of 20 replicates should return OORL results.

9.1.2 When calculated by cartridge, 96% of 70 replicates were below the assay range. When calculated by the mean of 3 cartridge replicates, 100% of 24 were below the detectable limit.

### 9.2 Verification of Limit of Detection

9.2.1 Acceptance Criteria: 90% of 60 replicates at the LLOQ should return quantifiable results, and 85% of 20 replicates should return quantifiable results.

9.2.2 When calculated by cartridge, 84% of 96 replicates were quantifiable. When calculated by the mean of 3 cartridge replicates, 94% of 32 replicates were quantifiable.

9.3 The LLOQ sample was diluted 1:1 and 20 replicates of the 1/2xLLOQ sample were tested. 19% of 21 were quantifiable, and no further dilutions were tested.

**Table 16: 1/2 LLOQ**

All Tips		Intra-Cartridge		
Tip1	Tip2	Mean	%CV	Result
109134	121590	115362	8%	0.81
133605	147113	140359	7%	OORL
88387	104173	96280	12%	1.04
173047	175087	174067	1%	OORL
213352	208376	210864	2%	OORL
139027	139308	139168	0%	OORL
122012	123939	122976	1%	0.73
197906	191604	194755	2%	OORL
117103	130207	123655	7%	0.73
178360	171786	175073	3%	OORL
168737	163295	166016	2%	OORL
173745	211088	192417	14%	OORL
137616	163736	150676	12%	OORL
159541	165396	162469	3%	OORL
154257	147185	150721	3%	OORL
161897	163285	162591	1%	OORL
130440	143163	136802	7%	OORL
145443	145965	145704	0%	OORL
163120	162362	162741	0%	OORL
184518	171154	177836	5%	OORL



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155698	141089	148394	7%	OORL
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**Table 17: Blank Replicates**

All Tips		Intra-Cartridge			Inter-Cartridge		
Tip1	Tip2	Mean	%CV	Result	Mean	%CV	Result
168166	194360	181263	10%	OORL	190703	15%	OORL
206254	236521	221388	10%	OORL			
159123	179796	169460	9%	OORL			
175907	186010	180959	4%	OORL	192957	12%	OORL
205095	232117	218606	9%	OORL			
172159	186453	179306	6%	OORL			
162959	167835	165397	2%	OORL	160710	9%	OORL
176183	168767	172475	3%	OORL			
137973	150540	144257	6%	OORL			
141906	143773	142840	1%	OORL	162218	12%	OORL
153412	165393	159403	5%	OORL			
181688	187137	184413	2%	OORL			
157498	144605	151052	6%	OORL	177578	23%	OORL
176087	133285	154686	20%	OORL			
232483	221511	226997	3%	OORL			
103743	98285	101014	4%	0.97	150697	35%	OORL
203895	226024	214960	7%	OORL			
127329	144908	136119	9%	OORL			
154431	143622	149027	5%	OORL	186136	25%	OORL
240391	251547	245969	3%	OORL			
156447	170377	163412	6%	OORL			
180477	174952	177715	2%	OORL	237194	28%	OORL
212687	215311	213999	1%	OORL			
317342	322392	319867	1%	OORL			
198607	185839	192230	5%	OORL	215822	13%	OORL
207010	202865	204938	1%	OORL			
252235	248374	250305	1%	OORL			
206678	212331	209505	2%	OORL	190677	12%	OORL
178655	206151	192403	10%	OORL			
154488	185761	170125	13%	OORL			
143539	157667	150603	7%	OORL	178537	20%	OORL
223057	223735	223396	0%	OORL			
149548	173673	161611	11%	OORL			
232429	248769	240599	5%	OORL	238972	9%	OORL
210486	218811	214649	3%	OORL			
263342	259996	261669	1%	OORL			
236778	239962	238370	1%	OORL	220365	24%	OORL
151837	158059	154948	3%	OORL			
251541	284014	267778	9%	OORL			
170473	186238	178356	6%	OORL	179754	6%	OORL
176089	196936	186513	8%	OORL			
174211	174577	174394	0%	OORL			
211018	196707	203863	5%	OORL	179393	20%	OORL

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153427	119621	136524	18%	OORL			
191903	203682	197793	4%	OORL			
177249	172099	174674	2%	OORL			
209955	213570	211763	1%	OORL	188222	11%	OORL
164324	192132	178228	11%	OORL			
173473	193966	183720	8%	OORL			
273237	274706	273972	0%	OORL	194096	35%	OORL
123423	125772	124598	1%	0.72			
147842	168030	157936	9%	OORL			
247521	270096	258809	6%	OORL	207654	22%	OORL
208497	203938	206218	2%	OORI			
144276	138274	141275	3%	OORL			
194803	189122	191963	2%	OORL	168403	14%	OORL
170259	173683	171971	1%	OORL			
189429	208614	199022	7%	OORL			
172215	176211	174213	2%	OORL	230824	31%	OORL
302115	336358	319237	8%	OORL			
226380	201992	214186	8%	OORL			
156184	175782	165983	8%	OORL	156809	36%	OORL
97045	83472	90259	11%	1.13			
189469	215420	202445	9%	OORL			
160186	157656	158921	1%	OORL	193496	15%	OORL
218576	219667	219122	0%	OORL			
204096	197242	200669	2%	OORL			
221189	252249	236719	9%	OORL	197012	20%	OORL
150716	156582	153649	3%	OORL			
172059	180849	176454	4%	OORL			
					176454	4%	OORL

**Table 18: LLOQ Replicates**

All Tips		Intra-Cartridge			Inter-Cartridge		
Tip1	Tip2	Mean	%CV	Result	Mean	%CV	Result
126403	134639	130521	4%	0.66			
96371	99639	98005	2%	1.01	103057	16%	0.95
100154	105960	103057	4%	0.95			
126203	122228	124216	2%	0.72			
120615	110131	115373	6%	0.81	115373	13%	0.81
92916	93263	93090	0%	1.08			
75441	78954	77198	3%	1.36			
81296	88319	84808	6%	1.21	84808	17%	1.21
107782	107498	107640	0%	0.89			
121931	126430	124181	3%	0.72			
110298	118189	114244	5%	0.82	114244	10%	0.82
95112	107307	101210	9%	0.97			
112894	117382	115138	3%	0.81			
125888	121527	123708	2%	0.73	123708	12%	0.73


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145228	148153	146691	1%	OORL			
90463	88437	89450	2%	1.14			
102516	102695	102606	0%	0.95	102606	21%	0.95
130758	139393	135076	5%	OORL			
154618	144254	149436	5%	OORL			
74086	75390	74738	1%	1.41	98900	35%	1.00
103727	94072	98900	7%	1.00			
98865	89007	93936	7%	1.07			
92605	107627	100116	11%	0.99	102597	16%	0.95
106329	133983	120156	16%	0.76			
83294	93443	88369	8%	1.15			
74061	81036	77549	6%	1.35	88369	34%	1.15
139056	139143	139100	0%	OORL			
110844	109655	110250	1%	0.86			
118370	119798	119084	1%	0.77	110250	4%	0.86
109527	108657	109092	1%	0.88			
137187	140522	138855	2%	OORL			
163676	156683	160180	3%	OORL	138855	18%	OORL
97969	110848	104409	9%	0.93			
135702	133475	134589	1%	OORL			
96823	111227	104025	10%	0.94	120897	12%	0.75
122479	119315	120897	2%	0.75			
156400	145782	151091	5%	OORL			
95620	93812	94716	1%	1.06	124117	21%	0.72
127006	121227	124117	3%	0.72			
203416	216698	210057	4%	OORL			
101144	114064	107604	8%	0.89	107604	53%	0.89
98344	93229	95787	4%	1.04			
104939	101379	103159	2%	0.95			
170197	171592	170895	1%	OORL	149023	21%	OORL
144673	153372	149023	4%	OORL			
73443	73610	73527	0%	1.43			
95008	110280	102644	11%	0.95	93178	16%	1.08
91347	98587	94967	5%	1.06			
110345	115501	112923	3%	0.83			
118009	120303	119156	1%	0.77	119156	21%	0.77
159891	169152	164522	4%	OORL			
131412	135019	133216	2%	0.64			
127641	128060	127851	0%	0.69	127851	8%	0.69
115225	110376	112801	3%	0.83			
130806	120949	125878	6%	0.71			
97959	90155	94057	6%	1.07	108062	15%	0.89
118164	97119	107642	14%	0.89			
87772	94384	91078	5%	1.11			
140565	137357	138961	2%	OORL	112291	21%	0.84
96370	128211	112291	20%	0.84			
109254	102505	105880	5%	0.91	105880	13%	0.91

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119390	125551	122471	4%	0.74			
97134	88653	92894	6%	1.09			
126352	127514	126933	1%	0.70			
105616	114025	109821	5%	0.87	126337	8%	0.70
126321	133620	129971	4%	0.67			
100495	100067	100281	0%	0.98			
100373	102401	101387	1%	0.97	101448	23%	0.97
148727	141837	145282	3%	OORL			
115087	89184	102136	18%	0.96			
74812	81475	78144	6%	1.34	89221	16%	1.14
99112	89257	94185	7%	1.07			
148606	152281	150444	2%	OORL			
93326	88464	90895	4%	1.12	96975	30%	1.03
93081	100624	96853	6%	1.03			
99325	93034	96180	5%	1.04			
82544	94190	88367	9%	1.15	96758	15%	1.03
119810	118101	118956	1%	0.77			
119383	118947	119165	0%	0.77			
105569	122165	113867	10%	0.82	118849	6%	0.77
118751	108594	113673	6%	0.83			
109671	108050	108861	1%	0.88			
96463	70614	83539	22%	1.24	95697	15%	1.05
94931	86711	90821	6%	1.12			
116126	117197	116662	1%	0.79			
107516	102257	104887	4%	0.93	104887	19%	0.93
67089	84130	75610	16%	1.39			
110669	92593	101631	13%	0.97			
103134	119741	111438	1%	0.85	112457	11%	0.84
114245	126183	120314	7%	0.76			
129247	129523	129385	0%	0.67			
91070	88687	89879	2%	1.13	92658	21%	1.09
91959	93357	92658	1%	1.09			
90417	99249	94853	7%	1.06			
69639	81233	75436	11%	1.39	94833	17%	1.06
106867	111579	109223	3%	0.87			

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**Table 19: Analytical Sensitivity Summary**

Blank Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% OORL	Mean	%CV
Intra-Cartridge	70	192546	23%	OORL	96%	0.85	21%
Inter-Cartridge	24	192546	13%	OORL	100%	NA	NA

LLOQ Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% Quantifiable	Mean	%CV
Intra-Cartridge	96	115797	22%	0.80	84.4%	0.94	21%
Inter-Cartridge	32	112247	14%	0.84	93.8%	0.89	17%

1/2 LLOQ Summary	N	RLUs		Calculated From Mean	Result		
		Mean	%CV		% Quantifiable	Mean	%CV
Intra-Cartridge	21	154711	18%	OORL	19%	0.83	18%

**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. The matched samples were tested in Theranos systems and the results were compared across three matrices. There was no significant difference among serum, EDTA plasma and heparin plasma. Either matrix is suitable for Theranos Total T4 assay.

**Table 20: EDTA Plasma**

All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
23253	23098	23253	23098	23176	0%			4.40	4.43		
14768	15835	14768	15835	15302	5%	18536	21%	6.68	6.26	5.42	19%
15336	18924	15336	18924	17130	15%			6.45	5.32		
19790	22402	19790	22402	21096	9%			5.10	4.56		
23800	22993	23800	22993	23397	2%	22055	6%	4.31	4.45	4.62	6%
21707	21640	21707	21640	21674	0%			4.69	4.70		
12463	11447	12463	11447	11955	6%			7.83	8.50		
13360	14434	13360	14434	13897	5%	14310	17%	7.34	6.82	6.88	16%
17331	16825	17331	16825	17078	2%			5.76	5.92		
8792	9797	8792	9797	9295	8%			11.03	9.89		
15507	17466	15507	17466	16487	8%	13716	26%	6.38	5.72	7.16	31%
15055	15678	15055	15678	15367	3%			6.56	6.32		
19139	20210	19139	20210	19675	4%			5.26	5.01		
17517	19284	17517	19284	18401	7%	18092	10%	5.71	5.22	5.54	10%
15353	17047	15353	17047	16200	7%			6.44	5.85		
25871	27821	25871	27821	26846	5%			3.99	3.74		
29629	30249	29629	30249	29939	1%	24413	26%	3.53	3.46	4.21	31%
14790	18115	14790	18115	16453	14%			6.67	5.53		
19770	21555	19770	21555	20663	6%			5.11	4.72		
20457	20082	20457	20082	20270	1%	20466	4%	4.95	5.03	4.95	3%
4	5	DARK	DARK								
14249	14243	14249	14243	14246	0%	14472	19%	6.91	6.91	6.81	15%

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19654	13828	19654	13828	16741	25%			5.13	7.10		
11873	12987	11873	12987	12430	6%			8.21	7.54		
20356	25544	20356	25544	22950	16%			4.97	4.04		
35069	34618	35069	34618	34844	1%	27974	21%	3.02	5.05	3.72	20%
26424	25831	26424	25831	26128	2%			3.92	4.01		
		DARK	DARK								
29083	26834	29083	26834	27959	6%	25274	15%	3.59	3.86	4.08	15%
20162	25018	20162	25018	22590	15%			5.02	4.12		
17711	17820	17711	17820	17766	0%			6.65	5.62		
14188	14207	14188	14207	14198	0%	15982	13%	6.93	6.93	6.21	12%
85	95	DARK	DARK								
12610	12939	12610	12939	12775	2%			7.75	7.56		
17384	17355	17384	17355	17370	0%	15773	15%	5.75	5.75	6.28	15%
17027	17324	17027	17324	17176	1%			5.86	5.76		
24506	24807	24506	24807	24657	1%			4.20	4.15		
34092	33336	34092	33336	33714	2%	31399	18%	3.10	3.16	3.34	18%
38370	33284	38370	33284	35827	10%			2.77	3.17		
16655	16884	16655	16884	16770	1%			5.98	5.90		
28913	27860	28913	27860	28387	3%	25211	27%	3.61	3.73	4.09	30%
28401	32554	28401	32554	30478	10%			3.67	3.23		
77	65	DARK	DARK								
33243	37696	33243	37696	35470	9%	25127	48%	3.17	2.82	4.10	52%
14899	14669	14899	14669	14784	1%			6.63	6.72		
26493	26392	26493	26392	26493	0%			3.91	3.92		
14308	14159	14308	14159	14234	1%	20412	27%	6.88	6.95	4.96	28%
20127	20994	20127	20994	20561	3%			5.02	4.83		
16531	17825	16531	17825	17178	5%			6.02	5.61		
5974	7004	5974	7004	6489	11%	12540	39%	16.79	14.02	7.79	61%
13757	14146	13757	14146	13952	2%			7.14	6.95		
68	52	DARK	DARK								
15179	13437	15179	13437	14308	9%	15766	12%	6.51	7.30	6.29	12%
17745	16702	17745	16702	17224	4%			5.64	5.96		
13625	11872	13625	11872	12749	10%			7.20	8.21		
12347	11493	12347	11493	11920	5%	13876	18%	7.90	8.47	7.08	16%
16985	16933	16985	16933	16959	0%			5.87	5.89		
18973	27204	18973	27204	23089	25%			5.30	3.81		
19133	21353	19133	21353	20243	8%	22352	14%	5.26	4.76	4.57	13%
24555	22892	24555	22892	23724	5%			4.19	4.47		

**Table 21: Li Heparin Plasma**

All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration			
Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
13394	15753	13394	15753	14574	11%			7.32	6.29		
20791	21578	20791	21578	21185	3%	16853	21%	4.88	4.71	5.91	18%
13912	15687	13912	15687	14800	8%			7.06	6.32		
29349	25503	29349	25503	27426	10%			3.56	4.05		
38105	36836	38105	36836	37471	2%	31548	16%	2.79	2.88	3.33	15%
28163	31332	28163	31332	29748	8%			3.69	3.35		

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15872	17646	15872	17646	16759	7%			6.25	5.67		
15361	14662	15361	14662	15012	3%	16103	7%	6.44	6.73	6.17	7%
15710	17368	15710	17368	16539	7%			6.31	5.75		
18749	17918	18749	17918	18334	3%			5.36	5.59		
12	4	DARK	DARK			16532	13%			6.02	12%
14448	15014	14448	15014	14731	3%			6.82	6.58		
21915	18556	21915	18556	20236	12%			4.65	5.41		
35213	35288	35213	35288	35251	0%	25956	28%	3.00	3.00	3.98	25%
21045	23717	21045	23717	22381	8%			4.82	4.32		
37543	38786	37543	38786	38165	2%			2.83	2.74		
29462	28695	29462	28695	29079	2%	31831	16%	3.54	3.63	3.30	13%
27770	28728	27770	28728	28249	2%			3.74	3.63		
20887	20202	20887	20202	20545	2%			4.86	5.01		
101045	108697	101045	108697	104871	5%	47678	93%	0.97	0.88	2.25	102%
17322	17916	17322	17916	17619	2%			5.76	5.59		
22959	23014	22959	23014	22987	0%			4.45	4.45		
20322	24468	20322	24468	22395	13%	21952	9%	4.98	4.20	4.64	8%
19297	21650	19297	21650	20474	8%			5.22	4.70		
16551	21767	16551	21767	19159	19%			6.01	4.68		
27907	28797	27907	28797	28352	2%	24493	19%	3.73	3.62	4.20	21%
26337	25598	26337	25598	25968	2%			3.93	4.03		
16463	16380	16463	16380	16422	0%			6.04	6.07		
22610	22405	22610	22405	22508	1%	19465	18%	4.52	4.56	5.18	17%
112	123	DARK	DARK								
15052	19374	15052	19374	17213	18%			6.56	5.20		
19815	19481	19815	19481	19648	1%	17248	15%	5.10	5.18	5.79	14%
14216	15549	14216	15549	14883	6%			6.92	6.37		
17734	18539	17734	18539	18137	3%			5.64	5.42		
16851	17817	16851	17817	17334	4%	16288	17%	5.91	5.62	6.10	21%
11039	15750	11039	15750	13395	25%			8.80	6.29		
28865	33807	28865	33807	31336	11%			3.61	3.12		
17967	20363	17967	20363	19165	9%	33995	43%	5.57	4.97	3.10	47%
51343	51626	51343	51626	51485	0%			2.09	2.08		
20212	23474	20212	23474	21843	11%			5.00	4.37		
25903	25016	25903	25016	25460	2%	21431	19%	3.99	4.12	4.74	19%
15947	18035	15947	18035	16991	9%			6.22	5.55		
12043	12910	12043	12910	12477	5%			8.09	7.58		
16831	18638	16831	18638	17735	7%	16551	21%	5.92	5.39	6.01	22%
18148	20738	18148	20738	19443	9%			5.52	4.89		
19986	23867	19986	23867	21927	13%			5.06	4.30		
27231	24314	27231	24314	25773	8%	25932	16%	3.81	4.23	3.99	15%
31563	28629	31563	28629	30096	7%			3.33	3.64		
8590	11032	8590	11032	9811	18%			11.29	8.81		
13331	12590	13331	12590	12961	4%	12330	18%	7.35	7.76	7.91	21%
14002	14435	14002	14435	14219	2%			7.02	6.82		
21633	22155	21633	22155	21894	2%			4.70	4.60		
12097	13560	12097	13560	12829	8%	16197	28%	8.06	7.23	6.13	24%
14008	13729	14008	13729	13869	1%			7.02	7.15		

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18714	18494	18714	18494	18604	1%	20359	9%	5.37	5.43	4.97	8%																																		
19673	20779	19673	20779	20226	4%			23339	21152			23339	21152	22246	7%	25058	25710	25058	25710	25384	2%	29978	31%	4.11	4.02	3.49	26%	37194	45645	37194	45645	41420	14%	21867	24394	21867	24394	23131	8%						
23339	21152	23339	21152	22246	7%																																								
25058	25710	25058	25710	25384	2%	29978	31%	4.11	4.02	3.49	26%																																		
37194	45645	37194	45645	41420	14%			21867	24394			21867	24394	23131	8%																														
21867	24394	21867	24394	23131	8%																																								

**Table 22: Serum**

All Tips		Dark Exclusion		Intra-Cartridge		Inter-Cartridge		Concentration																																																																																																																																																																																																																																																																																																	
Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV																																																																																																																																																																																																																																																																																														
20875	19868	20875	19868	20372	3%	20405	21%	4.86	5.08	4.96	21%																																																																																																																																																																																																																																																																																														
24335	26184	24335	26184	25260	5%			15224	15946			15224	15946	15585	3%	19594	24672	19594	24672	22133	16%	35691	36%	5.15	4.17	2.97	40%	34624	34792	34624	34792	34708	0%	48493	51973	48493	51973	50233	5%	11521	13561	11521	13561	12541	12%	14670	41%	8.45	7.23	6.72	40%	21842	22269	21842	22269	22056	1%	8517	10307	8517	10307	9412	13%	17864	17641	17864	17641	17753	1%	17207	17%	5.60	5.67	5.80	17%	19851	20296	19851	20296	20074	2%	13200	14389	13200	14389	13795	6%	22038	22201	22038	22201	22130	1%	26823	28%	4.62	4.59	3.86	23%	22655	21490	22655	21490	22073	4%	34465	38091	34465	38091	36278	7%	21554	20137	21554	20137	20846	5%	19528	8%	3.06	2.79	5.16	8%	18066	18355	18066	18355	18211	1%	50	57	DARK	DARK			22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%	16834	16152	16834	16152	16493	3%	17135	16339	17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%
15224	15946	15224	15946	15585	3%																																																																																																																																																																																																																																																																																																				
19594	24672	19594	24672	22133	16%	35691	36%	5.15	4.17	2.97	40%																																																																																																																																																																																																																																																																																														
34624	34792	34624	34792	34708	0%			48493	51973			48493	51973	50233	5%	11521	13561	11521	13561	12541	12%	14670	41%	8.45	7.23	6.72	40%	21842	22269	21842	22269	22056	1%	8517	10307	8517	10307	9412	13%	17864	17641	17864	17641	17753	1%	17207	17%	5.60	5.67	5.80	17%	19851	20296	19851	20296	20074	2%	13200	14389	13200	14389	13795	6%	22038	22201	22038	22201	22130	1%	26823	28%	4.62	4.59	3.86	23%	22655	21490	22655	21490	22073	4%	34465	38091	34465	38091	36278	7%	21554	20137	21554	20137	20846	5%	19528	8%	3.06	2.79	5.16	8%	18066	18355	18066	18355	18211	1%	50	57	DARK	DARK			22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%	16834	16152	16834	16152	16493	3%	17135	16339	17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																								
48493	51973	48493	51973	50233	5%																																																																																																																																																																																																																																																																																																				
11521	13561	11521	13561	12541	12%	14670	41%	8.45	7.23	6.72	40%																																																																																																																																																																																																																																																																																														
21842	22269	21842	22269	22056	1%			8517	10307			8517	10307	9412	13%	17864	17641	17864	17641	17753	1%	17207	17%	5.60	5.67	5.80	17%	19851	20296	19851	20296	20074	2%	13200	14389	13200	14389	13795	6%	22038	22201	22038	22201	22130	1%	26823	28%	4.62	4.59	3.86	23%	22655	21490	22655	21490	22073	4%	34465	38091	34465	38091	36278	7%	21554	20137	21554	20137	20846	5%	19528	8%	3.06	2.79	5.16	8%	18066	18355	18066	18355	18211	1%	50	57	DARK	DARK			22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%	16834	16152	16834	16152	16493	3%	17135	16339	17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																
8517	10307	8517	10307	9412	13%																																																																																																																																																																																																																																																																																																				
17864	17641	17864	17641	17753	1%	17207	17%	5.60	5.67	5.80	17%																																																																																																																																																																																																																																																																																														
19851	20296	19851	20296	20074	2%			13200	14389			13200	14389	13795	6%	22038	22201	22038	22201	22130	1%	26823	28%	4.62	4.59	3.86	23%	22655	21490	22655	21490	22073	4%	34465	38091	34465	38091	36278	7%	21554	20137	21554	20137	20846	5%	19528	8%	3.06	2.79	5.16	8%	18066	18355	18066	18355	18211	1%	50	57	DARK	DARK			22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%	16834	16152	16834	16152	16493	3%	17135	16339	17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																								
13200	14389	13200	14389	13795	6%																																																																																																																																																																																																																																																																																																				
22038	22201	22038	22201	22130	1%	26823	28%	4.62	4.59	3.86	23%																																																																																																																																																																																																																																																																																														
22655	21490	22655	21490	22073	4%			34465	38091			34465	38091	36278	7%	21554	20137	21554	20137	20846	5%	19528	8%	3.06	2.79	5.16	8%	18066	18355	18066	18355	18211	1%	50	57	DARK	DARK			22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%	16834	16152	16834	16152	16493	3%	17135	16339	17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																
34465	38091	34465	38091	36278	7%																																																																																																																																																																																																																																																																																																				
21554	20137	21554	20137	20846	5%	19528	8%	3.06	2.79	5.16	8%																																																																																																																																																																																																																																																																																														
18066	18355	18066	18355	18211	1%			50	57			DARK	DARK			22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%	16834	16152	16834	16152	16493	3%	17135	16339	17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																								
50	57	DARK	DARK																																																																																																																																																																																																																																																																																																						
22436	22563	22436	22563	22500	0%	18577	16%	4.55	4.53	5.41	14%																																																																																																																																																																																																																																																																																														
16834	16152	16834	16152	16493	3%			17135	16339			17135	16339	16737	3%	23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%	23059	19022	23059	19022	21041	14%	19906	21537	19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																																																
17135	16339	17135	16339	16737	3%																																																																																																																																																																																																																																																																																																				
23514	25405	23514	25405	24460	5%	22074	11%	4.36	4.06	4.62	10%																																																																																																																																																																																																																																																																																														
23059	19022	23059	19022	21041	14%			19906	21537			19906	21537	20722	6%	27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%	23193	23354	23193	23354	23274	0%	18534	24372	18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																																																																								
19906	21537	19906	21537	20722	6%																																																																																																																																																																																																																																																																																																				
27038	30377	27038	30377	28708	8%	24478	16%	3.84	3.45	4.20	16%																																																																																																																																																																																																																																																																																														
23193	23354	23193	23354	23274	0%			18534	24372			18534	24372	21453	19%	24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%	76	66	DARK	DARK			18301	19529	18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																																																																																																
18534	24372	18534	24372	21453	19%																																																																																																																																																																																																																																																																																																				
24077	27086	24077	27086	25582	8%	22248	18%	4.27	3.83	4.58	17%																																																																																																																																																																																																																																																																																														
76	66	DARK	DARK					18301	19529			18301	19529	18915	5%	15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%	14307	17647	14307	17647	15977	15%	17761	20012	17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																																																																																																																								
18301	19529	18301	19529	18915	5%																																																																																																																																																																																																																																																																																																				
15878	15559	15878	15559	15719	1%	16861	12%	5.48	5.16	5.91	11%																																																																																																																																																																																																																																																																																														
14307	17647	14307	17647	15977	15%			17761	20012			17761	20012	18887	8%	14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%	14588	13252	14588	13252	13920	7%	24519	26327	24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																																																																																																																																																
17761	20012	17761	20012	18887	8%																																																																																																																																																																																																																																																																																																				
14468	16402	14468	16402	15435	9%	18259	31%	6.81	6.06	5.49	26%																																																																																																																																																																																																																																																																																														
14588	13252	14588	13252	13920	7%			24519	26327			24519	26327	25423	5%	21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%	34232	36675	34232	36675	35454	5%																																																																																																																																																																																																																																																																								
24519	26327	24519	26327	25423	5%																																																																																																																																																																																																																																																																																																				
21660	23310	21660	23310	22485	5%	26964	25%	4.70	4.39	3.85	21%																																																																																																																																																																																																																																																																																														
34232	36675	34232	36675	35454	5%																																																																																																																																																																																																																																																																																																				



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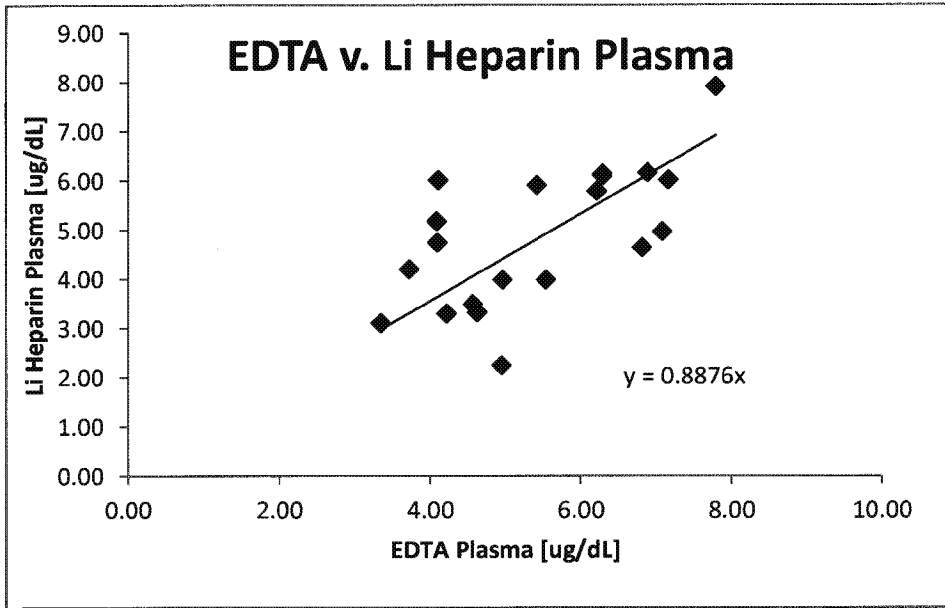
24426	21480	24426	21480	22953	9%			4.21	4.73		
17946	22414	17946	22414	20180	16%	18399	18%	5.58	4.55	5.45	19%
20011	20205	20011	20205	20108	1%			5.05	5.01		
12998	16817	12998	16817	14908	18%			7.53	5.92		
13709	13507	13709	13507	13608	1%	15372	12%	7.16	7.26	6.44	11%
15639	15070	15639	15070	15355	3%			6.33	6.56		
18826	15480	18826	15480	17153	14%			5.34	6.69		
21674	22694	21674	22694	22184	3%	23742	8%	4.70	4.50	4.32	8%
21677	24649	21677	24649	23163	9%			3.69	4.17		
25947	25813	25947	25813	25880	0%			3.98	4.00		
15660	18071	15660	18071	16866	10%	20937	24%	6.33	5.54	4.85	21%
18748	18858	18748	18858	18803	0%			5.36	5.33		
27653	26629	27653	26629	27141	3%			3.76	3.89		
7	10	DARK	DARK			19850	19%			5.09	19%
15137	18639	15137	18639	16888	15%			6.53	5.39		
22538	23084	22538	23084	22811	2%			4.53	4.43		
7392	7724	7392	7724	7558	3%	11003	30%	13.22	12.62	8.83	35%
11745	13306	11745	13306	12526	9%			8.29	7.36		
25	14846	DARK	14846	14846					6.65		
41514	39388	41514	39388	40451	4%	38853	23%	2.57	2.70	2.74	25%
46431	49599	46431	49599	48015	5%			2.31	2.16		
28881	27304	28881	27304	28093	4%			3.61	3.80		

**Table 23: EDTA v. Li Heparin v. Serum**

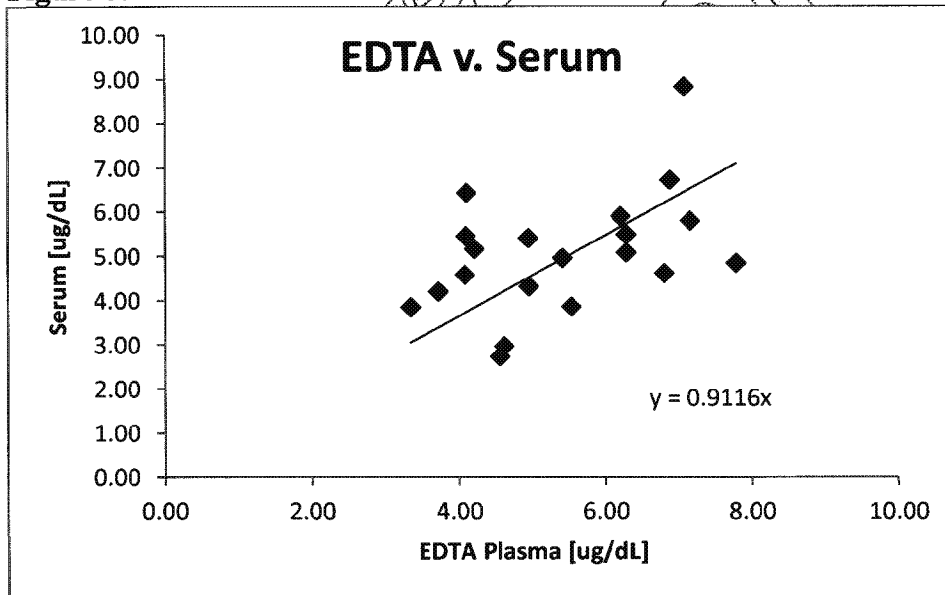
Sample ID	Theranos Reported		
	EDTA	Li Heparin	Serum
Patient 1	5.42	5.91	4.96
Patient 2	4.62	3.33	2.97
Patient 3	6.88	6.17	6.72
Patient 4	7.16	6.02	5.80
Patient 5	5.54	3.98	3.86
Patient 6	4.21	3.30	5.16
Patient 7	4.95	2.25	5.41
Patient 8	6.81	4.64	4.62
Patient 9	3.72	4.20	4.20
Patient 10	4.08	5.18	4.58
Patient 11	6.21	5.79	5.91
Patient 12	6.28	6.10	5.49
Patient 13	3.34	3.10	3.85
Patient 14	4.09	4.74	5.45
Patient 15	4.10	6.01	6.44
Patient 16	4.96	3.99	4.32
Patient 17	7.79	7.91	4.85
Patient 18	6.29	6.13	5.09
Patient 19	7.08	4.97	8.83
Patient 20	4.57	3.49	2.74

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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 (512 mg/dL Hemoglobin), icteric (20 mg/dL Bilirubin), and lipemic (5000 mg/dL Triglycerides) serum samples were evaluated on the Theranos System and compared to predicate method values. Icteric samples with Bilirubin at 20mg/dL and lipemic samples with Triglycerides at 5000mg/dL didn't show significant difference on results. Hemolyzed samples with 512 mg/dL Hemoglobin had low recovery so hemolyzed samples should not be tested in Theranos systems for Total T4 assay.

**Table 24: Hemolyzed Samples – 512 mg/dL Hemoglobin**

Reported Value [ug/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		
10.8	13560	12816	13560	12816	13188	4%	12624	6%	7.23	7.63	7.74	5%	72%
	12204	11914	12204	11914	12059	2%			7.99	8.18			
	6279	6986											
4.49	38541	40848					30903	16%	3.17	2.93	3.39	15%	76%
	33257	36188	33257	36188	34723	6%			3.59	4.11			
	29085	25083	29085	25083	27084	10%							
<1	115301	121640	115301	121640	118471	4%	93090	22%	0.81	0.74	1.08	27%	NA
	78655	75946	78655	75946	77301	2%			1.33	1.38			
	75310	91687	75310	91687	83499	14%			1.39	1.10			
<1	108218	128671	108218	128671	118445	12%	146811	22%	0.89	0.68	OORL	OORL	OORL
	183183	187623	183183	187623	185403	2%			OORL	OORL			
	140960	132211	140960	132211	136586	5%			OORL	0.65			

**Table 25: Icteric Samples – 20 mg/dL Bilirubin**

Reported Value [ug/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		
11.3	12648	12704	12648	12704	12676	0%	13284	17%	7.73	7.69	7.38	16%	65%
	10491	11772	10491	11772	11132	8%			9.25	8.27			
	16190	15898	16190	15898	16044	1%			6.13	6.24			
4.23	29968	32040	29968	32040	31004	5%	29035	7%	3.49	3.28	3.59	7%	85%
	26200	27565	26200	27565	26883	4%			3.95	3.77			
	28564	29871	28564	29871	29218	3%			3.65	3.50			
<1	73687	77930	73687	77930	75809	4%	100325	21%	1.43	1.34	0.98	30%	NA
	127636	115919	127636	115919	121778	7%			0.69	0.80			
	105234	101546	105234	101546	103390	3%			0.92	0.97			
<1	194936	170599	194936	170599	182768	9%	153037	26%	OORL	OORL	OORL	OORL	OORL
	140078	81598	140078	81598	110838	37%			OORL	1.27			
	162925	168086	162925	168086	165506	2%			OORL	OORL			

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**Table 26: Lipemic Samples – 5000 mg/dL Triglycerides**

Reported Value [ug/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		
13	7628	7260	7628	7260	7444	3%	7260	12%	12.78	13.48	13.48	13%	104%
	6080	6682	6080	6682	6381	7%			16.45	14.77			
	7363	8548	7363	8548	7956	11%			13.28	11.35			
5.31	29082	26929	29082	26929	28006	5%	22238	29%	3.59	3.85	4.39	35%	86%
	12550	16694	12550	16694	14622	20%			7.78	5.96			
	25322	22851	25322	22851	24087	7%			4.07	4.47			
<1	93784	96888	93784	96888	95336	2%	91124	6%	1.07	1.03	1.11	8%	NA
	90474	91212	90474	91212	90843	1%			1.12	1.11			
	80417	93969	80417	93969	87193	11%			1.29	1.07			
<1	168499	170578	168499	170578	169539	1%	158064	11%	OORL	OORL	OORL	OORL	OORL
	132761	160417	132761	160417	146589	13%			0.64	OORL			
	81	83	DARK	DARK									

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## 12 CROSSREACTIVITY

Information about cross-reacting analytes from predicate method insert.

These data were obtained from the assay development report. The cross-reactants were spiked into know standards and the recovery was calculated to determine the effect of the substance. No cross reactivity showed in tested substances.

**Table 27: Cross-reactive Samples**

Test Substance	[Test Substance] ug/dL	[T4] ug/dL	Calculated Conc. ug/dL		
			Mean	CV	Recovery
Control	-	25.7	25.6	5%	100%
		15.7	14.2	6%	90%
		10.7	12.5	15%	116%
		5.7	5.4	6%	95%
		2.7	2.8	4%	102%
		0.7	0.7	26%	102%
3,5-Diiodo-L-thyronine (T2)	3	25.7	27.9	6%	109%
		15.7	16.7	10%	106%
		10.7	10.6	8%	99%
		5.7	6.3	3%	111%
		2.7	2.7	21%	101%
		0.7	0.7	9%	99%
Diphenylhydantoin	30	25.7	30.2	-	118%
		15.7	15.3	14%	97%
		10.7	10.3	2%	96%
		5.7	5.8	10%	101%
		2.7	2.7	7%	100%
		0.7	0.7	3%	101%
3-Iodo-L-tyrosine	3	25.7	28.6	16%	111%
		15.7	13.4	-	86%
		10.7	12	5%	112%
		5.7	6	2%	105%
		2.7	3.2	14%	117%
		0.7	0.6	28%	90%
Triiodothyronine (T3)	3	25.7	28.3	20%	110%
		15.7	15.4	-	98%
		10.7	10.9	4%	102%
		5.7	6.8	10%	119%
		2.7	2.8	4%	103%
		0.7	0.6	2%	92%
Sodium salicylate	40,000	25.7	29.4	11%	114%
		15.7	18	23%	115%
		10.7	11.5	7%	108%
		5.7	6.3	7%	111%
		2.7	3.4	-	124%
		0.7	0.6	13%	82%

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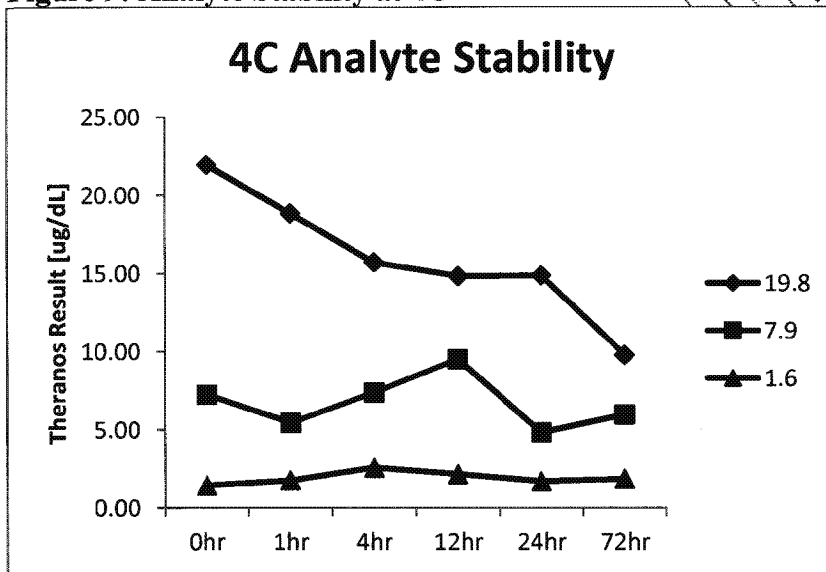
### 13 SAMPLE STABILITY

The stability of patient samples stored at 4C and room temperature were tested to mimic the conditions that clinical samples may be stored and handled. Samples were transferred from -80C to either room temperature or 4C at the 0hr time point, and stored at those temperatures for the remainder of testing. Overall the analyte stability data indicates that the samples should be processed within 24 hours when stored at 4C and room temperature.

**Table 28: Analyte Stability Summary**

	4C						Room Temperature					
Level	0hr	1hr	4hr	12hr	24hr	72hr	0hr	1hr	4hr	12hr	24hr	72hr
19.8	21.95	18.83	15.71	14.83	14.86	9.77	21.95	17.72	25.22	18.57	19.97	5.49
7.9	7.24	5.45	7.39	9.51	4.82	5.97	7.24	6.19	6.02	6.73	6.09	6.35
1.6	1.43	1.77	2.58	2.15	1.69	1.85	1.43	1.66	1.66	1.51	1.71	1.31

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




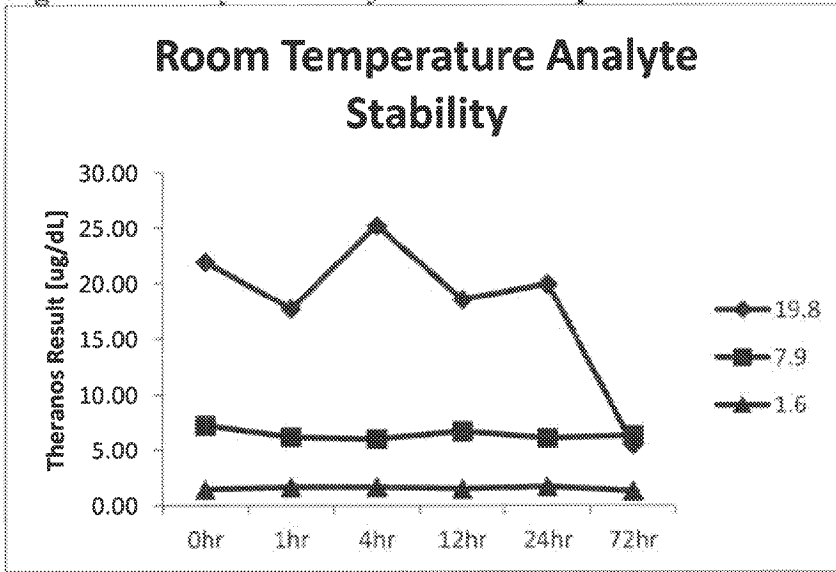
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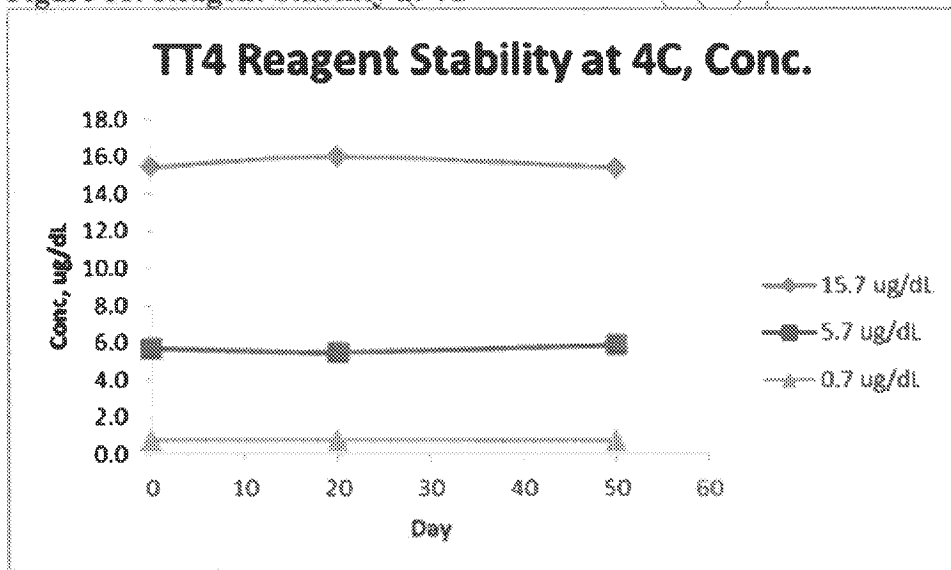
Figure 10: Analyte Stability at Room Temperature




#### 14 Reagent Stability

Reagent stability data was obtained from the assay development report. Theranos System reagents are stable up to 8 weeks at 4C.

Figure 11: Reagent Stability at 4C



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## 15 REFERENCES

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